

Notes on UNOS' Response to the SFC Oversight Letter

The impetus of the SFC letter to UNOS appears to have been a desire to gain a better understanding of the OPTN and UNOS' operations both on a day-to-day level as well as overall responsibilities and current processes and general oversight for organ transplantation. These questions were asked of UNOS, the longstanding vendor responsible for maintaining the OPTN. Many of the questions attempted to understand the ecosystem as a whole, as UNOS's centrality to that ecosystem positions them, likely singularly, to provide SFC with the information necessary to perform their Congressional duties to provide oversight.

UNOS' answers to SFC's letter, did not meet the spirit of SFC's questions, and were largely non-answers or deflections, or recitations of already-public information. In response to many of the questions UNOS simply asserted that they do not perform certain oversight functions or collect some of the specific information in question. While this is technically not inaccurate, the real point then becomes that UNOS *should* have this information; that they choose not to collect it is an indictment of their performance as the government contractor responsible for overseeing the system, not an actual reflection of the limitations of their authorities. As UNOS runs the OPTN, which is centralized to the whole organ transplantation system, UNOS' claim of not having data or information on large significant portions of the organ transplant system is deeply concerning. If this is truly the case, the government should not have faith UNOS's ability to run a data-driven system and process for something as important organ transplantation.

LEGEND:

Red = UNOS denial of responsibility/knowledge

Emphasis added throughout

SFC Question	Highlights of UNOS Response	Commentary
<p>1. How does UNOS fulfill the requirements of 42 C.F.R. § 121.10(b), which tasks the OPTN Contractor with monitoring and overseeing all 58 OPOs? Specifically:</p> <p>1a. How does UNOS currently fulfill its requirement for ongoing monitoring and periodic reviews of OPOs for underperformance and what triggers or performance measures are used by UNOS to define OPO underperformance?</p>	<p>UNOS references several pdfs of various OPTN policies and bylaws:</p> <ul style="list-style-type: none"> • https://optn.transplant.hrsa.gov/media/2937/optn_member_monitoring_processes.pdf • https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf • https://optn.transplant.hrsa.gov/media/1202/evaluation_plan.pdf • https://optn.transplant.hrsa.gov/media/2939/what_to_expect_performance_reviews.pdf • https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf#nameddest=Appendix_L (Appendix L - Reviews and Actions) 	<p>What was asked: List the ways you comply according to the law. How you must comply is already written in the law. Information provided is just parroting what is already in the law.</p> <p>Potential follow-up questions: How are OPO OPTN memberships impacted when OPOs are not in compliance? How often has the OPTN revoked OPO membership for transgressions?</p> <p>The response points to UNOS' documentation for monitoring processes. There isn't much in the way of enforcement.</p>

	<p>“The OPTN Final Rule defines the scope of the OPTN’s role in monitoring OPOs; it does not assign the OPTN the duty of monitoring OPO compliance with all OPO statutory and regulatory requirements that exist externally to the OPTN, such as compliance with CMS regulations or financial reporting requirements.”</p>	<p>It’s arguable what the scope of the OPTN’s monitoring role is, given that the OPTN has a broad mandate to do what is necessary to “improve the effectiveness of the nation’s organ procurement, donation, and transplantation system by increasing the availability of and access to donor organs for patients with end-stage organ failure.” (Organ Procurement and Transplantation Network (OPTN) definition)</p>
<p>1ai. What, if any, efforts has UNOS undertaken to ensure the accuracy and consistency of OPO outcome measure data?</p> <p>1aai. Does UNOS ever audit self-reported data submitted by OPOs in relation to the measures under 42 C.F.R. § 486.318(a) and (b)? If so, please detail how frequently such audits occur and what action is taken in response to an OPO that is found to have submitted inaccurate data.</p>	<p>“OPTN policy requires members to submit accurate data to the OPTN, and holds that “[m]embers are responsible for providing documentation upon request to verify the accuracy of all data submitted to the OPTN through the use of standardized forms.”</p> <p>UNOS cites “UNet’s UNOS Terms of Use, Data Accuracy provision.”</p> <p>Site surveyors review Deceased Donor Registration (DDR) form, Deceased Donor Feedback form, and Potential Transplant Recipient (PTR) refusal codes. (<i>Policy 18.1 in OPTN Member Evaluation Plan</i>)</p> <p>1aai answer: “In the previous answer, we explained how we ensure the accuracy of data reported to the OPTN. To the extent that OPTN data are used by CMS in the OPO outcome measure calculation, or what measures CMS takes to ensure the accuracy of those data or any other data CMS uses to calculate OPO outcome measures, we do not have information.”</p>	<p>What was asked: What are the theoretical ways that good data is coming into the system?</p> <p>Potential follow-up questions: What data validation systems are in place for outcomes and various other pieces of data at the OPTN and OPO system interfaces? Are the data validation systems automated?</p> <p>UNOS answered this question by saying they don’t have much, technically speaking, in the way of validating data that is submitted to their system -- they shift responsibility solely to the members of the OPTN.</p> <p>UNOS goes on to answer 1aai with “we ensure accuracy of data reported...” but said that it is the OPTN member’s responsibility to have accurate data according to their terms of service. Again, there is no mention of systematic, automated data validation checks.</p> <p>UNOS claims to conduct retrospective on-site surveys that look at sparse data points “to verify that data [...] is consistent”. UNOS, through its terms of service, has the assumption that all data coming into the system is accurate and valid thus kicking the can of responsibility to those that input into the system.</p>
<p>1aiii. Has UNOS provided guidance to OPOs on</p>	<p>“Yes. OPTN policy includes a definition of “eligible death,”</p>	<p>The training that is provided can be found on</p>

<p>the definition of "eligible deaths" for purposes of reporting the number of organs recovered per eligible death?</p>	<p>the current version of which has been in place since the OPTN adopted amendments to align the OPTN data collection with the CMS definition on January 1, 2017. This definition is also included in Help Documentation in the OPO application of our UNet System: DonorNet.</p> <p>Prior to the implementation, UNOS provided education, available to all members, in a module called "Modifications to the Imminent and Eligible Neurological Death Data Reporting Definitions."</p>	<p>the UNOS' "learning management system".</p> <p>Unclear on why this question was asked.</p>
<p>1b. What, if any, steps has UNOS taken in response to media reports about staffing shortages at selected OPOs?</p>	<p>"OPTN Bylaws require that "[e]ach OPO must have the necessary staff to recover and distribute organs according to OPTN obligations, including an administrative director, a medical director, an organ donation coordinator, and an organ procurement specialist."</p> <p>OPOs have to submit written notice of key personnel change (admin director or medical director).</p> <p>If UNOS learns of OPO's failure to adhere to OPTN obligations, it will initiate a patient safety/non-routine compliance review.</p>	<p>What was asked: Tell me your process if staffing shortages are encountered.</p> <p>Potential follow-up questions: When was the last time UNOS handled a short-staffed OPO incident? How many understaffing incidences has UNOS addressed in the last five years and how many unique OPOs were investigated?</p> <p>UNOS answered this question by talking about the process. UNOS triggers a "patient safety/non-routine compliance review" for OPO understaffing issues which basically leads to UNOS not doing much by determining if "OPTN policy or bylaw noncompliance [has] occurred."</p> <p>"OPO must have the necessary staff to [...] according to OPTN obligations" then later says "OPTN Obligations do not specify a minimum number of staff required to be employed by an OPO." It is unclear then how UNOS is going to make a determination about understaffing issues.</p> <p>Given that CMS's Conditions for Coverage for OPOs include that "All OPOs must have a sufficient number of qualified staff, including a director, a medical director, organ procurement coordinators, and hospital development staff to obtain all usable organs from potential donors", it is vital that the Senate Finance</p>

		Committee have access to OPO staffing information to ensure that OPOs, which are reimbursed by Medicare for their services, are actually meeting the necessary qualifications to receive such reimbursement.
1c. What, if any, steps has UNOS taken in response to findings in HHS OIG audits that multiple OPOs charged Medicare for unallowable expenditures?	The OPTN is not authorized to monitor or enforce CMS Conditions for Coverage.	<p>Why wouldn't UNOS be allowed to monitor what they can for the OPO condition for coverage? They might not be able to do anything directly, but it can certainly contribute to other authorized compliance duties.</p> <p>Just because UNOS is not authorized to enforce CMS's conditions for coverage doesn't mean they can't look into the same issues in parallel. For example, UNOS collects OPO data in parallel to OPO outcome measures. UNOS can use this data to monitor OPO performance as part of their OPTN oversight responsibilities, even though technically only CMS can decertify an OPO.</p>
1d. To what extent does the UNOS Membership & Professional Standards Committee (MPSC) conduct financial audits to ensure that all reported expenses in an OPO's Medicare Cost Reports are reasonable and focused on the OPO's mission of organ recovery? If the MPSC does not conduct any such audits, please explain why not.	The MPSC does not conduct financial audits. The OPTN is not authorized to monitor or enforce CMS Conditions for Coverage.	<p>What was asked: What does a specific subcommittee do to audit financials of a specific OPO report?</p> <p>Potential follow-up questions: When was the last time the government requested a UNOS/OPTN financial audit? Who was this provided to?</p>
1e. Is there an independent, third-party entity responsible for auditing each of the 58 OPOs to ensure that all costs are "reasonable," "necessary," "proper," and "allowable?" If so, please explain, including but not limited to the frequency with which such audits are conducted. If not, please explain why UNOS has not required any independent audits of OPOs.	<p>"UNOS and the OPTN do not require independent audits of OPOs for costs because cost reporting is not an OPTN Obligation, and the OPTN is not authorized to enforce non-OPTN obligations.</p> <p>To the best of UNOS's knowledge, such auditing would be conducted by CMS or by the Internal Revenue Service (or similar state agencies).</p> <p>If UNOS were to learn of unreasonable cost reporting through our incident handling process, we would refer the matter to HRSA for communication to CMS."</p>	

<p>2. Over the last 10 years, how many OPOs have been identified by the Scientific Registry of Transplant Recipients (SRTR) as statistically significantly underperforming over any reporting period?</p>	<p>“Since the OPTN began using these criteria for performance reviews in July 2012, the MPSC has conducted reviews of 23 OPOs for lower than expected yield in at least one organ. The average time between initial inquiry by the MPSC and the OPO’s release from review is 218 days.”</p>	<p>This number of OPOs that have been reviewed in the past 8 years seems very low, given that the NPRM showed that 37 OPOs would have been failing one or more of the original proposed outcome metrics based on 2017 alone, and the Final Rule based on 2018 data lists 34 OPOs as not meeting tier 1 criteria.</p>
<p>3. For each of these OPOs identified as statistically significantly underperforming by the SRTR, please provide a list of all instances of OPO underperformance in the last 10 years (as defined by statistical significance between the observed value and the expected value for the metrics reported on by the SRTR). For each instance, please describe:</p>	<p>“Since 2012, the OPTN has reviewed 23 different OPOs for performance under the metrics described in the responses to Questions 1.a. and 2. Four of those 23 OPOs have been reviewed by the MPSC on more than one occasion, when their organ yield improved and they later met criteria for review again.”</p> <p>Cites spreadsheet: “OPOs Identified by the SRTR as Statistically Significantly Underperforming”</p>	<p>NOTE: We don’t have access to the spreadsheet that lists the OPOs that aren’t hitting the mark.</p>
<p>3a. For each instance, please describe: the OPO in question; whether the instance was formally presented to the MPSC and the corresponding date; the review process; the composition of the relevant MPSC subcommittee(s) that reviewed each case, including any conflicts of interest for each MPSC member; the findings of such process; the recommended course of action, including whether a corrective action plan was implemented; and whether the respective OPO’s standing status was changed as a result of the instance.</p>	<p>Cites same spreadsheet referenced above, “OPOs Identified by the SRTR as Statistically Significantly Underperforming”</p> <p>UNOS describes the make-up of the MPSC, the peer performance review process, and the MPSC conflict of interest policy in place.</p>	<p>UNOS response is about the review process, the voting, etc, but doesn’t actually talk about the punishment that it can implement -- just the necessary steps to meet compliance.</p>
<p>4. What steps has UNOS taken to address delays and other issues of organ transportation, including to understand the impact of these issues on patient safety?</p>	<p>UNOS describes the UNOS Patient Safety team, OPTN Operations & Safety Committee, and UNOS Organ Center, as areas that allocate significant resources to understanding and addressing transportation issues.</p> <p>“While the Patient Safety team focuses on the compliance aspects of potential transportation issues learned about through these intake processes and conducts its investigations under the peer review process, the UNOS Research Department aggregates de-identified, summarized reports of patient safety situations (including</p>	<p>UNOS said that the Operations and Safety Committee (OSC) only does analysis on voluntary reported data. This is the biggest signal that OPTN/UNOS doesn’t have the information available to them to have a true understanding on how well things are working.</p> <p>If this data is voluntary, how do committees such as the OSC do actual analysis to “improve the quality, safety and efficiency of the organ donation and transplantation system”?</p>

	<p>both adverse events and near misses) submitted into the OPTN Improving Patient Safety (IPS) portal, and deliver them to the OPTN Operations and Safety Committee (OSC), which is charged to “improve the quality, safety and efficiency of the organ donation and transplantation system.”</p> <p>The OSC reviews these patient safety reports on a semi-annual basis. The purpose is to help the committee identify safety gaps and to proactively address high frequency and/or high impact events with system improvements. The committee uses this information to develop mechanisms that increase awareness and promote members to take measures to prevent repeat occurrences. Since reporting is voluntary is thus subject to underreporting, the purpose of analyzing this data at this time is not to estimate the true, underlying error rates, but instead to identify if certain types of events are becoming more frequent or if certain types of events are associated with loss of organs.”</p> <p>...In June 2019 the OSC prepared, and the OPTN Board of Directors approved, Guidance on Effective Practices in Broader Distribution.</p> <p>---</p> <p>From Guidance doc: The regions, as well as the AOPO, opined that the financial and billing information falls outside the purview of the OPTN.</p> <p>In response to the concerns raised about the financial and billing aspects of the guidance document, the Committee removed the following sections:</p> <ul style="list-style-type: none"> ● Establishing Fair Market Value for Organ Procurement Activity ● Organ Procurement Malpractice Coverage Considerations ● Organ Procurement Related Billing <p>How does this resource impact the OPTN Strategic Plan?</p> <ol style="list-style-type: none"> 1. Increase the number of transplants: There is no expected impact to this goal. 2. Improve equity in access to transplants: There is no expected impact to this goal. 3. Improve waitlisted patient, living donor, and 	<p>The guidance that OSC releases is “does not carry the weight of policies or bylaws. Therefore, members will not be evaluated for compliance with this document.” Which calls into question how effective these steps to addressing transportation issues.</p> <p>Similarly, UNOS lab is touted as an innovative way UNOS is addressing these issues, yet very little impactful work has come out of it. Logistics and transportation has already been figured out by existing companies and should not need to be reinvented for the organ transport system, especially given the low volume compared to other transportation systems.</p> <p>It’s a clear indication of how behind on technology UNOS is, given that their database system for tracking UNOS Organ Center transportation data was only formed in mid-2016.</p>
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	<p>transplant recipient outcomes: There is no expected impact to this goal.</p> <ol style="list-style-type: none"> 4. Promote living donor and transplant recipient safety: There is no expected impact to this goal. 5. Promote the efficient management of the OPTN: This guidance promotes the efficient management of the OPTN by providing information to members without adding additional requirements. <p>How will members be evaluated for compliance with this resource? Guidance from the OPTN does not carry the weight of policies or bylaws. Therefore, members will not be evaluated for compliance with this document.</p> <p>---</p> <p>Cites TransNet: “The OPTN is exploring ways in which the TransNet technology could be enhanced to integrate global positioning software (GPS) devices and third-party applications.”</p> <p>Cites “new project” with UNOS Labs: “UNOS also recently announced a new project to partner with OPOs throughout the country and the travel and logistics providers the OPOs use to conduct a “real-time data analysis to refine a feasibility algorithm aimed at predicting the optimal route for organ transplantation.”</p> <p>UNOS Organ Center: The UNOS Organ Center significantly improved its ability to collect and store more specific data when it implemented an online transportation form and underlying database form in late June of 2016. While this system was not specifically designed to track and trend transportation problems, it nevertheless created systems that can count and store those data. These data are relevant, but also limited; the data are input and reviewed by UNOS staff (not externally validated by the travel or logistics providers), and only include the small subset of transportations facilitated by the Organ Center for unaccompanied organs.</p>	
<p>4a. Please provide all documentation related to every instance, within the last 10 years, in which</p>	<p>“The data provided in response to these sub-questions are necessarily limited to only the small subset of organ</p>	<p>UNOS claims not to have any national data on this for OPOs (even though they are supposed</p>

<p>an organ was lost, delayed, damaged, or otherwise mishandled in transit, including the cause of the incident, the manner in which the incident was disclosed to the recipient and the family of the deceased donor, and all information related to the clinical impact these incidents have on recipients.</p> <p>4b. For each instance, please also indicate whether the organ was allocated by the UNOS Organ Center or the corresponding OPO.</p>	<p>transportation arrangements that were facilitated by the UNOS Organ Center, because the OPTN does not collect "transportation data" on a national, systematic basis."</p> <p>"The data collected by the UNOS Organ Center have several limitations. As noted above, the data have only been captured in this format since June 2016. The data include only information relative to shipments facilitated by the UNOS Organ Center and those data are not collected in a format that would demonstrate that organs that were "lost, delayed, damaged, or otherwise mishandled in transit." Rather, staff retrospectively document a "transportation issue" when an organ failed to reach its original intended destination within two hours of the original anticipated arrival time. So a "transportation issue" would include organs that were delayed and/or potentially mishandled in transit, but would not specifically capture an organ that was lost or damaged. When a "transportation issue" is identified, staff document and log the reason. As noted earlier, an important limitation of the data is the lack of any external validation of the staff- documented reasons by the commercial airlines or other logistics providers involved in the transportation."</p> <p>"It must be noted that it is not possible to determine whether or not a documented transportation issue was a factor in the transplant program's final decision whether to transplant an organ."</p> <p>--</p> <p>Neither UNOS nor the OPTN have any data available that would demonstrate "the manner in which the incident was disclosed to the recipient and the family of the deceased donor," nor any "information related to the clinical impact these incidents have on recipients."</p> <p>Disclosure to the family is entirely within the discretion of either the OPO or the transplant program, and the OPTN does not maintain any policies or bylaws on this topic.</p>	<p>to be monitoring OPOs), only providing data for organs handled by the UNOS Organ Center. This small subset is still large enough to be statistically significant (~4.5%). The organ center claims not to collect any of the types of data requested and only can give information on if an organ arrived 2 hours after initially intended -- all self reported too.</p> <p>Of the organs that were handled by UNOS Organ Center (over the 3.5 years they've reported), there was a 7.2% of "transportation issue". The data is small, but it suggests that if a "transportation issue" happens, there is a smaller percentage of an actual transplant happening. UNOS defends itself by saying it doesn't actually know why there is this percentage drop because it doesn't collect enough data from its own system. This calls into the question WHY it's "not possible to determine" if transportation was a factor in the organ not being transplanted. Why is this data not collected?</p> <p>In the end, UNOS doesn't even collect enough or the right data of its own systems - which begs the question on how well they are actually able to handle compliance on other areas of the system.</p>
<p>5. Please provide data on the number of organs eligible for transplant that were recovered for</p>	<p>Eligible Organs and Not Transplanted Data. Provided in Folder 5.</p>	

<p>transplant but not transplanted in the last 10 years, including the types of organs, the designated service areas (DSAs), and OPOs.</p> <p>5a. Please include all data related to the reasons why recovered organs were discarded.</p>	<p>“The reasons an organ that is recovered for transplant but not transplanted are often multifactorial. The reason provided to the OPTN by the OPO is the reason determined by the OPO to best fit the situation from the options provided.”</p>	
<p>6. In light of HHS OIG and Government Accountability Office (GAO) findings, as well as public reporting about various OPO improprieties (some of which resulted in prison sentences for OPO executives, misuse of taxpayer dollars, life-threatening patient safety issues, and troubling tissue recovery practices), please provide:</p> <p>6a. A list of any OPOs that have been accorded probationary status or named a "Member Not in Good Standing," including dates on which each such OPO's status changed.</p>	<p>Table 6.a.1: OPO Members that have experienced Adverse Actions</p> <p>Probation:</p> <ul style="list-style-type: none"> • New Mexico Donor Services • Nebraska Organ Recovery System • Indiana Donor Network <p>Member Not in Good Standing:</p> <ul style="list-style-type: none"> • Nevada Donor Network (Jul-11 to Jun-13) • Life Alliance Organ Recovery Agency - Florida OPO (Dec-15 to Dec-17) 	<p>It appears that UNOS' ability to discipline only goes as far as name and shaming. They did mention something interesting though -- "Probation and Member Not in Good Standing are the two adverse actions that the OPTN Board can impose that also require public notification. " Can UNOS do anything else on the discipline front that doesn't require public notification?</p> <p>This discipline action is incredibly weak.</p>
<p>6b. All materials related to the OPTN's fact-finding process with respect to any OPO that has ever been put on probation or listed as a "Member Not in Good Standing" by the OPTN, including all materials, reports, memos, audits, and correspondence relating to this process.</p>	<p>As previously explained, we respectfully cannot provide these materials because they are privileged, confidential medical peer review information.</p>	<p>How does UNOS protect against sham reviews?</p> <p>Electronic Code of Federal Regulations</p> <p>I couldn't find anything in the final rule that said peer reviews had to be protected, privileged, and confidential. UNOS is bringing this as an excuse to the table.</p> <p>OPTN Bylaws also states, "The medical peer review privilege will not be extended to withhold any document from the Secretary of HHS, or the Secretary's designee." (Pg198, OPTN Bylaws effective Aug 17 2020)</p>
<p>6c. All complaints made regarding (or violations alleged against) OPOs that have been reported to UNOS, including those considered to be</p>	<p>As previously explained, we respectfully cannot provide these materials because they are privileged, confidential medical peer review information. The success of our</p>	<p>UNOS claims privilege, but there is nothing defined in the final OPTN rule that backs this up. UNOS is making these claims on their</p>

<p>protected under peer review, both including cases referred and not referred to the MPSC, including all UNOS correspondence and corrective action plans, meeting minutes, and any other written records from MPSC deliberations related to those incidents.</p>	<p>member improvement processes are critically dependent on the trust our members have in the confidentiality of this process.</p> <p>While the MPSC cannot discuss the specifics of cases in order to help other programs avoid those particular problems, it is committed to searching for common themes and areas of weakness that can lead to general news articles, education events, or policy changes.</p> <p>UNOS staff often partner with MPSC members and with members who have interacted with the MPSC to present lessons and improvements that have been achieved as a result of the interactions. These presentations often occur at transplant conferences. (Gives example of conference presentations in separate folder)</p>	<p>own.</p> <p>It's also questionable what "successes" of UNOS member improvement processes there are that dependent on the peer review process.</p> <p>Lastly, given that it's clear that HHS can already access all MPSC files according to the policies noted above, no MPSC members should have participated in the MPSC process with any expectation that MPSC records would necessarily be shielded from the government. Given this, UNOS's assertion that introducing the ability for Congress to access this info would undermine the sanctity of the process, and that people wouldn't participate fully anymore as a result, is nonsensical.</p>
<p>6d. The names (and corresponding professional affiliations) of each individual that has ever served as chairperson of (1) the MPSC, and/or (2) the OPO subcommittee. (Please also provide a list of all members of the relevant MPSC subcommittee(s), and anyone else involved in the decision-making process regarding whether or not to investigate each complaint at the time of the referral or non-referral.)</p>	<p>Current MPSC Roster and Historical MPSC and Subcommittee Rosters provided in Folder 6.</p>	
<p>6e. A description of the MPSC's overall structure (as well as its subcommittee structure), including how the oversight and investigatory responsibilities are apportioned between and among the various committees and subcommittees, as well as the process by which complaints are directed to various subcommittees or committees of MPSC.</p>	<p>"The MPSC is made up of 38 voting members, including a Chair and Vice-Chair, 11 elected regional representatives known as Associate Councilors, and at-large representatives to promote representation from each area of specialty...The Associate Councilors are elected by their OPTN Region. Associate Councilors normally join the Board of Directors after a 2 year term on the MPSC."</p> <p>UNOS outlines MPSC's review process.</p> <p>"The MPSC's work to define the process for OPO Performance review involved a work group consisting of all the MPSC members who worked at an OPO."</p> <p>CONFLICT OF INTEREST POLICY</p>	<p>How does attestation protect against conflicts of interest? Who in UNOS is actively verifying compliance internally?</p> <p>It seems that most of the conflict of interest disclosure is voluntary and doesn't preclude MPSC members from acting in ways that might financially benefit them once they're on the committee (such as recommending certain services to OPOs).</p> <p>OPOs are members of the MPSC which is tasked with OPO performance reviews. There is an inherent conflict here.</p>

	<p>“Along with maintaining confidentiality, it is equally important to avoid conflicts of interests. MPSC members are considered to have a conflict with any case in which they have a personal or financial interest in the outcome. All MPSC members must disclose such conflicts of interest at the beginning of their term when they complete an agreement or during the year if a new conflict arises. In addition, an MPSC member is presumed to have a conflict of interest in any case involving an institution: at which the committee member is currently employed, or located in the same DSA, state, or Region as the committee member.</p> <p>The MPSC also recognizes that there are some gray areas where timing and context are relevant to determining a conflict of interest. There is a presumed conflict if, within the last five years, the MPSC member has: an advising, consulting, or mentoring relationship, has been previously employed or trained there, or trained individuals involved in the case</p> <p>If one of these criteria were met more than five years ago, there is no presumption of conflict unless the MPSC member has a personal or financial interest. MPSC members are instructed to assume that they are conflicted if they are unsure whether a conflict exists. MPSC members are also encouraged to speak if they believe that another member of the committee has a conflict with a matter.”</p>	
<p>7. Given that multiple OPOs recover tissue and some operate tissue banks, on what mechanisms does UNOS rely to minimize conflicts of interest, and what measures does UNOS take to protect against OPOs prioritizing tissue recovery over organ recovery due to financial incentives?</p>	<p>“Each year, as an OPTN Contract deliverable, UNOS submits to HRSA a Conflicts of Interests Mitigation Plan.”</p> <p>“All Board and committee volunteers must also sign the OPTN conflicts of interest and confidentiality agreement annually, and disclose conflicts on an ad hoc basis as they arise. The OPTN Bylaws also address conflicts of interests for Directors. UNOS and the OPTN do not have specific conflicts of interests policies with regard to members and the work they perform on a daily basis.</p> <p>UNOS and the OPTN do not have specific conflicts of interests policies with regard to members and the work they perform on a daily basis.</p>	<p>UNOS talks about how they generally manage conflicts of interests but does not sufficiently address the issue of financial incentives for tissues specifically.</p> <p>There is a clear financial incentive for OPOs to prioritize recovery of tissue, given that it is a multi-billion dollar lucrative business.</p> <p>UNOS is trying to reframe this as a question of whether OPOs would prioritize tissue over organ recovery in the case of a single donor who is able to donate both; the real question at hand is whether OPOs over-allocate resources to tissue recovery versus organ recovery on</p>

	<p>...As explained below, there is no incentive for OPOs to prioritize recovery of tissue.”</p>	<p>an annual basis, not a specific instance, which would be in line with what stakeholders tell us happens regularly and is one of the biggest problems plaguing the organ recovery system.</p>
<p>7a. Under what circumstances might financial incentives to recover tissue create a conflict of interest for an OPO? In the event that such a conflict arises, how does UNOS ensure that it is resolved?</p>	<p>“...The time that it takes to do the organ recovery leaves ample time for tissue recovery, so there is no need to choose between the two or prioritize tissue recovery over organ recovery.”</p> <p>UNOS and the OPTN do not have specific policies or bylaws with regard to prioritizing organ recovery over tissue recovery.</p>	<p>This does not address the financial incentive issue.</p> <p>As the OPTN contractor for 40 years, UNOS is still only looking at acute issues, rather than systemic failings of the system, such as financial abuses and mismanagement, as well as and conflict of interest problems in tissue recovery. Given the preponderance of research and investigative reporting about these problems, as well as how readily such issues were shared with us by stakeholders, it would strain credulity to believe that UNOS, having operated as the OPTN for decades, was not aware of them.</p>
<p>7b. Please provide a list of each OPO currently operating a tissue bank. For OPOs that do not operate a tissue bank, please list any tissue-related companies with which they are affiliated.</p> <p>7c. To what extent and how are the nature of OPO relationships with tissue companies disclosed to donor families as well as the general public?</p> <p>7d. Which OPO leaders, if any, have personal financial interests in tissue banks and/or tissue processing?</p>	<p>UNOS and the OPTN do not collect any of the information you seek in this question.</p>	<p>In this final set of questions, UNOS claims it does not collect any data that could help answer the question. This is a dodge. It might not officially collect data, but it certainly can figure out without much difficulty.</p>
<p>8. For each of the 58 OPOs, please provide the amount of compensation received by its chief executive officer (CEO) and its chief operating officer (COO) from the OPO or affiliated organization(s) (e.g., the OPO's foundation).</p> <p>8a. For each such CEO and COO, provide a</p>	<p>UNOS and the OPTN do not collect any of the information you seek in this question.</p>	

<p>breakdown of the compensation received from the OPO and/or affiliated organization(s) based on annual salary, bonuses, or other forms of compensation.</p> <p>8b. For each such CEO and COO, please disclose any business, entity, customer, supplier, contractor, or partner with which the OPO had a contract or financial relationship (e.g., tissue processors, cornea banks, funeral homes, OPO foundations, histocompatibility labs aviation companies, etc.), including but not limited to salary, consulting fees, sales commissions, or equity interests, and list the exact breakdown of compensation the CEO or COO receives.</p> <p>8c. How are these financial relationships disclosed to Federal entities and the public?</p>		
<p>9. Given that some OPOs provide financial compensation for their board members (beyond reasonable expenses for board-related activities and travel/lodging), please provide a list of which of the 58 OPOs compensate their board members, including via contracts or other relationships with external organizations with which the board member maintains a relationship, and the exact amount of compensation received by those board members.</p>	<p>UNOS and the OPTN do not collect any of the information you seek in this question.</p>	
<p>10. Which OPOs, or organizations affiliated with OPOs (e.g., TxJet) own, operate, or otherwise maintain a private plane? If multiple OPOs, jointly own, operate, or otherwise maintain a private plane, or a parent organization owning multiple OPOs (e.g., DCI Donor Services) owns, operates, or otherwise maintains a private plane, or if an OPO leases any of their planes to another OPO, transplant center, or other organization, please explain.</p> <p>10a. How does UNOS ensure that these private planes are not used for flights that are not</p>	<p>UNOS and the OPTN do not collect any of the information you seek in this question.</p>	

directly related to recovering or transplanting an organ?

10b. For each flight, please indicate whether there is a corresponding UNOS ID number. For any flight, or any leg of a flight, that does not have a corresponding UNOS ID number, please state the purpose for each leg of the flight-such as "maintenance," or "OPO employees fly to conference," or "personal travel for the CEO of the OPO."

10c. If a private plane is used for unrelated purposes, such as to attend conferences, fundraisers, or for an OPO employee's personal travel, please provide documentation showing to what entity each leg of the flight was billed.