Introduction
The DAC Committee met via Citrix GoTo teleconference on 05/20/2019 to discuss the following agenda items:

1. Review Draft Policy Language

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

1. Review Draft Policy Language

UNOS staff presented an overview of past decisions made regarding draft policy language for OPTN Policy 18: Data Submission Requirements.

Summary of discussion:

- There were no comments or questions concerning the elimination of OPTN Policy 18.4: Data Submission Standards.
- UNOS staff then discussed the proposed changes to OPTN Policy 18.1: Data Submission Requirements, including data submission timeframes, data reporting, and ensuring that OPTN members submit accurate data. UNOS staff asked whether the Committee agrees to apply submission requirements to the data shown in the proposed OPTN Policy 18.1.C.i: Applicability. UNOS staff clarified that a data lock would only apply to the forms outlined under this sub-policy. Furthermore, OPTN Policy 18.1.C outlines that these are the only forms subject to the data lock provisions and as such, there may be other forms that can or cannot be changed according to other OPTN policies.
- At this time, a Committee member commented that during the DAC in-person meeting, those Committee members present had agreed that it was not logical to have two different submission timeframes. In follow-up to this, another Committee member asked whether data could be entered early and then have quality checks done performed by the deadlines outlined under OPTN Policy 18.1: Data Submission Requirements. UNOS confirmed for the Committee that members would first have an opportunity to save entered data. Saved data is not considered final until the member selects/clicks “submit” in the system. For example, at their in-person meeting, some OPO representatives had stated that 30 days was too restrictive for data entry and validation, however agreed that extending this deadline would allow enough time to perform quality measures on the data. UNOS staff also confirmed for the Committee that there would be another step prior submission (e.g. a “save” button).
- There was concern from one Committee member that recipient data may not be submitted in time because certain results, such as an autopsy or cause of death, may come in after the submission deadline. In response, a Committee member said that at the in-person meeting they discussed having a list of options that members could choose from to indicate why data was changed. Other Committee members agreed with this suggestion, even though one member opined that death data may not be reported on any of the forms currently being evaluated at by the Committee. Also, some
Committee members agreed that the data presented at the DAC in-person meeting had shown most centers submitting their data within the newly proposed timeframes.

- Next, UNOS staff reviewed the proposed policy language OPTN Policy 18.1.C.ii: Requirements. Specifically, UNOS staff asked for Committee members to clarify the words “extensive” and “extraordinary circumstances” in the proposed language. During this discussion, one Committee member was undecided on whether programs could change all data errors post-submission, or only be able to make changes as a result of extensive data errors. An advocate for allowing programs to change every data error post submission were concerned that not ever allowing minor data changes could lead to inaccurate data, even though these errors might be known and correctable. An example given was that a data coordinator may inadvertently select “positive” instead of “negative” for an HIV result. The Committee member stated that this may not fall under the word “extensive”, but would need correction. Also, the Committee members stated that as long as there is a manual process for typing and submitting huge amounts of data, then data errors will occur. The Committee member also stated that 90 days is not enough for post-transplant data submission, including quality checks. This Committee member opined that the new deadlines for the TIEDI follow-up forms may not be an “extension”, because such deadlines would be shorter than the deadlines in outlined under current OPTN Policy 18.4: Data Submission Standards. Due to the above, this Committee member voiced considerable concern that there may be substantial public comment backlash, especially if the data entry personnel are unable to see if the data they enter is correct. The member indicated that this change may be particularly difficult to meet as it applies to the follow-up forms. Members submitting the follow-up forms are submitting based on the timeframes in Policy 18.4: Data Submission Standards, which add an extra three months to the existing timeframes in Policy 18.1: Data Submission Requirements.

- Other Committee members argued that data errors should only be allowable for extensive data errors. These Committee members stated that the goal of this project is to prevent single-data entry correction, and rather promote better data quality measures. Specifically, the Committee should focus on changing member behavior so that data is entered correctly the first time. Another Committee member commented that programs are not actually reviewing all their data to verify if a HIV positive candidate was marked as HIV negative. In fact, programs are barely keeping up with the huge amounts of data needing to be submitted. The extra time would allow programs to conduct additional quality checks. Other Committee members agreed, and stated that this would not be giving centers more work, but rather decreasing their work load. UNOS staff also stated that a longer time frame may help ease the transition for programs. UNOS staff also clarified that at the DAC in-person meeting, UNOS had agreed to develop more tools on the front end that could help members during a transition period. These tools could allow data entry personnel to view their errors or see the percentage of data missing prior to submission. Other Committee members agreed, and stated that members are in the habit of reviewing data prior to the release of their PSR reports. Lastly, these Committee members contradicted the opinion that the new deadlines would be shorter than the previous deadlines outlines under OPTN Policy 18.4: Data Submission Standards.

- All Committee members agreed that it would be reasonable to give a transition period prior to implementing any new deadlines. Furthermore, they agreed that there must be proper notice given to all OPTN members, and that additional monitoring tools must be provided. UNOS staff clarified that there would be a transition period, perhaps up to a year. Furthermore, UNOS staff had planned on reaching out to other transplant societies to further disseminate these policy changes.
In terms of the language, one SRTR staff member opined that the word “extensive” not be included into policy language, because errors should be corrected no matter how small or large they are. In this way, the project’s concept should not be to make it harder to fix data errors, but rather that there is more work involved to fix the errors. Furthermore, SRTR opined that programs should be allowed to make errors, and that correcting errors not be seen as a “privilege” to be done solely by low-performing programs. A few other Committee members agreed with SRTR, including having programs prove that the data they entered is incorrect. SRTR staff also suggested that instead of using the verbiage presented by UNOS staff, that the policy language should make it clear that there are significant consequences to having a high change rate for data, such as being reported to the MPSC. Furthermore, a SRTR staff member advocated for UNOS to approve all data change requests.

In response to the SRTR comments above, some Committee members stated that allowing all errors to be corrected is already in line with the status quo. UNOS staff went on to clarify that the proposed policy language would include provisions to show the reasoning why the data was changed. Furthermore, giving members a longer timeframe would help encourage centers to submit accurate data. Another Committee member stated that the policy language should be used to make it clear that programs should change their workflows prior to submitting data. Furthermore, the word “extensive” is meant to discourage members and create a difficult process for changing data. Also, a Committee member opined that the word “extensive” is less stringent than the original word “extenuating”. UNOS staff stated that the proposed policy language would include a system for checking that would capture low performing centers. However, UNOS staff also stated that creating a review board process within the OPTN would not be in the scope of this particular project, and would require significant effort and resources. Lastly, UNOS staff reiterated that the Committee had decided to extend the timeframes to encourage quality checks, and provide more data submission tools.

Next, Committee members generally agreed to the second paragraph of OPTN Policy 18.1.C.ii, but asked if the programs would need to keep a log of data changes. UNOS staff clarified that prior to making any changes, the OPTN representative would need to approve any changes and therefore maintain a log.

Next steps:
UNOS staff will circulate the draft policy language in order to get more feedback from Committee members.

Upcoming Meetings
- June 17, 2019
- October 10, 2019 (In-person)