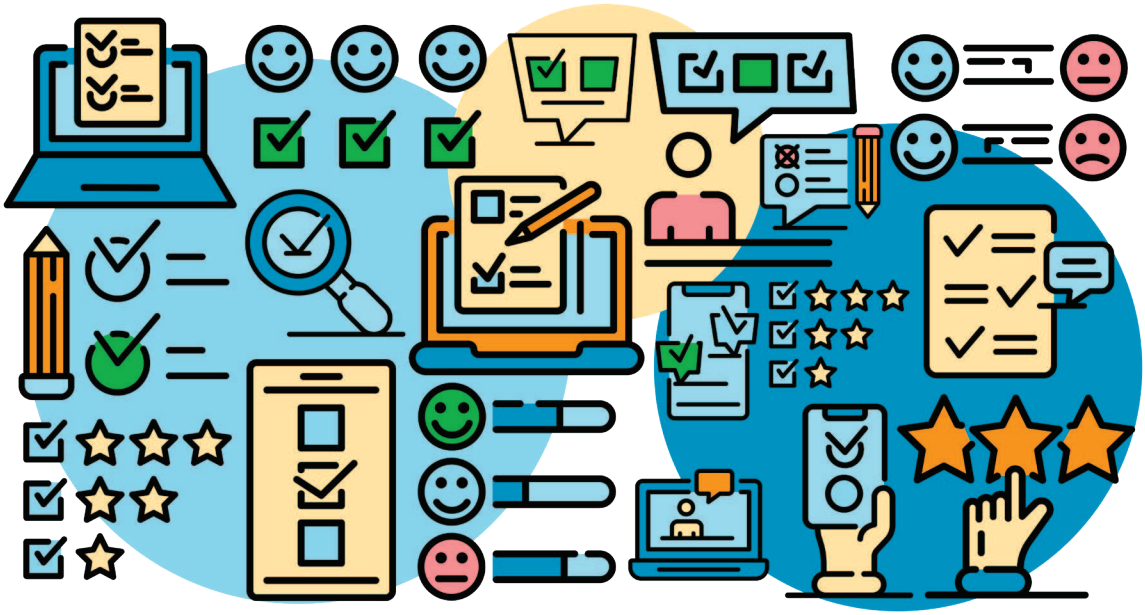
TRANSPLANT QUALITY CORNER
ESSENTIAL QUALITY-FOCUSED TOPICS FOR TRANSPLANTATION
APRIL 2025 ISSUE



A TRANSPLANT CENTER SURVEYOR'S GUIDEBOOK

The Key to a Successful CMS Recertification Survey

THE Alliance
Equipping a Modern Profession of Lifesavers in Organ Donation & Transplantation

THIS ISSUE

EDITOR'S NOTE

The Transplant Quality Corner presents a series of publications dedicated to enhancing transplant center outcomes through the utilization of the latest metrics, data collection techniques, and monitoring methods. Each publication encompasses an executive summary, background information, essential tools, actionable steps, references, and downloadable resources in the form of a concise one-page summary.

This edition explores the evolving landscape of transplant program oversight, highlighting the ongoing challenge of balancing regulatory compliance with clinical decision-making.

DEANNA FENTON
Senior Manager, Educational Program Development and Operations

We extend our deepest gratitude to our contributors for their tireless efforts in bringing Transplant Quality Corner to life. Their dedication and expertise have been invaluable to the success of this project, and we are truly appreciative of their hard work and commitment.

The Transplant Quality Corner offers a series of publications that focus on the latest metrics, data collection and monitoring methods for improving transplant center outcomes. Each issue includes an executive summary, background Information, essential tools, action items to implement, references and resources.

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WORKGROUP MEMBERS

ASHLEY CARDENAS
MAS, FAST
Renown

ADRIANA KOCHI
MHA, CPHQ
Inova Fairfax Hospital

JENNA LAWSON
MS
Vanderbilt University Medical Center

ABBEY OLSEN
MSN, RN, CCRN
Transplant Quality Manager
University of Utah Hospital

ALLISON PECK
MSN, CCTC RN-BC
Cedars Siani Medical Center

MELISSA ROBINSON
Loma Linda University Medical Center

LINDSAY SMITH
RN, MSN
Vanderbilt Transplant Center

LECIA SNELL KINEN
MSN, RN, CCTC
Keck Medical Center at USC

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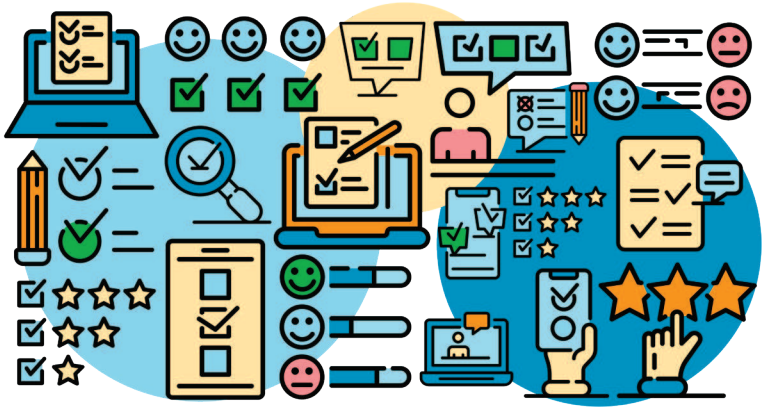
A TRANSPLANT CENTER SURVEYOR'S GUIDEBOOK

The Key to a Successful CMS Recertification Survey



From its inception in 1986 through continuous refinement in 2024, CMS's oversight of transplant programs is the federal government's earnest attempt at ensuring high standards of care. While CMS oversight has undoubtedly improved transplant program accountability and patient safety, many transplant centers still struggle with the balance between regulatory compliance and real-world clinical decision-making.

The 2024 updates reflect progress, but transplant leaders continue to advocate for a more streamlined, patient-centered approach that reduces administrative burdens while maintaining high standards of care. The Conditions of Participation (CoPs) and SOM Appendix X serve as an essential tool for transplant programs to be successful in meeting these standards.

Below is a brief timeline of the CoP and SOM development and key changes over time and an updated checklist for CMS recertification prep.

TIMELINE

1986

LAYING THE REGULATORY FOUNDATION: Early Oversight Of Transplant Programs

The Federal Government Steps In

- Following growing concerns over program variability, inconsistent patient outcomes there was a call for national oversight in the rapidly advancing field of transplantation.

- The Omnibus Budget Reconciliation Act (OBRA) of 1986 marks a pivotal moment in transplant program oversight by mandating that organ transplant programs receiving Medicare and Medicaid funding meet federal quality, safety and performance standards.
- The legislation charged the Health Care Financing Administration (HCFA) (the predecessor to CMS) with developing regulatory standards to ensure that transplant patients receive high-quality, life-sustaining care.
  - Surveys were conducted primarily by State Survey Agencies under CMS oversight.
- Prior to this, transplant programs operated with high variability in patient outcomes, quality standards, and eligibility criteria.

Impact on Transplant Programs:

- Establishes a basic regulatory structure, setting the stage for national quality benchmarks.
- Lack of clear implementation details leaves programs uncertain about compliance expectations.
- Creates a new administrative burden, requiring centers to track and report performance data without standardized metrics.

2007

ESTABLISHING COMPREHENSIVE NATIONAL STANDARDS

CMS Codifies Conditions of Participation (CoPs) for Transplant Programs

After years of inconsistent enforcement and ongoing concerns around transplant program performance and disparate patient outcomes, CMS introduced 42 CFR 482.68-482.104, the Conditions of Participation (CoPs) for transplant programs.

- This regulation formalized eligibility, performance measurement, patient safety protocols, and quality improvement requirements.
- The three key tenets of transplant program regulation emerge:

1. CMS Certification: Transplant centers must now be approved and regulated by CMS in order to participate in Medicare and Medicaid reimbursement.

2. With the introduction of formal transplant program CoPs in 2007, CMS regional offices took on direct responsibility for program recertification surveys and compliance evaluations.

    a. OPTN/UNOS Compliance: Programs must also adhere to the national policies of the Organ Procurement and Transplantation Network (OPTN), administered by the United Network for Organ Sharing (UNOS).

3. Quality & Outcome Measures: To maintain approval, centers must consistently meet performance benchmarks, report outcomes, and implement corrective action plans when indicated.

Impact on Transplant Programs:

- Brings structure and consistency to national transplant oversight.
- Outcome-based measures create unintended consequences—programs start to avoid high-risk transplants out of fear that poor results could trigger CMS penalties or loss of certification.
- New administrative burden: Programs must collect and report extensive data, often requiring additional staff and resources.

2008

ENHANCING SURVEY AND COMPLIANCE PROCESSES

Introduction of SOM Appendix X for Survey & Compliance Guidance

Recognizing the need for standardized enforcement, CMS released Appendix X of the State Operations Manual (SOM)—a comprehensive tool intended to guide surveyors in the "how to" of evaluating transplant programs.

The document:

1. Provided detailed interpretive guidelines to help surveyors assess transplant programs consistently and effectively.
2. Established survey procedures to guide how compliance with the CoPs is to be measured.

3. Outlined expectations for program reporting, patient and donor protections, and data integrity.

Impact on Transplant Programs:

- Creates more consistency in compliance inspections, making surveys more predictable.
- Surveyor subjectivity remains a problem—some programs experience inconsistent interpretations of compliance expectations.
- Centers must prepare for intensive, labor-heavy site visits, diverting resources away from patient care.

2010 - 2015

Increased Scrutiny & Living Donor Protections

- CMS worked to improve surveyor training and program self-monitoring in an attempt to shift focus toward preventative action rather than punitive enforcement.
  - In 2013, CMS shifted transplant program surveys to specialized third-party contractors with expertise in transplantation, operating under the Quality, Safety & Oversight Group (QSO) within CMS.
- At the same time, expanding oversight into living donor transplants, emphasizing donor safety, informed consent, and follow-up care.
- A revised manual was issued with strengthened requirements focused on:
  - Living donor protections to address growing concerns about donor safety and long-term outcomes.
  - Staff training and compliance documentation
  - Quality assurance performance improvement (QAPI) refinements, helping programs proactively address deficiencies.
  - Incident and adverse event reporting protocols to ensure timely intervention and transparency.

Impact on Transplant Programs:

- Improved living donor safety measures, benefiting donors and protecting programs from liability.
- Increased regulatory complexity: Programs struggle to balance CMS, OPTN, and institutional review board (IRB) requirements.
- Expanded documentation requirements place administrative strain on transplant teams.

2017

RESHAPING MODERN OVERSIGHT & FLEXIBILITY IN REGULATIONS

Major Revisions to SOM Appendix X for Consistency, Aligning with the OPTN Policies

CMS releases a significant revision of Appendix X to better align CMS oversight with OPTN and UNOS oversight, addressing concerns about duplicative and conflicting requirements and undue burden.

The revised guidelines emphasize:

- Harmonization with OPTN/UNOS policies to eliminate conflicting regulatory demands.
- Standardized assessment protocols for surveyors to ensure a uniform evaluation process.
- Improved clarity in compliance criteria, reducing ambiguity for transplant centers.
- More flexibility in corrective action plans.

Impact on Transplant Programs:

- Better alignment between CMS and OPTN reduces some regulatory redundancies.
- More structured corrective action plans allow programs to improve without immediate penalties.
- Programs still face dual oversight challenges, with discrepancies between CMS and UNOS expectations leading to confusion.
- Surveyor inconsistencies persist, with some programs receiving harsher scrutiny than others.

2019 - 2021

Aiming for Greater Flexibility in Quality Standards, Transition back to the State Agencies

- Recognizing the evolving landscape of transplant medicine, CMS again revises the CoPs with the intent of providing greater flexibility in how programs meet quality improvement goals.
- Programs are encouraged to implement tailored quality improvement initiatives rather than follow rigid corrective action models.
- More comprehensive risk-adjusted evaluations rather than blunt outcome-based penalties; Recognition that transplant success cannot be judged on simplistic survival statistics alone
- Stronger program self-monitoring to identify and correct deficiencies before regulatory intervention.
- Survey activities are also transitioned from federal contractors back to the state agencies, creating new opportunity for variability in interpretation and enforcement.

Impact on Transplant Programs:

- Programs treating complex cases and high-risk patients feel less pressure to manipulate transplant criteria to meet rigid outcome thresholds.
- QAPI programs gain more flexibility, allowing centers to focus on meaningful internal improvements rather than just checking CMS boxes.
- Some programs feel CMS still prioritizes documentation over practical, patient-centered transplant decision-making.

December 2024

THE LATEST UPDATES & THE FUTURE OF CMS OVERSIGHT

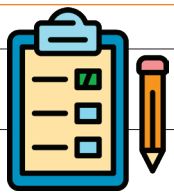
Latest Revision to SOM Appendix X

- The most recent CMS update to Appendix X reflects lessons learned from audits, patient safety reports, and input from transplant centers.

- Key changes:
  - Standardized surveyor training and a streamlined survey process to reduce inconsistencies across all programs
    - Enhanced patient safety protections, with a particular focus on living donors and high-risk transplants.
    - Digital health and data reporting integration, ensuring real-time tracking and analysis of transplant program performance.
    - Enhanced focus on multidisciplinary collaboration, adverse event protocols, and transplant staff training reinforcing multidisciplinary collaboration and program accountability.

Impact on Transplant Programs:

- More predictable survey processes, improving transparency.
- Programs have more flexibility in defining and addressing quality improvement initiatives.
- Patient safety enhancements are welcomed, especially for living donors and high-risk recipients.
- Administrative burden remains high, with continued concerns that CMS prioritizes reporting over real-world transplant complexities.
- Adverse event reporting requirements increase workload, requiring additional resources for data collection and compliance monitoring.



CHECKLIST

CMS Readiness Checklist 2025			
	SURVEY REPORTS (REQUIRED WITHIN 4 HOURS OF ARRIVAL)	**EXISTING ELEMENTS:**	**ADDED ELEMENTS**
☐	Active waiting list	☐ Name ☐ Date of Listing ☐ Wait List Status ☐ MRN ☐ Age ☐ Race ☐ Gender	☐ Total number of individuals on the waiting list
☐	Waitlist Removals for reasons other than death of transplant Past 12 months	☐ MRN	
☐	Waitlist Removals due to death or transplant past 12 months (New Report)	☐ MRN	
☐	Evaluation Declines past 12 months	☐ Name ☐ MRN	☐ Decision Date ☐ Decision Reason
☐	Transplanted last 18 months	☐ Name ☐ DOT ☐ MRN ☐ Age	☐ Race ☐ Gender ☐ Address ☐ Country of primary residence ☐ Date of Death/ Graft Failure
☐	Living Donors evaluated past 12 months	☐ Name ☐ MRN ☐ Organ donated ☐ Date of donation	
☐	Currently admitted transplant and living donor patients	☐ Unit ☐ Floor	
☐	Follow up visits for post-transplant & post-donation during survey time frame (New Report)		
☐	Declined Organ Offers for past 18 months (New Report)	☐ List and number of declined offers with decline code	

CMS Readiness Checklist 2025 (cont.)

	REQUIRED SCHEDULES FOR PRESENTATION AT ENTRANCE SURVEY	WHAT ARE SURVEYORS LOOKING FOR?
☐	Schedule for all multidisciplinary team meetings *including rounding	☐ Attendance and roles of the team members ☐ Leadership and collaboration within the team ☐ Communication among team members ☐ Involvement of recipient/family in care decisions ☐ Documentation and evidence of individualized implementation and evaluation of patient's plan of care to ensure they are meeting their goals
☐	Schedule of selection Committee meetings	☐ Attendance and leadership of the selection committee meeting ☐ Team participation and involvement in patient selection discussion ☐ Selection criteria used to make patient determinations ☐ Process for making patient determinations ☐ Outcome of the selection committee meetings ☐ Results of any committee meeting discussions are conveyed to the patient and/or their family ☐ Review previous meeting minutes and attendance for consistency with observed meeting
☐	Schedule of all QAPI meetings	☐ Attendance and roles of the team members ☐ Identification of QAPI leadership, as well as participation from all members of the team ☐ Identification of issues and concerns relative to the transplant program activities ☐ Follow-up and development of improvement plans to address gaps in care ☐ Action items and/or results of the QAPI meeting

	ADDITIONAL OPENING SURVEY REQUIRED DOCUMENTATION	
☐	Organizational chart	☐ Incorporates how the transplant center fits into overall hospital organization
☐	Contracts	To consider but not limited to: ☐ HLA services ☐ Living donor- NKR, APD
☐	Training schedule for personnel (New Documentation)	☐ Agenda ☐ Dates ☐ Evidence of attendance
☐	On-call schedule for transplant surgeons and physicians past 30 days	

	QUALITY RELATED DOCUMENTATION
☐	Adverse Events for the past 24 months (New extended time frame)
☐	Adverse Event/ Occurrence Policy
☐	Quality Assessment and Performance Improvement (QAPI) Plan
☐	Hospital QAPI Plan
☐	QAPI reports, records, minutes

	POLICIES	NEW/ EMPHASIZED REQUIREMENTS:
☐	Patient Selection Criteria for transplant and living donors	
☐	ABO Verification Policy Transplant Recipients & Living Donors	☐ Include associated blank forms
☐	Waiting list management policy	☐ Including patient notification
☐	Psychosocial Evaluation Policy for transplant candidates and living donors (new policy requirement)	Update policies to include the following: ☐ The length of time in which the psychosocial evaluation is deemed to be current and/or frequency of re-evaluation to determine continued appropriateness; ☐ The type of qualified professional healthcare personnel (MSW, LCSW, psychiatrist or psychologist) who may complete these evaluations; ☐ The follow-up and referral procedures if a transplant candidate requires such activities; and ☐ The method of communicating the psychosocial evaluation findings into the selection process.
☐	Patient Management Policies for transplant and Discharge	☐ Transplant programs should define the structure of their evaluation and transplant processes ☐ Patient management policies for the discharge phase of transplant should have mechanisms in place to identify, assess, and meet the medical and psychosocial needs of the patient to ensure they have the resources necessary to care for their transplant. ☐ These patients will require discharge planning at an early stage of their hospitalization to ensure their discharge needs are identified and addressed prior to actual discharge.

	POLICIES	NEW / EMPHASIZED REQUIREMENTS:
☐	Living Donor Management for Pre-donation, donation and discharge phases	☐ Transplant programs that provide living donor transplant services must develop and implement living donor policies that direct the care and management of donors through their evaluation, donation, and discharge after donation. ☐ The evaluation policies must ensure it incorporates at a minimum, all potential donors that have chosen to undergo all or any portion of the transplant program's evaluation process. ☐ Transplant programs should ensure its discharge policies for living donors are based on the hospital policies for discharge planning.
☐	Informed Consent policy for transplant recipients and living donors	Policy needs to be updated to include the following: ☐ who is responsible for discussing the informed consent process with the potential donor; ☐ where the discussions concerning the informed consent process are documented in the medical record; ☐ the methods used by the program to ensure and document the potential donor's understanding of the information being delivered; and ☐ when the discussion(s) will take place, if the information is provided at different points of the donation process.
☐	Communication between patients and dialysis centers	
☐	Availability of transplant team could impact potential to receive a transplant should an organ become available	☐ The transplant program's policies must address communication methods to inform patients of situations or events that would impact the program's ability to perform transplants. ☐ If the event is related to an emergency situation, which may or may not require transfer of patients to another hospital, the transplant program is expected to notify patients on the waiting list of the emergency plan in accordance with the program's emergency preparedness protocol in place.
☐	Potential unavailability at centers with Single surgeon/ physician	
☐	Emergency Management preparedness	
☐	Patient Education: all material used pre and post-transplant and pre and post living donation	☐ Including education that explains selection criteria

	ADDITIONAL REGULATIONS FOR CONSIDERATION
☐	A request for nutritional and/or social services can also be made by the patient, family member(s)/ caretakers, and/or the patient's multidisciplinary team.
	LIVING DONOR SERVICES UNDER CONTRACT ARRANGEMENT
☐	Have written evidence of a contract or agreement with the living donor transplant program(s). This may be a specific contract or agreement between two hospitals or programs, or it may include participation in a transplant registry for paired donation of living donors and recipients.
☐	Have a copy of the Medicare-approval letter for the living donor transplant program with which it has a contract or agreement, or have documented evidence that the CMS website listed below was reviewed prior to accepting the living donor organ to ensure that the program was a Medicare-approved program.
☐	Donor record information requirements: ☐ There is a complete medical and psychosocial evaluation in the medical record completed by the relevant professionals of a multidisciplinary team which has determined that the individual is a suitable living donor. ☐ An Independent Living Donor Advocate (ILDA) has met and worked with the potential living donor and has been included in the discussions of the potential donor's suitability. ☐ There is a fully documented informed consent process in the living donor's medical record that meets the minimum Medicare requirements.
☐	As part of the Quality Assessment and Performance Improvement (QAPI) requirement, ensure that there is a feedback system between the recipient and donor hospital to address any adverse events that occur in the donor or the recipient for a specific donation or transplant.

TOOLS AND RESOURCES

- Transplant Community Collaborative Crosswalk
- Updated CMS Guidelines
- CMS Readiness Checklist in Excel format
- Download Checklist in PDF format