

At-a-Glance

Proposal to Establish a Quality Assessment and Performance Improvement Requirement for Transplant Hospitals and Organ Procurement Organizations

- **Affected/Proposed Policy:** Bylaws, Appendix B (Membership Requirements for Organ Procurement Organizations (OPOs)); Appendix D (Membership Requirements for Transplant Hospitals and Transplant Programs)

- **Membership and Professional Standards Committee**

The Membership and Professional Standards Committee (MPSC) has noted that members having difficulty with compliance or performance often do not have well-developed quality assessment and performance improvement (QAPI) programs. Currently, OPTN bylaws do not require that members establish and implement a QAPI program. Motivated by this observation, the MPSC proposes modifications to OPTN Bylaws that require members to implement a QAPI program that must include certain essential elements that are outlined in the proposed Bylaws. A requirement that members develop and implement a comprehensive QAPI program should assist members in their efforts to improve performance and remain in compliance with OPTN obligations.

- **Affected Groups**

Directors of Organ Procurement
OPO Executive Directors
OPO Medical Directors
OPO Quality Staff
OPO Coordinators
Transplant Administrators
Transplant Data Coordinators
Transplant Physicians/Surgeons
PR/Public Education Staff
Transplant Program Directors
Transplant Social Workers
Transplant Hospital and Program Quality Staff

- **Number of Potential Candidates Affected**

N/A

- **Compliance with OPTN Strategic Plan and Final Rule**

This proposal addresses the OPTN key goals of promoting transplant patient safety and improving post-transplant survival. The proposal will provide a tool to the MPSC to encourage and assist OPTN members in the development and implementation of robust QAPI programs. Robust QAPI programs resulting in process and performance improvement will advance these goals of promoting transplant patient safety and improving post-transplant survival.

- **Specific Requests for Comment**

Should a requirement that organ procurement organizations and transplant hospitals develop and implement a Quality Assessment and Performance Improvement plan be included in the OPTN Bylaws?

Proposal to Establish a Quality Assessment and Performance Improvement Requirement for Transplant Hospitals and Organ Procurement Organizations

Affected/Proposed Policy: Bylaws, Appendix B (Membership Requirements for Organ Procurement Organizations (OPOs)); Appendix D (Membership Requirements for Transplant Hospitals and Transplant Programs)

Membership and Professional Standards Committee (MPSC)

Public comment response period: September 29, 2014 – December 5, 2014

Summary and Goals of the Proposal:

The MPSC has noted that members having difficulty with compliance or performance often do not have well-developed quality assessment and performance improvement (QAPI) programs. Currently, OPTN bylaws do not require that members establish and implement a QAPI program. Motivated by this observation, the MPSC proposes modifications to OPTN Bylaws that require members to implement a QAPI program that must include certain essential elements that are outlined in the proposed Bylaws. A requirement that members develop and implement a comprehensive QAPI program should assist members in their efforts to improve performance and remain in compliance with OPTN obligations.

Background and Significance of the Proposal:

The MPSC is charged with ensuring that OPTN/UNOS members comply with the criteria for institutional membership. As part of this charge, the MPSC monitors members' compliance with OPTN obligations including reviews of member performance and compliance with policies and bylaws. Within the context of these reviews, the MPSC may request information about a member's QAPI processes and request submission of plans for performance improvement, corrective action, or quality improvement. The MPSC has found that members under review for compliance matters with significant non-compliance history often have non-existent or minimal QAPI programs. This is also true for members under review for extended periods of underperformance. In addition, a common finding by peer visit teams has been the lack of a robust QAPI program. The MPSC concluded that many of these members would have been less likely to experience a long history of underperformance or multiple compliance issues if the members had robust QAPI programs. In response to these experiences, the MPSC established a project to investigate the options for an OPTN requirement for establishment and implementation of a QAPI plan. The inclusion of a QAPI requirement in the OPTN Bylaws would provide the MPSC a basis to require a member to implement or strengthen its QAPI program and to hold members accountable where the lack of an adequate QAPI program has resulted in serious lapses in compliance or performance.

The use of quality processes is a widely accepted tool for evaluation and implementation of process and performance improvements in healthcare.¹ The transplant community has recognized the need for and has been moving towards codified and more thorough quality improvement initiatives. The Centers for Medicare and Medicaid Services (CMS) requires that transplant hospitals and organ procurement organizations have Quality Assessment and

¹ Institute of Medicine. (2001) Crossing the quality chasm: A new health system for the 21st century. National Academy Press: Washington, D.C.

Performance Improvement (QAPI) programs in place and evaluates these programs during CMS surveys.²

Although CMS Conditions of Participation include a QAPI requirement, the MPSC proposes a separate OPTN QAPI requirement because the MPSC cannot rely on a CMS requirement to take action. The MPSC may request information about a member's QAPI processes and ask them to submit plans for performance improvement, corrective action or quality improvement. However, the MPSC has no basis within OPTN policy or bylaws for requiring a member to implement or strengthen its QAPI program. The MPSC also cannot hold members accountable where the lack of an adequate QAPI program has resulted in a serious lapse in compliance or performance. In addition, not all transplant programs are CMS approved. Approximately 13% of transplant programs are not CMS approved, and therefore, not required to comply with CMS' Conditions of Participation. In an effort to avoid an additional burden on those CMS approved organizations, the MPSC reviewed CMS requirements while developing proposed OPTN QAPI requirements, aiming for consistency between the two organizations' QAPI requirements. The requirements of this proposal are consistent with CMS' QAPI requirements.

The MPSC strived to reach a balance between a requirement that is too detailed, thereby creating an undue burden on members; and one that would be more general, thereby failing to provide members with notice of what is expected. Through the proposed requirements, the MPSC can request that members improve a QAPI plan and implement it. If a member fails to comply, the MPSC can then take an action, if needed. In addition, an action can be taken by the MPSC if a member does not have a QAPI program or has not implemented its plan. In order to develop the least burdensome solution to the problem, and recognizing the extensive reviews of QAPI programs recently implemented by CMS, the MPSC will only review compliance with the proposed QAPI requirements in conjunction with an identified compliance or performance issue.

The proposal includes QAPI requirements for OPOs and transplant hospitals. The Committee considered requirements for histocompatibility laboratories but deferred inclusion in the proposal. The Histocompatibility Committee is currently working on a substantial rewrite of the Bylaws applicable to histocompatibility laboratories. The MPSC provided suggested language that mirrors the language in this proposal to the Histocompatibility Committee with a recommendation that a QAPI requirement be included in the rewrite of the Bylaws applicable to histocompatibility laboratories.

Expected Impact on Living Donors or Living Donation:

The requirement for the development and implementation of a QAPI plan would apply to living donor components of transplant programs.

Expected Impact on Specific Patient Populations:

This proposal will not have a disproportionate impact on any specific patient population.

² *Code of Federal Regulations*, Condition of Participation: Quality Assessment and Performance Improvement (QAPI), title 42, sec. 482.96; *Code of Federal Regulations*, Condition: quality assessment and performance improvement (QAPI), title 42, sec. 486.348; Catapult Consultants, LLC. *Quality Assessment and Performance Improvement (QAPI) Programs: A Resource Guide for Transplant Surveyors*. ONLINE. 2010. Centers for Medicare and Medicaid Services. Available: <http://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/downloads/QAPIResourceGuide090810.pdf> [29 August 2014].

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

This proposal addresses the OPTN key goals of promoting transplant patient safety and improving post-transplant survival. The proposal will provide a tool to the MPSC to encourage and assist OPTN members in the development and implementation of robust QAPI programs. Robust QAPI programs resulting in process and performance improvement will advance these goals of promoting transplant patient safety and improving post-transplant survival.

Plan for Evaluating the Proposal:

The MPSC will monitor the usefulness of this requirement as the Committee continues to evaluate the effectiveness of members' QAPI programs in responding to inquiries and implementing successful improvement processes. This requirement should result in more robust and effective QAPI programs at member institutions which would be evidenced by more proactive responses by members to performance issues and events. Ultimately, the MPSC would expect that more effective QAPI programs will decrease the instances of non-compliance and underperformance. In addition, the Committee will track any unintended consequences that might place an undue burden on members.

Additional Data Collection:

This proposal does not require additional data collection.

Expected Implementation Plan:

If public comment is favorable, the proposal may be presented at the OPTN/UNOS Board of Directors meeting in June 2015 and implemented on September 1, 2015.

The MPSC will review compliance with this provision only in conjunction with its review of an identified compliance and performance issue.

Communication and Education Plan:

The proposal addresses new requirements and expectations for members' process improvement. Communication and education efforts will address awareness of the new requirements as well as steps members need to take to fulfill them.

Information about the new requirements would be included in ongoing efforts to inform members about OPTN monitoring for compliance and patient safety, as well process improvement to address areas of concern. The information also would be incorporated into the OPTN Evaluation Plan and included in a crosswalk document that lists CMS and OPTN member requirements in areas of similar authority.

In addition, notification of the amended Bylaws requirements would be included in the following routine communication vehicles:

- Policy notice
- Article on OPTN website and member e-newsletter
- Notification to a listserv group for transplant administrators

Compliance Monitoring:

The MPSC will review compliance with this provision only in conjunction with its review of identified compliance and performance issues. Member compliance will be monitored through requests for submission and MPSC evaluation of a member's performance improvement plans, corrective action plans, plans for quality improvement and information about the members QAPI plan and implementation of that plan.

Policy or Bylaw Proposal:

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

Appendix B:

Membership Requirements for Organ Procurement Organizations (OPOs)

B.3 Quality Assessment and Performance Improvement (QAPI) Requirement

A. OPOs must develop, implement, and maintain a written Quality Assessment Performance Improvement (QAPI) plan that includes the following elements:

1. QAPI Goals and Statement of Scope
2. Guidelines for Governance and Leadership
This portion of the plan must include at least all of the following:
 - a. How QAPI is integrated into the responsibilities and accountabilities of all members of the OPO, including management and the governing body.
 - b. How the OPO will ensure that resources are allocated to implement the QAPI including, who will be accountable for management and coordination.
 - c. A plan for leadership, management, and staff training.
 - d. A list of the key personnel who will manage QAPI and details on how this group will work together, communicate, and coordinate the reporting of QAPI activities to the governing body.
3. Data Systems and Monitoring
This portion of the plan must include at least all of the following elements:
 - a. Performance indicators that will be monitored on an ongoing basis.
 - b. Identified data sources and the process for data collection.
 - c. Description of the process and quality tools used (e.g. pareto charts, scatter diagrams, etc.) for analyzing data.
 - d. Description of the process for communicating the data and the analysis.
 - e. Recipients of the data analysis, and the format and frequency.

4. Guidelines for Conducting, Monitoring, and Evaluating Process Improvement Projects
Describe the overall plan for conducting process improvement projects to improve compliance and performance and the process for evaluating the effectiveness of the process improvements.
5. Adverse Event, Error Identification, and Investigation
Describe how adverse events and errors will be identified and evaluated. Include guidelines to assess the adverse event and error severity, actions to be taken based on the assessment, and monitoring and evaluation to ensure actions are effective.
6. Communications
Describe who in the organization will receive QAPI communications, the frequency of those communications and the format in which the information will be provided.
7. Evaluation of QAPI Process
Describe the process for assessing QAPI in the organization on an ongoing basis.

B. The OPO must document implementation of all of the required elements of the QAPI plan.

B.34 Facilities and Services

[Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.]

Appendix D:

Membership Requirements for Transplant Hospitals and Transplant Programs

A transplant hospital member is any hospital that performs organ transplants and has current approval as a designated transplant program for at least one organ.

D.1 Transplant Hospital Compliance

No change to this section.

D.2 Designated Transplant Program Requirement

No change to this section.

D.3 Quality Assessment and Performance Improvement (QAPI) Requirement

A. **Transplant hospitals must develop, implement, and maintain a written Quality Assessment Performance Improvement (QAPI) plan. The QAPI plan must incorporate all designated transplant programs at the transplant hospital and must include the following elements:**

1. QAPI Goals and Statement of Scope
2. Guidelines for Governance and Leadership

This portion of the plan must include at least all of the following:

- a. How QAPI is integrated into the responsibilities and accountabilities of all members of the transplant hospital, including management and the governing body.
- b. How the transplant hospital will ensure that resources are allocated to implement the QAPI including, who will be accountable for management and coordination.
- c. A plan for leadership, management and staff training.
- d. A list of the key personnel who will manage QAPI and details on how this group will work together, communicate, and coordinate the reporting of QAPI activities to the governing body.

3. Data Systems and Monitoring

This portion of the plan must include at least all of the following elements for each transplant program:

- a. Performance indicators that will be monitored on an ongoing basis.
 - b. Identified data sources and the process for data collection.
 - c. Description of the process and quality tools used (e.g. pareto charts, scatter diagrams, etc.) for analyzing data.
 - d. Description of the process for communicating the data and the analysis.
 - e. Recipients of the data analysis, and the format and frequency.
4. Guidelines for Conducting, Monitoring, and Evaluating Process Improvement Projects

Describe the overall plan for conducting process improvement projects to improve compliance and performance and the process for evaluating the effectiveness of the process improvements.

5. Adverse Event, Error Identification and Investigation

Describe how adverse events and errors will be identified and evaluated. Include guidelines to assess the adverse event and error severity, actions to be taken based on the assessment, and monitoring and evaluation to ensure actions are effective.

6. Communications

Describe who in the organization will receive QAPI communications, the frequency of those communications and the format in which the information will be provided.

7. Evaluation of QAPI Process

Describe the process for assessing QAPI in the organization on an ongoing basis.

B. The transplant hospital must document implementation of all of the required elements of the QAPI plan.

D.34 Facilities and Resources

[Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.]