

Updating the OPTN Definition of Transplant Hospital

OPTN/UNOS Membership and Professional Standards Committee

*Prepared by: Chad Waller
UNOS Member Quality Department*

Contents

Executive Summary	1
What problem will this proposal solve?	2
Why should you support this proposal?	2
How was this proposal developed?	3
How well does this proposal address the problem statement?	9
Was this proposal changed in response to public comment?	10
Which populations are impacted by this proposal?	12
How does this proposal impact the OPTN Strategic Plan?	12
How will the OPTN implement this proposal?	12
How will members implement this proposal?	13
Transplant Hospitals	13
Will this proposal require members to submit additional data?	14
How will members be evaluated for compliance with this proposal?	14
How will the sponsoring Committee evaluate whether this proposal was successful post implementation?	15
Policy or Bylaws Language	16

Updating the OPTN Definition of Transplant Hospital

Affected Bylaws: OPTN Bylaws Appendices D.2 (Designated Transplant Program Requirement); D.11.F (Veteran’s Administration (VA) Dean’s Committee Hospitals); and M (Definitions)

Sponsoring Committee: Membership and Professional Standards

Public Comment Period: August 15, 2016 – October 15, 2016

Executive Summary

Updates to how the OPTN defines a transplant hospital are needed to better describe attributes requiring consideration by the Membership and Professional Standards Committee (MPSC) when it reviews OPTN membership and transplant program designation applications. A transplant hospital member is currently defined by OPTN Bylaws as “a membership category in the OPTN for any hospital that has current approval as a designated transplant program for at least one organ” and by OPTN Policy as “a health care facility in which transplants of organs are performed.” A lack of distinguishing detail in these definitions has proven to be problematic when assessing the membership of healthcare institutional configurations consisting of multiple hospitals performing transplants of the same organ type at geographically separated sites. The goal of this proposal is to better define the basic accountable unit in which organ transplantation occurs so that meaningful, accurate, and conclusive assessments can be made regarding transplant program performance with patient safety, patient outcomes, and overall compliance with approved OPTN obligations.

What problem will this proposal solve?

The current definitions of a transplant hospital in OPTN Policy and Bylaws have not been modified since their original implementation in 1986. Development of the OPTN's definition of a transplant hospital at that time focused on political and membership representation considerations so that members would have an appropriate say in the development of the national transplant system and organ allocation policies. The evolving structure of hospitals and medical systems has rendered the current definitions too simplistic, and vulnerable to differing interpretations.

The MPSC often faces the issue of defining a transplant hospital, and has traditionally relied on a set of operational rules when reviewing applications:

- A discrete facility where an OPTN approved member transplant hospital performs organ transplants as allowed under its organ transplant program designation and approval
- The basic measurement unit is a single site (hospital)
- A single CMS Certification Number CCN awarded to distinct and separate hospitals does not mandate OPTN approval as a single member transplant hospital

More recently, the application of these operational rules has been challenged by some members. As a result, the OPTN/UNOS Board of Directors instructed the MPSC to update and improve the OPTN's definition of a transplant hospital.

Why should you support this proposal?

Adoption of the changes in this proposal will better define the basic accountable unit in which organ transplantation occurs. The MPSC recommends expanding the OPTN's definition of a transplant hospital as described in this proposal to reduce ambiguity, while still providing sufficient flexibility to accommodate members that may have a unique hospital arrangement not exactly captured by these proposed Bylaws. In doing so, these changes establish clearer parameters for the MPSC to assess transplant hospital membership applications, and will also provide members a clearer perspective of what is necessary and allowed when expanding, consolidating, or starting a transplant hospital.

Focusing on specific elements of this proposal:

- It has long been a standard that transplant hospitals can only have one transplant program for each respective organ. This proposal formalizes this consideration.
- In assessing transplant hospital applications, the MPSC has commonly considered multiple operating suites to transplant the same organ type as necessitating separate transplant hospital designations. This was formally reiterated most recently in a letter to HRSA from the MPSC Chair, dated November 10, 2010, "*...each transplant hospital facility, at which a same organ type transplant is being performed, must have the required organ transplant program designation approved for that facility. By adopting this principle, the OPTN, at this time, can assure accountability, transparency and monitoring for each transplant program regardless of its ownership and location.*" Public comment feedback provided in response to an earlier proposal to update the OPTN's definition of a transplant hospital (distributed September 2014) prompted the MPSC to reconsider this standard, especially considering growing and expanding hospitals. As such, this proposal formalizes that transplant hospitals may include multiple transplant facilities throughout the hospital that are used to transplant the same organ type. These facilities must be within the same hospital campus (as defined by this proposal), be under common executive leadership and governance oversight (to assure general organizational consistency and an overarching point of accountability), and each operating room must be documented with the OPTN prior to its use for performing transplants (to validate that a transplant hospital applicant meets the requirements outlined in this proposal).

Veteran's Administration (VA) Hospitals that are Dean's Committee Hospitals and share a common university based transplant team currently do not need to submit a separate membership application to

the OPTN Contractor, but may be considered members under the university program with which they are affiliated. This proposal recommends the elimination of the “Dean’s Committee Hospital” designation (OPTN Bylaws Appendix D.11.F), thereby requiring every transplant hospital to submit membership applications. The MPSC believes that the Dean’s Committee hospital arrangement is not much different from other transplant hospitals that may have the same key personnel but are otherwise separate and different. This is further illustrated by the fact that Dean’s Committee hospitals have separate UNOS naming codes for allocation and data collection purposes. The elimination of the Dean’s Committee hospital designation would create consistent expectations for all transplant hospitals (currently, there are two transplant hospitals with this designation). Additionally, these changes address potential, undesirable scenarios that could result from considering Dean’s Committee hospitals as members under the university program with which they are affiliated. As a hypothetical example, consider the possibility of a Dean’s Committee hospital being declared as a member not in good standing. As adverse actions are rendered at the organizational level, and because the current Bylaws indicate a Dean’s Committee hospital is considered a member “under the university program with which they are affiliated,” the affiliated university hospital in this hypothetical scenario would also be declared a member not in good standing.

How was this proposal developed?

The MPSC sponsored a proposal in September 2014 that similarly focused on updating the OPTN’s definition of a transplant hospital. This September 2014 proposal recommended incorporating the MPSC’s operational rules for evaluating a transplant hospital in the Bylaws. Public comment provided in response to this proposal was mixed, with numerous concerns raised that the proposed Bylaws changes were too ambiguous and did not sufficiently accommodate hospital arrangements in the current healthcare environment. Without more extensive support for this proposal, the MPSC agreed that it would not present this proposal for the Board of Directors’ consideration and that it would form a new work group to reevaluate this topic.

Multiple Operating Rooms for Transplanting the Same Organ Type

Based on public comment feedback, the work group believed that this proposal needed to accommodate scenarios where a transplant hospital may transplant the same organ using multiple operating room suites throughout the hospital. The work group initially discussed the possibility of establishing transplant “sites” that are associated with a transplant hospital. The work group suggested that each transplant “site” must have independent key personnel, functional and inactivity reviews, and coverage plans. Additionally, each transplant hospital member must at least have HLA and blood bank services, mental health and social services, clinical and financial coordinators, and a transplant pharmacist available (not necessarily dedicated to) for each of its transplant sites. Ultimately, the work group decided to move away from the concept of “transplant sites” as it seemingly created another layer of complexity without comparable benefit for transplant hospital members.

Although the work group agreed that it would not be prudent to update the OPTN’s transplant hospital definition by establishing “transplant sites,” and thereby introducing greater complexity to the oversight of transplant hospitals, it continued to believe there was value in expanding the OPTN’s definition of a transplant hospital. Building off its “transplant sites” discussions, the work group agreed that a transplant hospital may include multiple operating rooms, intensive care units, post-operative care units, etc. for transplanting a single organ type, as long as these facilities include the appropriate infrastructure for transplant patient care. During these discussions, the work group realized that its focus on transplant hospital “facilities” (e.g., operating rooms, intensive care units, post-operative care units, etc.) was likely too broad and may introduce unwarranted confusion. As such, and considering the current standard that transplant hospitals are defined by where transplant operations actually occur, the work group agreed that the proposed Bylaws language should focus on the transplant operating room locations. Proceeding this way, the work group also felt that few other considerations were necessary to address potential concerns with this approach:

- Considering that a hospital’s location does play a factor in organ allocation, and to avoid significantly disrupting the current allocation systems, the work group agreed that all of a transplant hospital’s

facilities must be within the same donation service area (DSA) to be considered one transplant hospital.

- For the sake of accountability and consistency at the transplant hospital, the work group also believed that all of a transplant hospital's operating rooms must be under "common executive leadership and governance oversight" to be considered a single transplant hospital by the OPTN.

The work group wrestled with the best way to describe this requirement to assure that there is central oversight over all operating rooms that are associated with one particular transplant hospital. Noting that hospital organization structures and the titles of hospital leadership bodies vary greatly (e.g., Board of Directors, Board of Visitors, Board of Governors, etc.), the work group was reluctant to try to list every possibility in the Bylaws out of concern that this list would never be exhaustive or all-inclusive. After much discussion, the work group agreed on "...must be under common executive leadership and governance oversight, demonstrated to satisfaction of the OPTN."

The work group discussed examples of common documentation that the OPTN would anticipate a member providing to demonstrate "common executive leadership and governance oversight:"

- Organization charts
- Organization bylaws that address general hospital oversight, medical oversight, and quality oversight
- 990 tax form
- Annual report

None of these items are explicitly required. Rather, this list exemplifies types of documentation that the MPSC would expect in a transplant hospital application to demonstrate central oversight over all the operating rooms associated with that particular transplant hospital.

- The work group also proposed that each operating room that a transplant hospital intends to use for transplanting organs must first be documented with the OPTN. Specifically, the following information must be documented for each operating room that will be used for transplantation:
 - Maps that illustrate the transplant hospital campus and the location of each operating room facility
 - Building name and address
 - Floor number
 - Unit identifier

The work group thought this information was critical for the MPSC in its review of applications to make sure the transplant hospital meets the requirements proposed in this document, particularly the transplant hospital map and building name and address where each operating room is located. Additionally, should the hospital experience a patient safety event, this information may also help the MPSC work with the member to focus on whether infrastructure issues at a particular location in the hospital may be a factor.

It is also important to note that members will be expected to notify the OPTN to document any operating room facilities not previously provided, prior to using those operating rooms for transplant surgery. For example, if a brand new building is being constructed on the campus of a transplant hospital, the transplant hospital must document the above information with the OPTN for the operating rooms that may be used for transplant surgery prior to those operating rooms being used for transplant surgery.

Geographic Considerations

The work group also discussed if other geographical considerations were necessary to supplement the OPTN's definition of a transplant hospital. Discussion revealed two examples of hospital arrangements that the group believed would be important to address with this proposal- transplant hospitals on a "contiguous campus," and transplant hospitals that have buildings and facilities scattered around an area that also includes other buildings and space that are not affiliated with the transplant hospital. The work group also recognized that there might be other transplant hospital arrangements outside of these two

scenarios that the MPSC would deem acceptable. As such, to accommodate what is expected to be a small number of members that do not completely align with the requirements of the contiguous campus or “non-contiguous campus” options, the work group suggested a third option that would allow the member to engage the MPSC to explain its unique circumstance.

The work group thought transplant hospitals with everything located within single boundary that encompasses land and buildings directly associated with the hospital was fairly intuitive. The work group looked at a number of maps of university hospitals to confirm its comfort with this approach. The work group also felt it was important to define a “contiguous campus” explicitly to minimize confusion around this concept.

Next, the group focused on developing requirements for transplant hospitals that did not have all of its transplant operating rooms within a contiguous campus. During these discussions, the work group commonly referenced transplant hospitals in highly populated, urban areas. The group agreed that a single transplant hospital in these environments should be approved as long as all of the hospital’s transplant operating room facilities are within a pre-determined radius of the hospital’s primary address. A specific point of reference in this definition is necessary because otherwise, a hospital could theoretically extend an indefinite distance as the pre-determined radius could repeatedly extend from the furthest point of the hospital campus. The work group chose the main hospital address as the reference point because it would be a clear point to assess hospital campus proximity, and one that could be easily determined for every transplant hospital.

Deciding the appropriate radius to define a transplant hospital campus in this manner was not as obvious. Early in its discussions, the work group recognized that there were limited resources to draw from to guide its decisions such that whatever was decided would be somewhat arbitrary. The work group did reference numerous maps that illustrated the locations of transplant hospitals to help guide its decision. First, the work group pondered what the average distance of a “contiguous campus” might be such that this could guide what should be expected of a “non-contiguous campus.” Debating this possibility, the work group ultimately agreed that there was too much variability across hospital campuses to rely on this value. Next, the work group considered a half-mile radius. This distance was ultimately decided to be too short, possibly resulting in a substantial number of transplant hospitals requesting a discussion with the MPSC to seek approval of their transplant hospital’s arrangement. The work group proceeded to consider a two-mile radius, but ultimately determined that this distance was too expansive. The work group acknowledged that whatever it determined would be the starting point of discussion around this detail, and it reached consensus around the idea of a one-mile radius. The work group also liked the idea of a one-mile radius because it approximately reflects a distance that most people can walk in 15-20 minutes. The work group thought the ability to travel the campus by foot in a timely manner could be helpful in certain emergencies.

This one-mile radius decision prompted additional considerations about significant differences between transplant hospitals that may exist within their respective one-mile radius. For example, what if there is a major geographic (e.g., mountain range, river) or man-made (interstate) impediment that bisects the one-mile radius; additionally, traveling one mile in New York City is different (mode of travel, time it takes, etc.) than traveling one mile in more rural areas. To “normalize” this one-mile radius so that a similar standard applies in all situations across the country, the work group recommended that this consideration reflect a “one mile walking distance.” Under this approach, transplant operating room facilities that are within a one-mile radius of the hospital’s main address, may not be approved as a single transplant hospital unless there is a path to those operating facilities from the main hospital address that can be traversed and is less than a mile long. To conclude discussion of this particular consideration, the work group proposed that any transplant hospital not located on a “contiguous campus” could be approved as a single transplant hospital if all of its operating room facilities used for transplantation are within a one-mile walking distance radius of the main hospital address.

If a transplant hospital is not located on a contiguous campus, or all of its operating room facilities are not within a one mile walking distance from the main hospital address, then there is a third option for transplant hospital applicants to explain their unique situation so that the MPSC may consider its

approval. Although the work group believes that the overwhelming majority of current members will be accommodated by one of the two set transplant hospital campus considerations, it thought there was a need to include some flexibility with these requirements to accommodate unique transplant hospital arrangements, including ones in the future that may not have been considered during these efforts. The work group aimed to accommodate all current transplant hospital members with its recommendations, and it felt that greater simplicity (through discretion and flexibility) in what defines a transplant hospital was a better approach than trying to craft more complicated and nuanced Bylaws that would more rigidly accommodate every transplant hospital arrangement. Discussing this proposed flexibility, the work group made clear that the burden of proof for the approval of a unique transplant hospital arrangement rests with the transplant hospital applicant. The proposed Bylaws reflect this by requiring these transplant hospital applicants to provide a written explanation of the circumstances that necessitate the designation of a single transplant hospital, or preclude the registration of a second transplant hospital. At the very least, this written explanation must address these considerations as it relates to transplant patient safety, the impact on patient access, and the utilization of organs. Additionally, the transplant hospital must provide its plan for patient care to demonstrate that all necessary services and support will be available to transplant candidates and recipients. The written documentation provided will serve as the foundation for an informal discussion between the transplant hospital applicant and the MPSC. Upon the conclusion of this informal discussion, the MPSC (or an ad hoc subcommittee) will determine whether to grant the transplant hospital interim approval (pending final decision by the full MPSC or Board of Directors).

Throughout these discussions, the group worked from the assumption that each transplant hospital could only include one transplant program for each respective organ type. This has always been a fundamental consideration of the MPSC when reviewing applications, and Bylaws language is proposed to formalize this. During the development of this proposal, as an extension of this consideration, the work group recommended that only one transplant hospital could cite any one transplant hospital campus. Reviewing transplant hospital maps during these discussions prompted additional questions regarding children's hospitals and Department of Veteran Affairs hospitals (VA hospitals). With respect to the desire for this proposal to accommodate all current transplant hospital members, the work group thought exceptions were necessary for children's hospitals and VA hospitals on the same transplant hospital campus so that they had the option to continue as separate transplant hospitals.

After establishing the need for these exceptions, conversation turned to how this would be monitored. Although it may not be a frequent scenario, how can the OPTN assure that transplant hospitals granted these exceptions would continue as VA hospitals or hospitals that predominantly transplant pediatric patients? Regarding pediatric transplant hospitals, the work group first needed to define which hospitals it is referencing, as the OPTN does not have a formal definition for "pediatric transplant hospital." The work group referenced the Centers for Medicare and Medicaid Services (CMS) interpretation of the Conditions of Participation¹ for transplant hospitals regarding the approval of adult and pediatric transplant programs. It states that, "a transplant program that performs 50% or more of their total transplants (in a 12-month period) on a given age group (majority), adult or pediatric, is not required to apply and be approved separately for the minority age group." The work group thought a similar 50% threshold would be acceptable to define a pediatric transplant hospital for the purposes of these Bylaws to establish that children's hospitals performing transplants can cite the same transplant hospital campus as another transplant hospital. With this exception (and assuming all other transplant hospital criteria are met), a pediatric transplant hospital that shares a campus with another transplant hospital would have the option of continuing as two separate transplant hospitals or the two hospitals on the same campus could combine as one OPTN transplant hospital. Both of these scenarios currently exist, and future decisions about how hospitals in this scenario would like to be arranged would be left to the respective hospital administrations.

¹ "Notice to Transplant Programs: Applications and Approval for Adult and Pediatric Transplant Programs," accessed June 20, 2016, <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/Downloads/Programsservingadultsandpeds.pdf>

With clarity on what hospitals this exception could apply, the work group's discussion returned to what type of monitoring would be necessary to assure that the conditions of this exception continue to be adhered to. The work group ultimately agreed that the MPSC should review these pediatric hospitals periodically to verify that they performed 50 percent or more of their transplants in patients less than 18 years of age during the previous 12 months. Failure to meet this threshold will prompt an informal discussion with the MPSC to allow the member an opportunity to explain the situation. This informal discussion is intended to proceed similarly to other MPSC informal discussions outlined in the Bylaws. If the MPSC is not satisfied with the explanation as to why the hospital did not primarily transplant pediatric patients in the previous 12 months, or the transplant hospital's progress towards rectifying the situation, the transplant hospital will no longer be seen as suitable for the exception that allows more than one transplant hospital on one transplant hospital campus. As such, the MPSC may ask one of the transplant hospitals to inactivate due to it no longer meeting the transplant hospital campus exception requirement. The work group originally suggested that this review occur every year; however, because the exception is primarily directed at children's hospitals, it is expected that this exception will rarely, if ever, be problematic. As such, the MPSC agreed that it will look at these transplant hospitals periodically and as it becomes aware of possible problems, but it did not think it was necessary to routinely monitor adherence to this requirement.

Regarding VA hospitals, the work group stated that VA hospitals are a clear designation that is not likely to change, and not something that needed further monitoring by the OPTN. The work group agreed with this approach for the purpose of this transplant hospital campus exception, but focus on VA hospitals raised additional questions regarding the "Dean's Committee Hospital" designation found in OPTN Bylaws Appendix D.11.F (Veteran's Administration (VA) Dean's Committee Hospitals). Much like the OPTN's transplant hospital definitions in Policy and Bylaws, the Board of Directors approved the Dean's Committee Hospitals Bylaws in 1988 and this language has not been significantly modified since. The work group questioned if it was still reasonable to allow these hospitals to be considered members under the university programs with which they are affiliated and not requiring the submission of a separate membership application. Currently there are two VA Dean's Committee Hospitals, and at the time of these discussions, there were three. Discussion highlighted that the work group believed all transplant hospitals should be expected to submit membership applications, including VA Dean's Committee hospitals. Even though these hospitals may be staffed by exactly the same people as the university's transplant hospital, the work group thought a separate application process would contribute towards a clearer delineation between the university transplant hospital and the VA hospital that shares the same staff and facilities. To proceed in this fashion also establishes a standard expectation for all transplant hospitals. The work group concurred that if the community supports the recommendation that VA hospitals may be an exception to the "one campus, one transplant hospital" rule and that all transplant hospitals, VA or otherwise, must submit membership applications to the OPTN, then it does not seem critical for OPTN purposes to continue distinguishing between an "independent" VA hospital, and a "Dean's Committee" VA hospital.

Alignment with CMS Definition of a Transplant Hospital

Another topic the MPSC transplant hospital definition work group considered was the CMS definition of a transplant hospital. Early in this group's efforts and in response to public comment feedback provided in response to the MPSC's previous transplant hospital definition proposal, it discussed whether the OPTN should simply adopt what is used by CMS, or something very similar. During these discussions, the work group reviewed the following federal regulations-

- 42 CFR 482.70²
Transplant center means an organ-specific transplant program (as defined in this rule) within a transplant hospital (for example, a hospital's lung transplant program may also be referred to as the hospital's lung transplant center).

² "42 CFR Ch. IV (10–1–10 Edition)," accessed June 20, 2016, <https://www.gpo.gov/fdsys/pkg/CFR-2010-title42-vol5/pdf/CFR-2010-title42-vol5-sec482-72.pdf>

Transplant hospital means a hospital that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients.

- 42 CFR 482.72³
A transplant center must be located in a transplant hospital that is a member of and abides by the rules and requirements of the Organ Procurement and Transplantation Network (OPTN) established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274).
- 42 CFR 413.65 (a)(2)⁴
Campus means the physical area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office, to be part of the provider's campus.

Remote location of a hospital means a facility or an organization that is either created by, or acquired by, a hospital that is a main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. A remote location of a hospital comprises both the specific physical facility that serves as the site of services for which separate payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. The Medicare conditions of participation do not apply to a remote location of a hospital as an independent entity. For purposes of this part, the term "remote location of a hospital" does not include a satellite facility as defined in §§ 412.22(h)(1) and 412.25(e)(1) of this chapter.

The work group did not believe that these definitions would sufficiently cover all OPTN considerations and responsibilities, so the OPTN's solution cannot simply be to adopt a similar version of the language used by CMS. The work group was not overly concerned with these differences due to the two organizations having fundamentally different focuses, and acknowledging that there is already precedence for multiple OPTN transplant hospitals having a single CMS certification number and for a single OPTN transplant hospital to have multiple CMS certification numbers. Furthermore, the work group expressed concerns with the detail and complexity of the CMS "campus" definition, indicating that it wanted to develop a simpler approach. Although the work group did not believe that the CMS and OPTN definitions of a transplant hospital needed to be exactly the same, the work group stressed that it must keep CMS definitions in mind as it works through this topic. It will be important to make sure that the MPSC's proposal does not create vast differences to avoid confusion and an undue burden on member transplant hospitals. Along these lines, and understanding that CMS has an interest in the final outcome of this proposal, members requested that HRSA staff participating in these discussions keep CMS abreast of this project's developments.

Additional Considerations

In addition to CMS, the MPSC also thought it would be beneficial to reach out to a number of other stakeholders to get preliminary feedback prior to public comment on the recommendations developed by the MPSC transplant hospital definition work group. The MPSC Vice Chair presented these recommendations and engaged the following groups in discussing the MPSC's recommendations for updating the OPTN's definition of a transplant hospital:

³ Ibid.

⁴ "§413.65 Requirements for a determination that a facility or an organization has provider-based status.," accessed June 20, 2016, http://www.ecfr.gov/cgi-bin/text-idx?rqn=div5&node=42:2.0.1.2.13#se42.2.413_165

- OPTN/UNOS Operations and Safety Committee
- OPTN/UNOS Pediatric Transplantation Committee
- OPTN/UNOS Policy Oversight Committee
- OPTN/UNOS Transplant Administrators Committee
- 2016 Transplant Management Forum breakout session
- 2016 June OPTN/UNOS Board of Directors meeting breakout session

During these discussions, there was limited feedback and it was mostly supportive and complimentary. The primary questions brought up during these discussions pertained to this proposal's impact on who could serve as key personnel at these hospitals, and how this definition aligned with CMS. In response to these questions, the MPSC Vice Chair made clear that these proposed Bylaws do not change any of the key personnel Bylaws; qualified individuals may still serve as key personnel at multiple transplant hospitals. Regarding CMS, responses centered on the different focuses of these organizations justifying the differences in how a transplant hospital is defined, and the precedence for multiple OPTN transplant hospitals having a single CMS certification number and vice-versa. The lack of reservations expressed during these conversations strengthened the MPSC's confidence in the recommendations it had developed, and it supported proposing Bylaws changes to incorporate the concepts presented to these groups.

Throughout the development of these recommendations, and in consideration of some of the public comment feedback received in response to the previous transplant hospital definition proposal sponsored by the MPSC, the work group also contemplated sending a survey to transplant hospital members that focused on how transplant hospitals are arranged. Ultimately, the work group and MPSC decided against a survey. The time it would take to create, distribute, and analyze the results of this survey would extend the timeline of this proposal. Further delaying these updates to the OPTN's transplant hospital definition was not desirable considering the current Bylaws' deficiencies are no longer supplemented by the operational guidelines that the MPSC had traditionally used when evaluating transplant hospital membership applications. Additionally, the MPSC felt that feedback provided during its spring 2016 consensus building discussions would give insights into how applicable or problematic its recommendations are, and how the transplant community generally feels about its proposed approach. Major or repeated concerns would have initiated the MPSC to reconsider and refine its recommendations, but since this was not the case, the MPSC believed that these consensus-building discussions sufficiently diminished the need to distribute a network-wide transplant hospital survey.

As a final note, the MPSC's Transplant Hospital work group regularly updated the full MPSC on its progress and recommendations. The work group originally discussed all of the recommendations outlined in this proposal, but only built on its recommendations at each stage of its discussions after receiving positive feedback and support from the full MPSC. The MPSC formally indicated its support for moving this proposal forward to public comment during its June 28, 2016, teleconference. During this teleconference, the MPSC passed a resolution (25- support, 0- oppose, 0- abstain) to distribute the draft Bylaws included in this proposal for public comment during the August-October 2016 OPTN public comment cycle.

How well does this proposal address the problem statement?

Based on the expert opinions of the MPSC, the MPSC's transplant hospital definition work group, and the limited feedback received when presenting these concepts to different groups in the transplant community, the MPSC believes that Bylaws changes proposed in this document will sufficiently address the problems faced with the OPTN's current transplant hospital definitions. Reviews of transplant hospital maps during the development of these discussions further increased the work group's and the MPSC's confidence in these recommendations.

This proposal establishes two explicit transplant hospital arrangements that would be accepted by the OPTN (assuming all other Bylaws requirements are met), and it also creates an approval process for

transplant hospitals that may not be able to meet all of the exact requirements in these proposed Bylaws. The MPSC believes that the clarity, simplicity, and flexibility of this approach is a strength of this proposal.

MPSC discussions about these recommendations have also recognized a few weaknesses of this proposal that should be highlighted. One is the “one mile walking distance” decision to define the radius that all transplant operating room facilities must be within for a non-contiguous campus to be approved as a single transplant hospital. The work group had some rationale for recommending “one mile walking distance” (as explained above); however, it realizes the somewhat arbitrary nature of this decision. The work group knew that it had to make a decision for the sake of discussing possible solutions, and it thought a one-mile walking distance was reasonable starting point for discussion. Subsequent presentations and discussion of this recommendation have not revealed a better, or more preferred distance.

Other potential weaknesses of this proposal pertain to its implementation. Proceeding with the recommendations included in this proposal will entail the collection of additional information from every current transplant hospital member. Each current transplant hospital will need to submit information about its operating rooms used for transplantation to comply with these new Bylaws. The OPTN is currently working to improve its systems for collecting membership information, and these new systems will be in place prior to the implementation of these proposed Bylaws. Although each current transplant hospital will need to submit information to implement this proposal, it is anticipated that these new systems will reduce the burden that this data collection process may place on members.

Additionally, the MPSC strongly believes that the overwhelming majority of transplant hospitals will be accommodated by the proposed “contiguous campus” or “non-contiguous campus” arrangements. The MPSC believes that the limited feedback received during the consensus building discussions focused on these recommendations is also an indicator of this. However, should there be a substantial number of transplant hospitals that wish to request the MPSC’s approval of their unique transplant hospital arrangement; this will require a significant amount of time for the MPSC to go through this process with all. Should the MPSC find itself in this situation, it may be necessary to adjust the timeline for implementing these Bylaws changes.

Was this proposal changed in response to public comment?

No, the MPSC voted in support (37 support, 0 oppose, 0 abstentions) of sending the Bylaws language proposed during public comment for the OPTN/UNOS Board of Directors final consideration at its December 2016 meeting.

Prior to reaching this decision, the MPSC reviewed all of the public comments provided in response to this proposal. MPSC discussion yielded the following responses to the feedback provided:

- *Support for the proposal.*
 - The MPSC appreciates the commenters’ review and support of this proposal.
- *Region 7 commented that legacy data from separate hospitals that combine should remain available and that hospitals should not be able to avoid MPSC review or adverse actions by merging.*
 - The MPSC appreciates these considerations, agrees with these sentiments, and feels it is important to clarify that this proposal will not impact how these situations are handled. Currently, legacy data from OPTN members are retained and hospitals cannot avoid MPSC review or adverse action through restructuring. One of the MPSC’s responsibilities is to monitor performance, and it would not allow performance concerns to be absolved simply through reorganization.

- *Region 7 and the American Society of Transplantation (AST) requested that the MPSC remove the “one mile walking distance” campus arrangement option. Concerns were raised that this criterion is arbitrary and will result in hospitals submitting exceptions to the MPSC when the hospital is close, but more than one mile walking distance from the main hospital.*
 - The MPSC believes that geographic considerations are a requisite component of any proposal to update the OPTN’s definition of a transplant hospital. The “contiguous campus” option included in this proposal is seemingly the most obvious consideration, but the MPSC knows this definition would not apply in every instance. As reflected in this proposal, the MPSC agreed that operating rooms within a one mile walking distance of the main hospital address was appropriate to accommodate hospitals that are not located within one contiguous campus. The Committee recognized that these two options still would not appropriately accommodate all transplant hospital arrangements (e.g., hospitals with operating rooms slightly further than one mile walking distance away), and this was the main impetus for the third campus arrangement option which allows transplant hospital applicants to make a case for the approval of their unique situation. Excluding the “one mile walking distance” option from this proposal would necessarily prompt more transplant hospital exception requests.

Regarding the inclusion of one mile to define this option, the Committee liked the idea that, regardless of where the transplant hospital may be located, most individuals could traverse this one mile distance by foot with 15-20 minutes if their assistance was necessary to respond to a transplant-related emergency. Further, the MPSC was reliant on the community’s response to determine whether a shorter or longer distance would be appropriate for this campus arrangement consideration. During public comment, and the consensus building efforts that preceded public comment, limited feedback was provided on this particular consideration (or what would be a more appropriate distance). The large amount of support for this proposal as written ultimately persuaded the MPSC to move forward with the “one mile walking distance” campus arrangement option.

- The American Society of Transplant Surgeons (ASTS) opposed this proposal, indicating that it is needlessly onerous and likely unnecessary for the smooth functioning of a transplant center; required documentation of physical addresses with maps to show which operating rooms are used for transplant seems unnecessary; patient safety as it relates to infrastructure *could be asked of a specific transplant center during an MPSC review, as opposed to making every transplant center do this; many transplant centers may have satellite centers or pediatric hospitals which are physically more than a mile away; and, as long as the medical and administrative teams are the same, this physical distance should not have a bearing on the program's ability to perform safe and effective transplants.*
 - The MPSC appreciates the thorough consideration of this proposal and the feedback provided by ASTS; however, the Committee is still supportive of this proposal as written to address the current deficiencies with the OPTN’s definition of a transplant hospital and satisfy the OPTN/UNOS Board of Directors directive to address this problem.

Updates to the OPTN’s definition of a transplant hospital are necessary to guide the MPSC, and members, in the consideration of transplant hospital OPTN membership applications. Due to the simplicity of the current definitions which renders them unusable for the MPSC’s specific purposes, and due to recent decisions by the OPTN/UNOS Board of Directors that the operational rules that the MPSC had traditionally used to supplement these definitions was no longer a suitable approach, addressing this topic was a directive from the OPTN/UNOS Board of Directors. In that pursuit, geographic considerations are thought to be a necessary component of any proposal that updates the OPTN definition of a transplant hospital. Within the specific context of this proposal, geographic considerations are needed to accommodate hospitals that are not located within one contiguous campus. The MPSC also recognizes that the proposed “one mile walking distance” boundary may not be sufficient in every scenario, which is what prompted the inclusion of a third option for transplant hospital

applicants to engage the MPSC to present and request approval of their unique situation. This third option could be used to accommodate “satellite centers.”

Additionally, with this proposal formally recognizing that transplant programs may conduct transplants in numerous operating room facilities at the hospital, the committee believes it is important that hospitals document where these procedures may occur. This information is important to confirm that the member meets the requirements included in this proposal, and so that this information is immediately available should the MPSC need to work with a member to focus on potential infrastructure issues in the case of a patient safety event. The Committee recognizes that providing this information will create some additional burden on members, but believes this possible burden to be minimal and necessary for implementing this updated approach for defining a transplant hospital.

Which populations are impacted by this proposal?

This proposal affects how the organization of every transplant hospital is viewed by the OPTN, and therefore it indirectly impacts every patient in need of an organ transplant. Because the MPSC drafted this proposal with intentions of accommodating all current members to the extent possible, this proposal is anticipated to have a small impact on most transplant hospitals. The greatest impact is expected to be the submission of additional information required by these proposed Bylaws by every transplant hospital that is currently approved. As such, the MPSC expects transplant administrators (or the individuals employed by a transplant hospital who are responsible for managing the OPTN application’s process) to be impacted the most by this proposal.

How does this proposal impact the OPTN Strategic Plan?

1. *Increase the number of transplants:* There is no expected impact on this goal.
2. *Improve equity in access to transplants:* There is no expected impact on this goal.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* There is no expected impact on this goal.
4. *Promote living donor and transplant recipient safety:* There is no expected impact on this goal.
5. *Promote the efficient management of the OPTN:* As the definition of a transplant hospital is critical for the MPSC to execute its responsibilities of assessing transplant hospitals for transplant safety, performance, and compliance with OPTN Policy and Bylaws, and considering the ambiguity and concerns raised with the operational definition that has traditionally been used by the MPSC, updating the OPTN’s transplant hospital definition should promote the efficient management of the OPTN.

How will the OPTN implement this proposal?

If approved by the OPTN/UNOS Board of Directors, these proposed Bylaws will be implemented pending programming and notice to members. During this time, the OPTN will provide updates on the pending implementation date.

Implementing these Bylaws will require programming changes to the UNOS membership database, and potentially UNetSM if a member applies to separate into multiple transplant hospitals, or multiple transplant hospitals apply to consolidate into one. Additionally, the OPTN will need to submit updated application forms to the Office of Management and Budget (OMB) for approval. UNOS is currently planning to collect the information relating to this proposal electronically through a new membership database, which is anticipated to reduce the burden of supplying this information.

Upon completion of OMB approval, membership database programming, and notice to members, there will be a 60-day period for members to submit the new information required by this proposal:

- Type of campus arrangement (i.e., contiguous campus, one mile walking distance radius)
- Transplant operating room documentation
 - Maps that illustrate the transplant hospital campus and the location of each operating room facility
 - Building name and address
 - Floor number
 - Unit identifier

The proposed Bylaws will be slated for implementation approximately 12 months after the conclusion of the 60-day period to collect this information. During these 12 months, the OPTN and the MPSC will process this information for each transplant hospital member. This will include the engagement of all transplant hospitals with operating rooms beyond the established geographic boundaries seeking approval through an informal discussion with the MPSC, and the completion of any UNetSM programming that corresponds the separation of one transplant hospital into multiple transplant hospitals or the consolidation of multiple transplant hospitals into one.

The ultimate goal over these 12 months will be to have each transplant hospital member's information on file to comply with these new Bylaws prior to their implementation. Considering this goal, it will be critical for members to adhere to the allotted timeframe for submitting the necessary information to avoid implementation delays. UNOS Member Quality staff will be in contact, as necessary, with transplant hospital members after this 60-day transplant hospital information submission period to make sure that all the newly required information is gathered. After all reasonable measures have been taken to collect the necessary information, and after sufficient warning, implementation of these Bylaws may not be further delayed such that a current transplant hospital member that still has not supplied the appropriate information would be found out of compliance with these Bylaws.

Subsequent to the implementation of these Bylaws, all OPTN transplant hospital applicants will be expected to complete the application updated in response to the approval of these proposed changes.

How will members implement this proposal?

Transplant Hospitals

Upon notice by the OPTN, transplant hospitals will need to provide the following information within the 60-day period established by the notice:

- Type of campus arrangement (i.e., contiguous campus, one mile walking distance radius)
- Transplant operating room documentation
 - Maps that illustrate the transplant hospital campus and the location of each operating room facility
 - Building name and address
 - Floor number
 - Unit identifier

Assuming members satisfactorily provide the necessary information introduced by these proposed Bylaws, no other action will be necessary.

During this 60-day period, transplant hospitals with operating rooms beyond the established geographic boundaries seeking approval through an informal discussion with the MPSC will also be able to indicate their intent to proceed in this manner. These members will need to explain their specific situation and why the MPSC should consider an exception to the explicit boundaries included in the Bylaws used to define a

transplant hospital. UNOS staff will contact these transplant hospital members to arrange an informal discussion with the MPSC.

If the implementation of these Bylaws prompts a current transplant hospital member to separate into multiple transplant hospitals, or if multiple transplant hospitals request to be merged into one, transplant hospitals may be asked to provide additional information. This additional information may be necessary so that the OPTN can make the necessary changes, including changes to UNetSM, to combine or separate transplant hospitals.

Will this proposal require members to submit additional data?

All current transplant hospital members will need to submit data relating to the arrangement of its transplant hospital in order to demonstrate compliance with these new Bylaws before they are implemented. This will primarily include the transplant hospital campus arrangement relative to these Bylaws (i.e., contiguous campus, one mile walking distance radius) and the required information regarding the locations of each operating room that may be used for transplantation (i.e., maps that illustrate the transplant hospital campus and the location of each operating room facility, building name and address, floor number, unit identifier). Transplant hospitals will only need to provide this information one time, unless there are subsequent changes to how the transplant hospital is arranged, or if the transplant hospital needs to make changes to its list of operating rooms that may be used for transplant surgery.

Transplant hospitals with operating rooms beyond the established geographic boundaries seeking approval through an informal discussion with the MPSC will also be required to submit additional data. Specifically, a written explanation detailing the circumstances that necessitate designation of a single transplant hospital or preclude registration of a second transplant hospital, and a written plan for transplant patient care, including evidence that all necessary services and support will be available to transplant recipients. This information will serve as the foundation for the informal discussion with the MPSC, and subsequently, the MPSC's deliberations.

The collection of these data primarily aligns with OPTN data collection principles of determining if institutional members are complying with policies, and fulfilling the requirements of the OPTN Final Rule.

How will members be evaluated for compliance with this proposal?

After reviewing all OPTN transplant hospital members prior to the implementation of these Bylaws changes, there is no plan to maintain an ongoing compliance monitoring process. If transplant hospital configurations change and the hospital finds itself not in compliance with the existing transplant hospital definition, transplant hospitals are expected to contact the UNOS Member Quality department, discuss its new situation, and as necessary, submit any required applications for new membership and transplant program designations.

If the MPSC becomes aware of changes in an approved transplant hospital's configuration, an inquiry will be made to the hospital and assistance will be provided as necessary for the transplant hospital to come into compliance with existing requirements.

How will the sponsoring Committee evaluate whether this proposal was successful post implementation?

Upon implementation, evaluation of this proposal will occur in real time by the MPSC. If the proposed changes are effective, the assessment of new member and transplant program applications will have less uncertainty than they can have now. The applicants will have a clearer description of what a transplant hospital's attributes are so fewer uncertainties should exist to be addressed by the MPSC.

The MPSC expects to monitor the impact of these changes and will revisit this subject as necessary and as healthcare organizational structures continue to change.

Policy or Bylaws Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs

D.2 Geographic Requirements for Transplant Hospitals

A transplant hospital must be entirely within a single donation service area (DSA) and all of its operating room facilities used for organ transplantation must be under common executive leadership and governance oversight, demonstrated to the satisfaction of the OPTN.

All transplant hospital operating rooms where transplants are performed must also meet at least *one* of these requirements:

- Are within a geographically contiguous campus
- Are within a one mile walking distance from the main hospital's physical address

Each operating room that the transplant hospital may use to perform transplants must be documented with the OPTN prior to its use for transplant surgery. This operating room documentation requirement includes any additional transplant operating rooms that are not listed on the transplant hospital's initial application. Documentation of the operating rooms where organ transplants may occur must at least include *all* of the following:

1. Maps that illustrate the transplant hospital campus and the location of each operating room facility
2. Building name and address
3. Floor number
4. Unit identifier

Transplant hospitals that do not meet these requirements will not be approved as a single transplant hospital and will require separate OPTN memberships, unless the transplant hospital is approved according to *D.2.A: Approval of Transplant Hospitals with Operating Rooms Beyond the Established Geographic Boundaries*. Any application recommended for rejection by the MPSC or the Board of Directors entitles the applicant to due process as specified in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.

A. Approval of Transplant Hospitals with Operating Rooms Beyond the Established Geographic Boundaries

As long as the hospital is able to fulfill all other requirements established in these Bylaws, the OPTN may approve transplant hospitals that have operating rooms used for transplantation beyond the geographical boundaries established above. The hospital may submit an application to the OPTN to consider its specific circumstances if *all* of the following conditions are met:

1. The hospital provides a written explanation detailing the mitigating circumstances that necessitate designation of a single transplant hospital or preclude registration of a second transplant hospital. The written explanation must at least address the following:
 - a. Transplant patient safety
 - b. Impact on patient access
 - c. Organ utilization

- 40 2. The hospital provides a written plan for transplant patient care, including evidence that all
41 necessary services and support will be available to transplant recipients.
42 3. The hospital participates in an informal discussion with the MPSC.

43 The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC
44 Chair is authorized to conduct the informal discussion and grant interim approval, according to
45 Appendix A.3: Applying for Membership in the OPTN. Interim approvals are:

- 46 ▪ Advisory to the MPSC, Board of Directors, or both, who have the final authority to grant
47 approval of a transplant hospital.
48 ▪ Effective temporarily, pending final decision by the MPSC or Board of Directors.

49 **B. Multiple Transplant Hospitals Citing the Same Campus Boundaries**

50 A transplant hospital campus may only be associated with one transplant hospital unless the
51 other transplant hospital is either of the following:

- 52 ▪ Has approval as a transplant hospital in a Department of Veterans Affairs, Department of
53 Defense, or other Federal hospital.
54 ▪ Primarily serves pediatric patients. Transplant hospitals that annually perform, or intend to
55 perform, 50 percent or more of their total transplants in patients less than 18 years of age will
56 be identified as primarily serving pediatric patients.

57 **C. Review of Pediatric Transplant Activity at Transplant Hospitals that** 58 **Share a Campus**

59 Transplant hospitals that primarily serve pediatric patients, and that share a campus with another
60 transplant hospital, will be reviewed periodically by the MPSC to verify that it performed 50
61 percent or more of its transplants in patients less than 18 years of age during the previous 12
62 months. Any transplant hospital that is identified as not meeting this 50 percent threshold in any
63 12 month period will have the opportunity to explain its pediatric inactivity in a report to the
64 MPSC.

65
66 As part of its review of pediatric transplantation activity at transplant hospitals that share a
67 campus, the MPSC may require that the member participate in an informal discussion. The
68 informal discussion may be with the MPSC, a subcommittee, or a work group, as determined by
69 the MPSC. The informal discussion will be conducted according to the principles of confidential
70 medical peer review, as described in Appendix L: Reviews, Actions, and Due Process of these
71 Bylaws. The discussion is not an adverse action or an element of due process. A member who
72 participates in an informal discussion with the MPSC is entitled to receive a summary of the
73 discussion.

74
75 The MPSC may recommend that a transplant hospital sharing a campus with another transplant
76 hospital inactivate due to one hospital no longer primarily serving pediatric patients. If the hospital
77 fails to inactivate when the MPSC recommends it do so, the MPSC may recommend that the
78 Board of Directors take appropriate action as defined in Appendix L: Reviews, Actions, and Due
79 Process of these Bylaws.

80 81 **D.23 Designated Transplant Program Requirement**

82 In order to receive organs for transplantation, a transplant hospital member must have current approval
83 as a designated transplant program for at least one organ. A transplant hospital can only have one
84 designated transplant program for each respective organ. Designated transplant programs must meet at
85 least *one* of the following requirements:

- 86 ▪ Have approval as a transplant program by the Secretary of the U.S. Department of Health and
87 Human Services (HSS) for reimbursement under Medicare.
- 88 ▪ Have approval as a transplant program in a Department of Veterans Affairs, Department of Defense,
89 or other Federal hospital.
- 90 ▪ Qualify as a designated transplant program according to the membership requirements of these
91 Bylaws.

92
93 The OPTN does not grant designated transplant program approval for any type of vascularized organ
94 transplantation for which the OPTN has not established specific criteria. In order to perform vascularized
95 organ transplantation procedures for which there are no OPTN-established criteria, including multi-
96 visceral transplants, a hospital must be a transplant hospital member and have current approval as a
97 designated transplant program for at least one of the organ types involved in multi-visceral transplant. In
98 the case of abdominal multi-visceral organ transplants, the transplant hospital must have approval as a
99 designated liver transplant program.

100
101 *[Subsequent headings and cross-references to headings affected by the re-numbering of this policy will*
102 *also be changed as necessary.]*
103

104 **D.142 Additional Transplant Program Requirements**

105 **~~F. Veteran's Administration (VA) Dean's Committee Hospitals~~**

106 ~~VA Hospitals that are Dean's Committee Hospitals and share a common university based~~
107 ~~transplant team, do not need to submit a separate membership application to the OPTN~~
108 ~~Contractor, but may be considered members under the university program with which they are~~
109 ~~affiliated.~~

110
111 ~~Independent VA Hospitals, or VA Hospitals that are not Dean's Committee Hospitals sharing a~~
112 ~~common university based transplant team, must submit an application and be approved for OPTN~~
113 ~~membership in order to receive organs for transplantation.~~

114
115 *[Subsequent headings and cross-references to headings affected by the re-numbering of this policy will*
116 *also be changed as necessary.]*
117

118 **Appendix M: Definitions**

119 **Geographically Contiguous Campus**

120 The physical area within an enclosed boundary drawn on a map that exclusively encompasses land and
121 buildings owned by, or directly associated with, the hospital. Separate commercial or residential property
122 adjacent to hospital property must be excluded from the boundary.

#