

At-a-Glance

- **Proposal to Change the UNOS Bylaws to Reconcile Discrepancies in Patient Volume Requirements for Full and Conditional Program Approval When Qualifying Kidney, Liver and Pancreas Primary Transplant Physicians**
- **Affected/Proposed Bylaws:**
 - **Appendix B, Attachment I, Section XIII (Transplant Programs), D, (1) Kidney Transplantation, (jj) Conditional Approval, (ii) and (v);**
 - **Appendix B, Attachment I, Section XIII (Transplant Programs), D, (3) Liver Transplantation, b (hh) Conditional Approval, (ii) and (v); and**
 - **Appendix B, Attachment I, Section XIII (Transplant Programs), D, (5) Pancreas Transplantation, b (ee) Conditional Approval, (ii) and (v).**

- **Membership and Professional Standards Committee**

This proposal will reconcile the current patient volume discrepancies between the requirements for full and conditional OPTN/UNOS program approval when qualifying primary physicians at kidney, liver and pancreas transplant programs. The bylaws currently permit programs to propose and qualify primary physician candidates for conditional program approval without meeting the MPSC desired 50 percent of full approval primary care volume requirements when submitting their application. The primary physician at the conditionally approved program can then qualify that program for full approval status after one year at conditional approval without ever having met the same total patient volume requirements as the primary physician originally qualifying at a fully approved program. The proposed language **does not change** any prior Board approved total patient volume requirements used to qualify for full program approval as the primary physician at kidney, liver and pancreas transplant programs when using either experience or training pathways. Additionally, it clarifies the initial minimum required patient volume to qualify a candidate for consideration as the primary kidney, liver or pancreas physicians at a program seeking conditional approval.

- **Affected Groups at Kidney, Liver and Pancreas Transplant Programs**

Primary Transplant Physicians
Transplant Program Directors
Transplant Administrators

- **Specific Requests for Comment**

- Does this proposal clearly state the volume of transplant cases required (experience) when proposing a primary physician for conditional program approval at a kidney, liver and pancreas transplant program?
- Does this proposal clearly state the volume of transplant cases required (experience) of a primary physician to be granted full approval after serving under the one year conditional program approval at a kidney, liver and pancreas transplant program?
- Does this proposal clearly state the total number of transplant cases required (experience) for a primary physician to be granted full approval under experience and training pathways at a pancreas transplant program?

Proposal to Change the UNOS Bylaws to Reconcile Discrepancies in Patient Volume Requirements for Full and Conditional Program Approval When Qualifying Kidney, Liver and Pancreas Primary Transplant Physicians

Affected/Proposed Bylaws: Appendix B, Attachment I, Section XIII (Transplant Programs), D,

- (1) Kidney Transplantation, (jj) Conditional Approval, (ii) and (v)
- (3) Liver Transplantation, b (hh) Conditional Approval, (ii) and (v)
- (5) Pancreas Transplantation, b (ee) Conditional Approval, (ii) and (v)

Membership and Professional Standards Committee (MPSC)

Summary and Goals of the Proposal:

This proposal will reconcile current patient volume discrepancies between the requirements for full and conditional OPTN/UNOS program approval when qualifying primary physicians at kidney, liver and pancreas transplant programs.

Table 1 summarizes what the current required primary care patient volume criteria are under clinical experience qualification pathway for kidney, liver, and pancreas primary physicians at fully and conditionally approved transplant programs. It also presents the proposed criteria under the bylaw modifications. **The proposed bylaws do not seek input regarding the values in the “Total Primary Care Patient Volume Requirement – Full Approval” column.**

	Total Primary Care Patient Volume Requirement	Total Primary Care Patient Volume Requirement	Total Primary Care Patient Volume Requirement	Cumulative Primary Care Patient Volume Requirement after 1 year Conditional to Achieve Full Program Approval	Cumulative Primary Care Patient Volume Requirement after 1 year Conditional to Achieve Full Program Approval
	Full Approval	Conditional Approval	Conditional Approval	Full Approval	Full Approval
	Current	Current	Proposed	Current	Proposed
Kidney	45	15	23	30	45
Liver	50	15	25	30	50
Pancreas *	8	5	4	10	8

Table 1: Proposed Primary Care Patient Volume Revisions

* applies to both (aa) training and (bb) acquired clinical experience qualification pathways

Reconciliation of the volume requirements provides UNOS staff and MPSC application reviewers with codified standards which provide understandable and consistent values.

Background and Significance of the Proposal:

On July 1, 2006, the OPTN/UNOS Board of Directors approved policy changes to the physician and surgeon criteria for transplant center membership recommended by the Membership and Professional Standards Committee (hereafter referred to as “the Committee”). These proposed changes were a

result of work by the Subcommittee on Membership Criteria Review (hereafter referred to as “the Subcommittee”) in 2005. The proposed modifications were intended to bring greater consistency to the primary surgeon and physician qualifying requirements between different organs; update the requirements to reflect current practices; clarify language to make the requirements easier to understand, and codify committee interpretations of certain requirements. Several modifications to existing criteria were proposed and adopted, but the ones relevant to this discussion were kidney, liver and pancreas total primary care case volume changes.

Kidney

To qualify under the kidney physician experience pathway, the Committee recommended that the number of patients a physician must have provided primary care to should be changed from 30 to 45. This change would make the required case numbers equivalent to the comparable surgeon requirement. This could be achieved over a two to five year period. This would average to providing care to 9 new transplant recipients annually, which can be accomplished at a majority of transplant centers.

Liver

To qualify under the liver physician experience pathway, the Committee recommended changing the number of patients for whom the physician must have provided primary care from 30 to 50. For this pathway, the case numbers increased, but at the same time, the time over which this can be achieved was extended to five years.

Pancreas

To qualify under the pancreas physician experience pathway, the Committee recommended that the number of patients followed during training be changed from 10 to 8. This change was recommended to reflect the activity in the field. The mean of pancreas transplants performed annually at a majority of training programs is 8. The Committee determined that it would be appropriate to amend the required number of patients based on this information.

The new primary care volume numbers were to qualify for full program approval. Discussions were held by the Subcommittee regarding what the qualifications should be for one year conditional program approval. They agreed upon 50 percent of the full approval primary care volume to make application for conditional program approval with the expectation that the primary physician would achieve 100 percent of the full program approval volume after one year or the program would have to voluntarily inactivate until a primary physician could be qualified. This desire mistakenly did not make it into bylaw modification language, so it is being forwarded now due to conflicting criteria in the bylaws.

Alternatives considered: The MPSC considered continuing to use the primary care patient volumes as is, but this results in having primary physician candidates who have initial primary care volume numbers below what the expected minimum should be. There is the real possibility that after the one year conditional approval period, a primary physician may be unable to achieve the expected full approval primary care volume numbers. Ultimately, the Committee agreed that the conditional program approval pathway volume bylaws needed to be modified to agree with the improvement intent of the July 2006 actions.

Strengths and weaknesses: MPSC members are currently being asked to review and approve primary physicians under conditional kidney, liver and pancreas conditional program approval pathways who may not meet this intended minimum volume for consideration and are not required to meet the full program approval volumes after the one year conditional period. The strengths of these bylaw changes

are to correct this and provide the intended enforceable qualification criteria. The Committee has not identified any weaknesses associated with approval of the proposed bylaw modifications.

Description of intended and unintended consequences:

Intended Consequences:

- Clarify and correct the expected primary care patient volumes for member kidney, liver and pancreas programs for their primary physicians to qualify under the conditional program approval pathway.
- Reaffirm the requirement that to achieve full program approval the primary physician must document full approval primary care patient volume totals after the one year conditional period.
- Submit only proposed primary physician applications who at least meet the minimum primary care patient volumes for conditional program approval for kidney, liver and pancreas transplant programs.

Unintended Consequences:

- None

Burden on Programs:

- Kidney, liver and pancreas transplant programs will need to be aware of and understand the primary care patient volume requirements for proposing a candidate under the conditional program approval pathway.
- Kidney, liver and pancreas transplant programs will need to be aware of and understand the primary care patient volume requirement totals required to qualify the primary physician for full program approval after one year of conditional program approval.
- Kidney, liver and pancreas transplant programs will need to develop primary physician succession planning strategies that will ensure whenever possible that qualified primary physician applicants are available for submission when a change occurs.

Supporting Evidence and/or Modeling:

Membership staff frequently receive inquiries regarding the primary care volume requirements for qualifying a kidney, liver or pancreas primary physician under the conditional program approval option. UNOS staff understands that the current bylaw volume numbers do not reflect the desired 50 percent of total for full approval and will advise the applying program that it is the 50 percent volume value which is expected to be met. The same practice occurs with the total volume expectation for full program approval after one year conditional approval. These desired values need to be codified in the bylaw language.

Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

The OPTN has certain responsibilities that are specified by NOTA and the Final Rule. They include establishing experience and training criteria for key surgical and medical transplant personnel and protecting the public health and safety in the context of transplantation.

Statutes pertaining to the OPTN which pertain to this proposal are found in *Title 42, United States Code (USC), Public Health, PART 121—ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK*.

§ 121.9 Designated transplant program requirements.

(a) To receive organs for transplantation, a transplant program in a hospital that is a member of the OPTN shall abide by these rules and shall:

(1) Be a transplant program approved by the Secretary for reimbursement under Medicare; or

(2) Be an organ transplant program which has adequate resources to provide transplant services to its patients and agrees promptly to notify the OPTN and patients awaiting transplants if it becomes inactive and which:

(i) Has letters of agreement or contracts with an OPO;

(ii) Has on site a transplant surgeon qualified in accordance with policies developed under §121.4;

(iii) Has on site a transplant physician qualified in accordance with policies developed under §121.4;

(...)

<i>HHS Program Goals</i>	<i>Strategic Plan Goals</i>
Patient Safety	The OPTN will promote safe, high-quality care for transplant candidates, transplant recipients, and living donors.

Plan for Evaluating the Proposal:

The Committee will evaluate the bylaw modifications as part of its frequent reviews of criteria used to qualify primary surgeons and physicians. These bylaw modifications occur as improvement initiatives in an attempt to keep the criteria relevant and current with acceptable practice in transplantation. The Committee anticipates that these modifications will also reduce the MPSC workload because transplant programs will now forward appropriately qualified proposed primary physician applicants. Primary physician candidate qualification conformance will be used to evaluate the proposal and address issues as they arise.

Policy Performance Measures:

Personnel and application data which is stored in the Membership Database will be used to evaluate member understanding of and compliance with the bylaw modifications.

Time Line for Evaluation:

Monitoring of primary physician applications for conditional program approval at kidney, liver and pancreas programs will occur during the first year to make sure that programs understand the primary care volume changes and what needs to be done for the program to receive full program approval after one year conditional approval. Since primary physician changes occur frequently, assessment of criteria such as these is constant.

Additional Data Collection:

This proposal does not require additional data collection.

Expected Implementation Plan:

Transplant Centers are responsible for notifying UNOS Membership staff immediately upon knowledge of a change in primary physician. A completed, appropriate key personnel change application proposing a qualified primary physician to replace the departing individual must be received by UNOS at least 30 days before the change occurs.

This proposal will not require programming in UNetSM.

Communication and Education Plan:

Communication Activities			
Type of Communication	Audiences	Delivery Method	Timeframe
Policy Notice - Modified Bylaw Language	Kidney, Liver & Pancreas Programs <ul style="list-style-type: none">• Primary Transplant Physicians• Transplant Administrators• Transplant Program Directors	Electronic (email sent from the UNOS Communications mailbox)	Within 30 days of Board Approval

Communication Activities (cont.)			
Type of Communication	Audiences	Deliver Method	Timeframe
UNOS Update (short article in the policy section)	Kidney, Liver & Pancreas Programs <ul style="list-style-type: none">• Primary Transplant Physicians• Transplant Administrators• Transplant Program Directors	US Mail	Next issue following approval by the Board
Regional Meetings	Kidney, Liver & Pancreas Programs <ul style="list-style-type: none">• Primary Transplant Physicians• Transplant Administrators• Transplant Program Directors	Face-to-face meetings or teleconferences, or both	Next meeting after approval by the Board

Monitoring and Evaluation:

Compliance with this bylaw will be monitored by the Committee. The Committee anticipates that these modifications will improve understanding of what the primary care volume requirement is for the primary physician if conditional program approval is sought by a kidney, liver or pancreas program. It also reinforces the expectation that the total primary care volume for full approval is expected at the end of one year conditional approval for the granting of full program approval. If this behavior is not observed, then UNOS will take steps to address issues with compliance.

Bylaw Proposals:

UNOS Bylaws Appendix B, Attachment I, XIII, D, (1), (b), (jj) for **Kidney Transplantation**

- (jj) In the case of a change in the primary kidney transplant physician at a UNOS approved kidney transplant program, if items (cc) iii or (ee) i-ii are not met, the replacement physician, a nephrologist can function as a kidney transplant physician for a maximum period of twelve months if the following conditions are met:
- (i) That the remaining parts of (cc) or (ee), as applicable, are met.
 - (ii) That the individual has been involved in the primary care of ~~15~~ **23** or more kidney transplant recipients, and has followed these patients for a minimum of 3 months from the time of their transplant. The application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number of the recipient and date of transplant. Beginning January 1, 2007, this log should be signed by the program director, division chief, or department chair from program where the experience was gained.
 - (iii) That if the individual is qualifying as primary transplant physician by virtue of acquired clinical experience, this experience is equal to 12 months on an active kidney transplant service as the kidney transplant physician or under the direct supervision of a qualified kidney transplant physician and in conjunction with a kidney transplant surgeon at a UNOS approved kidney transplant center. This 12 month period of experience on the transplant service must be acquired over a maximum of 2 years.
 - (iv) That a consulting relationship with counterparts at another UNOS member transplant center approved for kidney transplantation has been established and documented.
 - (v) That activity reports are submitted to UNOS at two month intervals describing the transplant activity and results, physician recruitment efforts, and such other operating conditions as may be required by the Membership and Professional Standards Committee to demonstrate to the satisfaction of the Committee ongoing quality and efficient patient care. The reports must show that the individual is making sufficient progress to meet the objective of involvement in the primary care of at least ~~30~~ **45** kidney transplant recipients or that the program is making sufficient progress in recruiting and bringing to the program a transplant physician who meets this criterion as well as all other UNOS criteria for a qualified renal transplant physician by the date that is 12 months from the date of approval of the program under this section.
 - (vi) If the program is unable to demonstrate that it has an individual on site who can meet the requirements as described in sections (cc), (dd), (ee), (ff), (gg), (hh), or (ii) above at the end of 12 months, it shall inactivate. The requirements for program inactivation are described in Section II. The Membership and Professional Standards Committee may consider on a case by case basis, and grant a six month extension to a program that provides substantive evidence of progress towards completing the requirements but is unable to complete the requirements within one year.

UNOS Bylaws Appendix B, Attachment I, XIII, Transplant Programs, D, (3), **Liver Transplantation** , b

- (hh) In the case of a change in the primary liver transplant physician at a UNOS approved transplant program, if items (aa) iii or (cc) i-ii are not met, the replacement physician, must be a gastroenterologist/hepatologist and can function as a liver transplant physician for a maximum period of twelve months if the following conditions are met:
- (i) That the remaining parts of (aa) or (cc), as applicable, are met.
 - (ii) That the individual has been involved in the primary care of ~~15~~ **25** or more liver transplant recipients, and has followed these patients for a minimum of 3 months from the time of their transplant. The application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number of the recipient and date of transplant. Beginning January 1, 2007, this log must be signed by the director and/or the primary transplant physician at the transplant program where the individual trained or gained this experience.
 - (iii) That if the individual is qualifying as primary transplant physician by virtue of acquired clinical experience, this experience must be a minimum of 12 months on an active liver transplant service as the qualified liver transplant physician or under the direct supervision of a qualified liver transplant physician and in conjunction with a liver transplant surgeon at a UNOS approved liver transplant center or an active foreign liver transplant program accepted as equivalent by the MPSC. This 12 month period of experience on the transplant service must be acquired over a maximum of 2 years.
 - (iv) That a consulting relationship with counterparts at another UNOS member transplant center approved for liver transplantation has been established and documented.
 - (v) That activity reports are submitted to UNOS at two month intervals describing the transplant activity and results, physician recruitment efforts, and such other operating conditions as may be required by the Membership and Professional Standards Committee to demonstrate to the satisfaction of the Committee ongoing quality and efficient patient care. The reports must show that the individual is making sufficient progress to meet the objective of involvement in the primary care of at least ~~30~~ **50** transplant recipients or that the program is making sufficient progress in recruiting and bringing to the program a transplant physician who meets this criterion as well as all other UNOS criteria for a qualified liver transplant physician by the date that is 12 months from the date of approval of the program under this section.

UNOS Bylaws Appendix B, Attachment I, XIII, Transplant Programs, D, (5), **Pancreas Transplantation, b**

- (ee) In the case of a change in the primary transplant physician at a UNOS approved pancreas transplant program, if items (aa) iii or (cc) i-ii are not met, the replacement physician, a nephrologist/endocrinologist/diabetologist can function as a pancreas transplant physician for a maximum period of twelve months if the following conditions are met:
- (i) That the remaining parts of (aa) or (cc), as applicable, are met.
 - (ii) That if the individual is qualifying as primary transplant physician by virtue of training, the individual has been involved in the primary care of ~~5~~ **4** or more pancreas transplant recipients, and has followed these patients for a minimum of three months from the time of their transplant. The application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number of the recipient and date of transplant. Beginning January 1, 2007 this log must be signed by the program director, division chief, or department chair from program where the experience was gained.
 - (iii) That if the individual is qualifying as the primary pancreas transplant physician by virtue of acquired clinical experience, this experience is equal to 12 months on an active pancreas transplant service as the pancreas transplant physician or under the direct supervision of a qualified pancreas transplant physician and in conjunction with a pancreas transplant surgeon at a UNOS approved pancreas transplant center. Additionally, the individual will have been involved in the primary care of eight or more pancreas transplant recipients, and have followed these patients for a minimum of three months from the time of their transplant. This 12 month period of experience on the transplant service must be acquired over a maximum of 2 years. The application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number of the recipient and date of transplant.
 - (iv) That a consulting relationship with counterparts at another UNOS member transplant center approved for pancreas transplantation has been established and documented.
 - (v) That activity reports are submitted to UNOS at two month intervals describing the transplant activity and results, physician recruitment efforts, and such other operating conditions as may be required by the Membership and Professional Standards Committee to demonstrate to the satisfaction of the Committee ongoing quality and efficient patient care. The reports must show that the individual is making sufficient progress to meet the objective of involvement in the primary care of at least ~~10~~ **8** or 15, as applicable, transplant recipients or that the program is making sufficient progress in recruiting and bringing to the program a transplant physician who meets this criterion as well as all other UNOS criteria for a qualified pancreas transplant physician by the date that is 12 months from the date of approval of the program under this section.

- (vi) If the program is unable to demonstrate that it has an individual on site who can meet the requirements as described in sections (aa), (bb), (cc), or (dd), above at the end of 12 months, it shall inactivate. The requirements for program inactivation are described in section II. The Membership and Professional Standards Committee may consider, on a case by case basis, and grant a six month extension to a program that provides substantive evidence of progress towards completing the requirements but is unable to complete the requirements within one year.