Process for Requesting Consideration of Mitigating Factors in the Centers for Medicare & Medicaid Services' (CMS)' Determination of Medicare Approval of Organ Transplant Programs

A. Background

Under 42 CFR §488.61(f), a transplant program may request that the Centers for Medicare & Medicaid Services (CMS) consider mitigating factors for the initial approval and re-approval of a transplant program that does not meet the Conditions of Participation (CoPs) §482.80 or §482.82. Mitigating factors will not be considered in situations of immediate jeopardy.

The regulation describes general areas that will be reviewed in determining whether a program can be approved based on mitigating factors at 42 CFR §488.61(f)(1). These areas include (but are not limited to):

1. The extent to which outcome measures are not met or exceeded;
2. Availability of Medicare-approved transplant centers in the area;
3. Extenuating circumstances (for example, natural disasters) that have a temporary effect on meeting the CoPs;
4. Program improvements that substantially address root causes of graft failures or patient deaths, that have been implemented and institutionalized on a sustainable basis, and that are supported by outcomes more recent than the latest available Scientific Registry of Transplant Recipients (SRTR) report, for which there is a sufficient post-transplant patient and graft survival period and a sufficient number of transplants such that CMS finds that the program demonstrates present-day compliance with the requirements at §482.80(c)(2)(ii)(C) or §482.82(c)(2)(ii)(C);
5. Whether the program has made extensive use of innovative transplantation practices relative to other transplant programs, such as a high rate of transplantation of individuals who are highly sensitized or children who have undergone a Fontan procedure, where CMS finds that the innovative practices are supported by evidence-based published research literature or nationally recognized standards or Institution Review Board (IRB) approvals, and the SRTR risk-adjustment methodology does not take the relevant key factors into consideration; and
6. Whether the program's performance, based on the Organ Procurement and Transplantation Network (OPTN) method of calculating patient and graft survival, is within the OPTN's thresholds for acceptable performance and does not flag OPTN performance review under the applicable OPTN policy.

B. Requesting Approval Based on Mitigating Factors

A transplant program seeking initial approval or re-approval based on the presence of mitigating factors must complete the following three steps:

1. Initial Response to the CMS Notification of Noncompliance :
   - Initial approval: If CMS determines a transplant program has not met the data submission, clinical experience, or outcome requirements, CMS may deny the request for approval. The program will receive a letter- notifying the program of its denial. A response to the CMS's letter, which includes the program's plan to apply for mitigating factors, is required to be sent to CMS.
     Note: Form CMS-2567 will not be issued for applications of initial approval of Medicare.
   - Re-approval: On the Statement of Deficiencies (Form CMS-2567), the program must state that it is planning to apply for mitigating factors as its plan of correction (POC) for non-compliance with data submission, clinical experience, or outcomes noncompliance. If there are deficiencies with other CoPs, they must be addressed in the POC as well.

2. Send Timely Letter of Intent to Apply for Mitigating Factors:
   Within 14 calendar days after the CMS has issued formal written notice of a condition-level deficiency to the program, the CMS must receive notification of the program's intent to seek mitigating factors. All requests for consideration of mitigating factors should be sent electronically to Sherry Clark at sherry.clark@cms.hhs.gov.

   Additional contact information for Sherry Clark is outlined below:
   Sherry Clark
   Centers for Medicare & Medicaid Services
   Center for Clinical Standards & Quality
   Survey & Certification Group
   7500 Security Blvd, Mailstop C2-21-16
   Baltimore, MD 21244
   Phone: (410) 786-8476
   Fax: (410) 786-0194

3. Send Timely and Complete Mitigating Factors Application:
   All information necessary for consideration must be received **within 120 calendar days** of the CMS' written notification for a deficiency due to noncompliance at §482.80 or §482.82. Please contact the CMS for submission instructions. (See section C for the content requirements for the application and mitigating factors checklist.)

Note: Pursuant to 42 CFR §488.61(f), a request for consideration of mitigating factors must include sufficient information to permit an adequate review of the transplant program, factors that have contributed to outcomes, program improvements or innovations that have been implemented or planned and in the case of natural disasters, the recovery actions planned. **Failure to submit a complete and timely application within 120 calendar days may be the basis for denial of mitigating factors.**

C. Preparing the Mitigating Factors Application

The application must be formatted to match the mitigating factors application checklist in Appendix 3.1.

The pages of application documents should be sequentially numbered and sent as a single Adobe Portable Document Format (.pdf) or Microsoft Word (.doc or .docx) file. This will ensure that the CMS is aware of all supporting documentation provided and will greatly facilitate the review process.

Mitigating factors application materials must have all Personally Identifiable Information (PII) removed prior to submission to ensure a timely review. Please contact the CMS for submission instructions.

The application narrative should be concise and the supporting documentation relevant to the rationale and mitigating factors requested. The program should limit the file size to a maximum of 200 pages.

D. The CMS Process for Reviewing Requests for Approval Based on Mitigating Factors

The CMS review will include analysis by the CMS staff and technical experts with programmatic and clinical expertise for each program on a case-by-case basis.

Upon review of the request to consider mitigating factors, CMS may take the following actions:

1. Grant initial approval or re-approval of a program's Medicare participation based upon approval of mitigating factors;
2. Deny the program's request for Medicare approval or re-approval based on mitigating factors. CMS will notify the transplant center in writing if its approval is being revoked and of the effective date of the revocation, providing the program with the opportunity to voluntarily withdraw from Medicare; or
3. Offer a time-limited Systems Improvement Agreement (SIA) in accordance with 42 CFR §488.61(h), when a transplant program has waived its appeal rights, has implemented substantial program improvements that address root causes and are institutionally supported by the hospital's governing body on a sustainable basis, and has requested more time to design or implement additional improvements or demonstrate compliance with CMS outcome requirements. Upon completion of the SIA or a CMS finding that the hospital has failed to meet the terms of the Agreement, CMS makes a final determination of whether to approve or deny a program's request for Medicare approval or re-approval based on mitigating factors.

   A SIA is a binding agreement, entered into voluntarily by the Hospital and the CMS, through which the CMS extends the prospective Medicare termination date. This offers the program additional time to achieve compliance contingent on the hospital's agreement to participate in a structured regimen of quality improvement activities, demonstrate improved outcomes, and waive the right to appeal termination based on the identified deficiency or deficiencies (that led to the Agreement). In some cases, transplant programs may enter a period of inactivity—voluntarily, or imposed as a condition of the SIA.

All programs that submit a mitigating factors application for review will receive written notification of CMS' decision prior to the prospective termination date.

E. Time Period of Approval Based on Mitigating Factors

Approval of a mitigating factors application for a transplant program is time-limited and does not guarantee any subsequent re-approvals. The CMS will determine if the circumstances that originally warranted approval based on mitigating factors still apply at the time of the program's subsequent Medicare re-approval survey and/or in the event of a complaint survey. If deficiencies with data submission, clinical experience, or outcomes requirements were found, the transplant program would be required to submit a new request for consideration of mitigating factors, including updated supporting documentation for review.

Appendices

These appendices contain additional information about the mitigating factors application process and systems improvement agreements.

Appendix 1: Process Timelines and Workflow Guides:

- Appendix 1.1: Summary of Mitigating Factors Process Timeline
- Appendix 1.2: Systems Improvement Agreement Workflow Guide

Appendix 2: Examples of Mitigating Factors that May Be Considered

Appendix 3: Mitigating Factors Application Templates

- Appendix 3.1: Mitigating Factors Application Checklist
- Appendix 3.2: Summary of Mitigating Factors Requested

Appendix 4: Transplant Systems Improvement Agreement Templates and Guides

- Appendix 4.1: Independent Peer Review Team Assessment Guide
- Appendix 4.2: Staffing Analysis Guide
- Appendix 4.3: Action Plan for Quality Improvement Guide
- Appendix 4.4: Comparative Effectiveness Analysis of Policies and Procedures Guide
- Appendix 4.5: Lessons Learned Teleconference Agenda Template
- Appendix 4.6: Lessons Learned Report Guide

Appendix 1
Process Timelines and Workflow Guides

Appendix 1.1 Summary of Mitigating Factors Process Timeline

The table below summarizes the Mitigating Factors application process and timeline. Additional information for each of these steps is in Sections A through D of this document on pages 1 through 4.

Step	Timeline	Description
1-Plan of Correction (POC)	By the due date on the Form CMS-2567	For re-approval applications only, the program states on the Form CMS-2567 its plan to apply for mitigating factors as its POC for non-compliance. If there are deficiencies with other CoPs, they must be addressed in the POC as well.
2-Letter of Intent to Apply for Mitigating Factors	Must be received by CMS within 14 calendar days of the CMS' notice of CoP deficiency.	The program submits the Letter of Intent to Apply for Mitigating Factors electronically to Sherry Clark at sherry.clark@cms.hhs.gov.
3-Mitigating Factors Application	Must be received by CMS within 120 calendar days of the CMS' notice of CoP deficiency.	The program contacts CMS for submission instructions and submits the Mitigating Factors Application with all information necessary for consideration of the request. The application content must be in accordance with the requirements in Section C-Content of the Mitigating Factors Application and the Mitigating Factors Application Checklist in **Appendix 3.1**.
4-The CMS Review of Request for Approval Based on Mitigating Factors	Before the prospective termination date on CMS' notice of CoP deficiency.	The CMS review will include analysis by the CMS staff and technical experts with programmatic and clinical expertise for each program on a case-by-case basis.
5--Determination of Request for Approval Based on Mitigating Factors	Before the prospective termination date on the CMS' notice of CoP deficiency.	Upon review of the request to consider mitigating factors, CMS may: 1.Approve initial approval or re-approval of Medicare participation based upon approval of mitigating factors; 2. Deny the request for Medicare approval or re-approval based on mitigating factors; or 3. Offer a time-limited Systems Improvement Agreement (SIA), in accordance with 42 CFR §488.61(h), when a transplant program has waived its appeal rights, has implemented substantial program improvements that address root causes and are institutionally supported by the hospital's governing body on a sustainable basis, and has requested more time to design or implement additional improvements or demonstrate compliance with CMS outcome requirements.
6-Notification of the Mitigating Factors Decision	Before the prospective termination date on the CMS' notice of CoP deficiency.	CMS will provide written notification to the program of their decision for consideration of mitigating factors.

Appendix 1.2: Systems Improvement Agreement (SIA) Workflow Guide

The CMS may offer the program a SIA when a transplant program has waived its appeal rights, has implemented substantial program improvements that address root causes and are institutionally supported by the hospital's governing body on a sustainable basis, and has requested more time to design or implement additional improvements or demonstrate compliance with CMS outcome requirements. The workflow described below is a general guide of activities that commonly occur during a transplant SIA. The hospital must perform all activities in accordance with the requirements and completion dates in the SIA document signed by the Hospital and the CMS. The templates and guides in **Appendix 4** are to be used during the term of the SIA.

Workflow	Description
1	**SIA Agreement** • Initial discussion between the CMS and program • Program's verbal commitment to enter into an SIA • Draft version of SIA sent to program by the CMS • Final version of SIA signed by the CMS and the Hospital
2	**Monthly reports/ ongoing update requirements for the program to the CMS** • Reporting patient deaths and/or graft failures within 5 days • Updating patient outcomes • Reporting selection criteria changes • Monthly calls with the program, onsite consultant and the CMS
3	**Patient Notification Letter** • Draft version submitted to the CMS for review • Final version sent to all patients on the waitlist
4	**Patient Assistance Fund** • Establishing the fund at the beginning • Accounting of the fund at the end
5	**Quarterly Reports of Updated Outcomes Data** (using template in final, signed SIA)
6	**Independent Peer Review Team (IPRT)** • Proposed composition and qualifications of IPRT • Plan for scope, methodology and composition of the IPRT's assessment • IPRT completes onsite independent review • Written report submitted to the hospital by IPRT • Confidential verbal report of findings by IPRT to CMS (and HRSA/OPTN, upon request)
7	**Report on SRTR Outcomes Data** (using template in final, signed SIA)
8	**Report on Quality Assessment and Performance Improvement (QAPI) baseline measures**
9	**Staffing Analysis** • Written plan for conducting staffing analysis • Written report with analytic results from staffing analysis and description of resultant actions
10	**Onsite Consultant** • Written evidence that position filled or will be filled
11	**Action Plan for Quality Improvement** (based on recommendations from IPRT and Onsite Consultant) • Formation of Action Plan • Written evidence Action Plan has been substantially implemented
12	**Comparative Effectiveness Analyses review of policies, procedures, and/or protocols**
13	**Report of Programmatic Lessons Learned to CMS Center for Clinical Standards & Quality (CCSQ) Survey & Certification Group (SCG) Director**
14	**The CMS' determination on the request for mitigating factors**

Appendix 2
Mitigating Factors that May be Considered

The following is a list of the general areas that CMS may consider when reviewing a mitigating factors request. The program may use this list for reference in preparing the summary of mitigating factors requested, its rationale/supporting evidence and, if applicable, its description of internal program improvements (see sections A-2d through A-2f of the Mitigating Factors Application Checklist, Appendix 3.1 and the Summary of Mitigating Factors Requested in Appendix 3.2)
Note: It is not expected that programs address each issue to be considered. In fact, we advise programs to only make a case with respect to factors that have strong evidentiary basis.

A. Extent and Nature of the Program's Inability to Meet Outcome Thresholds

1. ***Degree***: To what extent has risk-adjusted performance departed from the standard?
2. ***Trend Line of Outcomes***: To what extent has the outcomes trend been improving, staying the same, or worsening?
3. ***Effect of Risk-Adjustment:*** To what extent is there evidence that performance has been adversely affected by transplant risks not captured in the SRTR risk-adjustment methodology? If cohorts of patients not accounted for in the SRTR risk adjustment model were removed, would the program's outcomes demonstrate compliance?

B. Access-to-Care Issues

1. ***Evidence of Access:*** To what extent is there evidence that the absence of this Medicare-approved transplant program will cause significant access-to-care problems for Medicare beneficiaries?
2. ***Population Considerations:*** Are there any special access-to-care issues related to the population being served?
3. ***Organ-Type Considerations:*** To what extent would the absence of this Medicare-approved transplant program impact the ability to use viable organs that are recovered from this Donation Service Area (DSA)?

C. Extenuating Circumstances

1. ***Natural Disasters:*** What are the recent Federal Government-determined natural disasters that significantly affected the ability of the transplant center to meet the CoPs? What is the timeline for recovery?
2. ***Other Factors:*** For example, have any personnel changes affected compliance with the CoPs (e.g., the primary transplant surgeon leaving the program and delays in replacement were beyond the control of the hospital)?

D. Substantial Program Improvements and Supporting Data

1. ***Quality Assessment and Performance Improvement (QAPI):*** To what extent has the program identified and analyzed the root causes of poor outcomes for graft failures or patient deaths?
    a) To what extent have the following occurred:

i. There have been improvements in the transplant program that substantially address the root causes of graft failures or patient deaths;

ii. The improvements have been implemented and institutionalized on a sustainable basis, e.g., there have been significant improvements in the transplant hospital's management interventions and involvement of the Governing Body that substantially address the root causes of graft failures or patient deaths; and

iii. There is a sufficient post-transplant patient and graft survival period and a sufficient number of transplants such that the program demonstrates present-day compliance with the requirements at §482.80(c)(2)(ii)(C) or §482.82(c)(2)(ii)(C), i.e., the number of observed events divided by the number of expected events is greater than 1.5.

b) What is the relationship of the above factors (a)(i-iii) to the root causes of failure to meet the CoPs?

E. Recent Outcomes Showing Compliance

1. Provide the clinical experience and survival data since the period covered in the most recent SRTR report for the CMS to conclude that the program would be in compliance, except for the data lag inherent in the reports from the SRTR.

F. Extensive Innovation

1. ***Use of Innovative Practices:*** Has the program made extensive use of innovative transplantation practices relative to other transplant programs, such as a high rate of transplantation of individuals who are highly sensitized or children who have undergone the Fontan procedure?
2. ***Evidence-based Research or Standards:*** To what extent is the program's use of the innovative transplantation practices supported by evidence-based, published research or nationally recognized standards or IRB approvals?
3. ***SRTR Risk-adjustment Methodology:*** To what extent does the SRTR risk-adjustment methodology not consider the relevant key factors?

G. In Compliance with OPTN Performance Thresholds

1. To what extent is the program's performance, based on the OPTN method of calculating patient and graft survival, within the OPTN's thresholds for acceptable performance and is not flagged for OPTN performance review under the applicable OPTN policy?

Appendix 3
Mitigating Factors Application Templates

The mitigating factors application templates described below are included on the following pages:

Appendix 3.1: Mitigating Factors Application Checklist

- The purpose of this checklist is to assist the program in preparation of the mitigating factors application.
- The mitigating factors application must be formatted to match the checklist.
- This document is required to be submitted as part of the mitigating factors application (see Section A-1 of the Mitigating Factors Application Checklist, listing the completed checklist as a component of the Program Application Summary).

Appendix 3.2: Summary of Mitigating Factors Requested

- This document serves as a template for the program summary of the mitigating factors requested. Refer to **Appendix 2** for examples of the mitigating factors that may be considered. The program must generate this descriptive summary with content that is specific to the program issues and activities that relate to each of the associated mitigating factors being requested.
- This document is required to be submitted as part of the mitigating factors application as Section A-2d of the Program Application Summary.

Appendix 3.1: Mitigating Factors Application Checklist

Hospital Name:	
OPTN Code/ Transplant CCN #:	
Organ/ Program Type:	
Address, City & State:	
Program Contact Name, phone number, and e-mail:	
Date Prepared:	

Note: Any changes in the program's contact person must be communicated to the CMS within 72 hours to ensure timely communication.

This checklist will assist the program in the preparation of a mitigating factors application. The completed checklist must be submitted with the application. All of the information included on this checklist is required as part of the mitigating factors application.

Note: Failure to submit a complete and timely application may be the basis for denial of mitigating factors.

Description	**Application Page Number(s)**
Section A - Program Application Summary	
(1) The completed **Mitigating Factors Application Checklist**.	
(2) An **application summary** in letter format on the program or hospital's letterhead that includes: (2a) The name of the transplant hospital and hospital address (as it appears on the Medicare-Approved Transplant Programs list on the CMS website) with the OPTN code and Transplant CCN #.	
(2b) The type of organ transplant program for which approval of mitigating factors is requested. *(Separate applications must be submitted if more than one organ transplant program at the same hospital is applying for consideration under mitigating factors.)*	
(2c) The Conditions of Participation (CoPs) that the program failed to meet: §42 CFR 482.80 – Data submission, clinical experience and/or outcome requirements for initial approval of transplant programs; or §42 CFR 482.82 – Data submission, clinical experience and/or outcome requirements for re-approval of transplant programs	
(2d) A brief summary of the mitigating factors requested (template provided in Appendix 3.2).	
(2e) Rationale/Supporting Evidence: The rationale for requesting approval of a given program based on mitigating factors and a description of the evidence the program believes supports its request for mitigating factors.	

Description	Application Page Number(s)
(2f) Internal Program Improvements: The extent to which the transplant program has identified, tracked, and analyzed the root causes of non-compliance. Additionally, the program must submit the specific findings of its analysis and the specific changes made by the program to address the non-compliance.	
(3) As attachments to the application summary, include copies of documentation relevant to the application process: (3a) Copy of the CMS' **written notification of CoP deficiency.**	
(3b) Copy of the **Letter of Intent** to request mitigating factors, which was due 10 calendar days after the CMS' notice of CoP deficiency.	
(3c) Copy of **Form CMS-2567** with the survey results (also with the program's Plan of Correction, if available).	
Section B – Data	
(4) Outcomes Data (if applicable): If the program is requesting approval based on mitigating factors for non-compliance with outcomes, provide the following information in 6-month intervals-starting from the most recent SRTR period under consideration to present date, as available: (4a) Total number of all patients that received transplants for that organ type; (4b) Total number of patient deaths at 1-month and 1-year post-transplant; (4c) Total number of organs transplanted (includes any re-transplants); and (4d) Total number of graft failures at 1-month and 1-year post-transplant (of the grafts transplanted in that 6-month period).	
Section C - QAPI Materials	
(5) **Quality Assessment and Performance Improvement (QAPI) information** specific to the organ transplant program for which approval of mitigating factors is requested, including, but not limited to: (5a) QAPI Plan.	
(5b) Quality dashboard and other performance indicators with definitions.	
(5c) QAPI Program meeting minutes from the most recent four meetings and attendance rosters from the most recent 12 months.	

Description	Application Page Number(s)
Section D: Root Cause Analysis Reports	
(6) **Root Cause Analysis of patient deaths and graft failures**, The required content for mitigating applications involving substandard patient or graft survival includes, but is not limited to "Root Cause Analysis for patient deaths and graft failures, including factors the program has identified as likely causal or contributing factors for patient deaths and graft failures" and "Program improvements that have been implemented and improvements that are planned."(42 CFR § 488.61(f)(2)(v)(A) and (B). For purposes of the Root Cause Analysis component of a mitigating factors application, CMS will accept thorough analyses that used a methodology other than "Root Cause Analysis" if the documentation demonstrates that they were conducted consistent with the above guidelines. Root Cause Analysis report must include the analyses of patient deaths and graft failures beginning from the most recent SRTR period under consideration to current time.	
Section E - Additional Information	
(7) **Pertinent policies, protocols, procedures, and practices** specific to the organ transplant program for which approval of mitigating factors is requested, including, as applicable: (7a) Patient and donor/organ selection criteria and evaluation protocols, including methods for pre-transplant patient evaluation by cardiologists, hematologists, nephrologists, and psychiatrists or psychologists, etc. (7b) Waitlist management protocols and practices. (7c) Pre-operative management protocols and practices. (7d) Organ procurement protocols and practices. (7e) Intraoperative surgical protocols and practices. (7f) Immunosuppression/infection prophylaxis protocols. (7g) Post-transplant monitoring and management protocols and practices.	
(8) Information about the program's personnel, including, but not limited to: (9a) **Key personnel list** with the names and roles of key personnel of the transplant program. (9b) **Organizational chart** with full-time equivalent levels, roles, and structure for reporting to hospital leadership.	
(9) **Program improvements or innovations** that have been implemented and planned improvements in response to the root cause analysis of poor outcomes, or as part of a performance improvement project.	
(10) **Results/summary of any external review of the program** in the past 3 years, including any recommendations that were made and follow-up actions in response to the recommendations.	
(11) **Optional** - Any **other documentation** to support the mitigating factors requested. *(It is not required to submit other documentation; any other documentation submitted must be relevant to your program's non-compliance with the CoPs and the mitigating factors you have requested.)*	

Appendix 3.2: Summary of Mitigating Factors Requested

Hospital Name:	
OPTN Code/ Transplant CCN #:	
Organ/ Program Type:	
Address, City & State:	
Program Contact: Name, phone number, and e-mail:	
Date Prepared:	

Summarize the mitigating factors requested on this template and provide it along with the narrative and documentation evidence in section A-2d of the program application summary section of the mitigating factors application. Refer to Appendix 2 for the mitigating factors that may be considered. Summarize in the "Description" column the program's specific issues and activities that relate to the associated mitigating factor(s) being requested.

Category	Subcategory	Summary Description of Related Program Issues/Activities

Appendix 4
Transplant SIA Templates and Guides

If a program enters into a Systems Improvement Agreement (SIA), the templates and guides described below and shown on the following pages should be used under the terms of the SIA.

Appendix 4.1: Transplant SIA Independent Peer Review Team Assessment Guide

- The purpose of this document is to guide the program's development of a plan for the comprehensive onsite assessment of the program by an Independent Peer Review Team (IPRT).
- The plan must detail the composition of the IPRT, scope of the team's program assessment, methodologies, materials, assignments, and agendas.

Appendix 4.2: Transplant SIA Staffing Analysis Guide

- The purpose of this guide is to assist the program's development of the Staffing Analysis Plan and Staffing Analysis Report & Table.
- This document is a two-part report detailing program resources, alignment of job descriptions with activities and personnel, and level of effort in terms of sustainable quality improvement.

Appendix 4.3: Transplant SIA Action Plan for Quality Improvement Guide

- The purpose of this guide is to assist the program in developing a highly detailed plan that adequately responds to the IPRT's findings and recommendations.
- The Action Plan for Quality Improvement must contain comprehensive strategic plans that address systemic issues.
- A sample Action Plan is provided following the guide.

Appendix 4.4: Transplant SIA Comparative Effectiveness of Policies and Procedures Guide

- The purpose of this document is to guide the program's development of a comprehensive analysis of select policies and protocols, comparisons to evidence- based best practices, rationalizations for the continuance of current processes, and detailed program strategies for the implementation of planned modifications.
- A sample report is provided following the guide.

Appendix 4.5: Transplant SIA Lessons Learned Teleconference Agenda Template

- The purpose of this document is to provide the template generally used by the CMS during the teleconference to gather feedback from the transplant program about its experiences with the SIA and lessons learned.

Appendix 4.6: Transplant SIA Lessons Learned Report Guide

- The purpose of this document is to provide a guide for information to include in the review report concerning experiences, challenges, and lessons learned during the SIA process.

Appendix 4.1: Transplant SIA Independent Peer Review Team Assessment Guide

Overview

The Independent Peer Review Team (IPRT) conducts a comprehensive onsite assessment to assist the program with looking beyond immediate factors and to help the program identify the underlying causes of adverse outcomes. The guide is intended to assist the program with formulating a plan for an organized and comprehensive IPRT assessment.

I. Scope

Summarize the goal and purpose of the IPRT's review, the issues that will be analyzed, as well as the estimated date for completion and submission of the IPRT's written report to the hospital. The scope of the IPRT's assessment should cover clinical, environmental, and operational aspects of the transplant program, and must meet the minimum requirements established in the SIA. The IPRT should identify the issues preventing the program from attaining and maintaining compliance and document the findings in the report. Recommendations for program adjustments to promote improved outcomes should be incorporated in the written report.

II. Composition of Independent Peer Review Team

List the names, titles, team roles, institutional affiliations, and other relevant qualifications of the proposed individuals responsible for conducting the assessment and preparing the written report. At a minimum, the team must consist of a Transplant Surgeon, Physician, Administrator, Coordinator, Social Worker, and Quality Assessment and Performance Improvement Coordinator with expertise in the organ program type under review. Except for the transplant surgeon, CMS may permit substitution of one type of expertise for another individual who has expertise particularly needed for the type of challenges experienced by the program, such as substitution of an infection control specialist in lieu of, or in addition to, a social worker. An IPRT member must not have been employed at or affiliated with the facility in the past three years. All prior relationships, including consulting relationships, must be disclosed to the CMS. The proposed IPRT members must not have a conflict of interest (COI) with the program, must fulfill the roles required in the SIA, and must be approved by the CMS prior to engaging in the assessment.

Sample IPRT Chart*

Name	Title	Position on IPRT	Institution
John Doe, MD	Surgical Director	Transplant Surgeon	Constitution University Transplant Center
Jane Doe, DO	Physician	Transplant Physician	College of Science and Independent Research Transplant Institute
John Garcia, APRN, MSN, CCTC, FAAN	Nurse Practitioner	QAPI Consultant	University of Natural History and Medicine
Jane Johnson, RN, BS, CCTC, CCTN	Nurse Practitioner	Transplant Coordinator	College of Eureka Transplant Program
Jane Smith, PhD, RN	Administrator	Transplant Administrator	Transplant University of America
John Johnson, MSW, LISW, CCTSW	Social Worker	Transplant Social Worker	American College of Medicine and Infectious Disease

**This table should be customized according to program needs.*

- **Methodology**

  Note important dates and discuss the processes and investigative methods that will be used to conduct the assessment. Investigative methods should include all or most of the following: observations, evaluations, one-on-one meetings with patients and staff to facilitate open communication, medical record reviews, and other document reviews. Include a list of documents and other materials that will be provided to the IPRT for its review and analysis. Preliminary off-site review of documents should be completed to maximize the use of time on- site. An agenda should also be incorporated into this section.

  Note: Task Assignment Table, Materials Checklist, and Agenda samples are provided below for reference.

  TOOLS FOR THE PROGRAM ASSESSMENT PLAN

  Task Assignment Table

  Summarize the tasks to be completed for the assessment. At a minimum, include all the topics for review provided in Attachment A of the SIA and the person responsible for completing the task.

Task Assignment

Task	Person Responsible	Date
1. Review clinical capabilities of the transplant team and the transplant outcomes as these may relate to the team's composition, staffing level capabilities, including any patterns related to team composition and follow-up care.		
2. Evaluate the transplant program's outcomes and the changes made transplant program pursuant to correcting or improving the outcomes meet the CMS regulatory compliance.		
3. Assess the program's causal analysis of each death/graft failure that during the specified timeframe, including:		
a. Factors associated with these deaths/graft failures as well as an analysis of other adverse events relevant to the Root Cause Analysis (RCA) of poor graft or patient survival outcomes.		
b. Program's own analysis of the root causes of the deaths/graft failures to evaluate the thoroughness and comprehensiveness of the review and the identification of all systemic factors.		
c. Any trends or patterns in the factors associated with the deaths/graft failures		
d. Work done in any areas that were identified as needing corrective action by any external entities as well as self-reports of needed changes, and the extent to which the changes have been implemented		
4. Analysis of the adequacy of the QAPI program		
5. Examine through one-on-one interview, observation, and record and policy review pre-, peri- and post-transplant activities in the following areas:		
a. Staffing levels and training		
b. Performance improvement activities		
c. Patient selection criteria		
d. Donor selection criteria		

e. Waitlist management		
f. Surgical protocols		
g. Multidisciplinary team care and performance		
h. Program's policies and procedures		
i. Post-transplant follow-up		
j. Coordination of patient care and post-transplant management		

**This table should be customized according to the program's needs.*

IPRT Program Assessment Agenda

Include a copy of the agenda in the Methodology section. The Agenda should specify the date, time, location, purpose, methodology/process, and attendee(s) for each activity.

Date							
	8:30 – 9:00AM	Smith Complex Tx Conf. Rm	IPRT Call with the CMS	Understand the CMS' expectations of IPRT	Teleconference	All Members	N/A
	9:00 – 9:30AM	Hoffman Bldg. Rm. 400	Introduction	Introduce IPRT; Review Agenda	Presentation; Q&A	All Members	All Staff
	9:45AM – 12:00PM	Keiser Bldg. Board Rm 1	Tour	Tour of the unit for familiarity and observations	Observation	All Members	John Doe, Administrator
	9:00 AM– 12:00 PM	Smith Complex Conf. Rm 3	Review Program's Clinical Protocols	Conversation with clinical staff; Identify potential improvements and gaps	One-on-One Interview	Dr. Cristina Smith; Marcus Johnson, RN	Transplant Clinical Staff
	12:15 – 2:00 PM	Smith Complex Tx Conf. Rm	Document Review/ Working Lunch	Identify potential improvements and gaps; Internal discussion	Document Review	Dr. Peter Robertson; J. Diaz, PhD	N/A

Materials Checklist

Include a list of materials that will be made available to the IPRT in the Methodology section. Preliminary off-site review of documents should be completed to maximize the use of time on- site. The Materials Checklist provides a list of suggested items that should be shared with the IPRT.

Materials Checklist
Organizational Charts
Peer Review Plan
Systems Improvement Agreement
Listing of Hospital Leadership and Transplant Program Personnel
Scientific Registry of Transplant Recipients (SRTR) Report
Electronic access to archived reports and hospital and clinical records
Transplant Policies and Procedures
Clinical Protocols
Quality Assessment and Performance Improvement (QAPI) Reports and Plans
Listing of Programmatic Changes
Organ Procurement and Transplantation Network (OPTN) Performance Improvement Plan
Inventory of Program Protocols
Transplant Survival Outcomes Analysis and Reports
Past submissions to the CMS related to Application for Consideration of Mitigating Factors
Correspondence with Regulatory Bodies
Documents requested by IPRT before and during review

**These examples should be customized according to program needs*

Appendix 4.2: Transplant SIA Staffing Analysis Guide

Overview

The purpose of the Staffing Analysis is to determine whether the program has adequate resources, ensure job descriptions match activities performed by personnel, and verify that the level of effort for all personnel is sufficient to sustain quality improvements. When completing a Staffing Analysis, evaluate the personnel involved in the transplant program, as well as the activities performed by the personnel. The Staffing Analysis Report should include any staffing recommendations provided by the Independent Peer Review Team (IPRT).

Staffing Analysis

Document the role, job description, actual activities performed, credentials, and level of effort pre- and post-SIA for each individual included in the Staffing Analysis. Indicate the method used to calculate full-time equivalency (FTE) hours for the Level of Effort sections. Include any relevant trainings, conferences, forums, certifications, and experiences for each personnel in the Credentials/ Ongoing Education section. Use multiple methods such as questionnaires, observations, and one-on-one interviews to complete the Staffing Analysis.

Example:

Personnel	Role	Job Description	Activities Performed	Credentials/ Ongoing Education	Pre-SIA Level of Effort*	Post-SIA Level of Effort*
John Doe, MD, Director of Transplant Nephrology	Transplant Nephrologist	Lead physician of unit that provides care for patients with kidney disease preparing to undergo a transplant.	Actively involved in patient selection, updating clinical protocols, and staff trainings.	Board Certified with over 15 years of experience in transplant nephrology	0.7 FTE dedicated to nephrology and kidney transplant	0.9 FTE dedicated to nephrology and kidney transplant and now oversees operating room procedures (+0.2 FTE)
Jane Smith, MD, Director of Nephrology	Nephrologist	Lead physician of unit that provides care for patients with kidney disease.	Team evaluation, policies and procedures, morbidity & mortality evaluation	Board Certified with 10 years of experience in nephrology	0.8 FTE dedicated to nephrology and kidney transplant	0.6 FTE provides minimal oversight in surgical procedures (-0.2 FTE)
Joe Doe, MD	Kidney Transplant Surgeon	Performs transplant surgery and organ recovery, assesses donor organ offers	Reviewing and revising selection criteria and QAPI processes	Board Certified, active on UNOS committees	1.0 FTE Surgical Director	1.0 FTE Surgical Director (no change)
John Smith, PhD.	Transplant Administrator	Responsible for management of the kidney transplant program	Regulatory compliance reporting to include the UNOS, DoH, the CMS, and the Joint Commission	Doctorate degree in Health Administration with 15 years of experience in transplant administration	0.5 FTE	0.9 FTE will have more involvement in QAPI and pre- and post-transplant procedures (+0.4 FTE)

**Indicate method for calculating FTE*

Independent Peer Review Team (IPRT) Recommendations

Include IPRT staffing recommendations for the program and the status of those recommendations.

Staff Program Activities

For each staff position in the transplant program, use the table below to document assigned activities and responsibilities. Program activities included in the table may change.

Example: Program Activity or Responsibility

	Staff Trainings	Patient Selection	Policies & Procedures	Waiting List Review	QAPI	Team Evaluation	Pre-Transplant Care	Post-Transplant Care	Clinical & Surgical Protocols	Morbidity & Mortality Evaluation
Transplant Nephrologist		✓	✓	✓	✓	✓	✓	✓	✓	✓
Transplant Surgeon		✓	✓	✓	✓		✓		✓	✓
Transplant Administrator	✓		✓	✓	✓	✓			✓	✓
PA/APRN	✓				✓		✓	✓	✓	✓
Transplant Social Worker	✓			✓	✓		✓	✓		✓

Staffing Questionnaire

Use a staffing questionnaire to allow transplant program personnel to express their experiences with the program. Ask open-ended questions that focus on the roles and responsibilities of personnel at the transplant program.

Suggested Staffing Questions

- Do you feel that orientation adequately prepared you for your new role?
- Do you feel that you have enough resources and support to effectively perform your duties?
- Are there activities that you perform that are not listed in your job description?
- Describe any activities you feel should have required training.
- Describe any activities that have required training that you feel should have scheduled skills updates.

- Are there any activities for which you feel training occurs frequently?
- Which activities do you perform that you feel may benefit from additional staffing?
- Are there activities that you feel contribute to patient delays, rework, retesting, or inconvenience?

What are your current credentials and licensure?

Appendix 4.3: Transplant SIA Action Plan for Quality Improvement Guide

Overview

The Action Plan for Quality Improvement (Action Plan) is an opportunity for the program to respond to the findings of the program assessment and recommendations provided by the Independent Peer Review Team (IPRT) with a detailed strategy to address systemic issues. The purpose of this guide is to assist in the development of a comprehensive Action Plan that includes:

- Brief introduction of the significant issues;
- Action(s) recommended by the IPRT;
- Strategy developed by the program to mitigate or eliminate the issue(s);
- Implementation strategy for each action;
- Mechanism for monitoring the progress of implementation; and
- Metrics for continuous monitoring of the outcomes of the action(s).

The Action Plan should be as detailed as possible to link the action to the issue and to allow outcomes to be associated with the actions implemented. A sample Action Plan for Quality Improvement is provided at the end of this document.

Identify the Issue and the Root Cause

Use the RCAs as the primary source of information to describe the significant issues that contributed to non-compliant outcomes along with the root cause(s) identified by the IPRT. Assign a category to each finding, such as Communication, Staffing, and QAPI, to help classify major areas for program improvement. Include the transplant phase during which the issue predominantly occurs.

Provide a summary of other details that may be necessary to demonstrate a thorough review of the issues and the associated root causes.

Detail the Action Plan

Describe the recommended action for each issue that was provided by the IPRT in the written report. Provide the program's Action Plan to address the issue. The Action Plan must map back to the issue and the root cause(s) that was identified. Include a description

of the rationale behind each proposed change and the strategy for implementing each action. Assign staff and other resources necessary to implement the action item.

Track Progress and Outcomes

Monitor the progress of the Action Plan implementation and the outcomes of each program change. Assign process and outcome measures to each action item as appropriate to track the effects of the changes on patient outcomes and to identify a goal for the program to reach once the issue has been fully addressed. For each action item, track the target start and end dates and the actual start and end dates to monitor progress. If implementation of any action item is significantly behind schedule, must be cancelled, has not met its target date, or has been significantly modified, provide the reason in a comments or notes section.

Sample Action Plan for Quality Improvement

Root Case Category: Communication

Phase of Transplant	Issue and Root Cause Description	Recommended Action	Action Plan	Team Members Required	Process/Outcome Measure	Target Start and End Dates	Start Date	Status	Progress	Completion Date	Comments
Pre-transplant	Issues of hemodynamic instability preventable with better coordination with Anesthesia.	Include Anesthesiology in multidisciplinary selection committee.	Add Transplant Anesthesiologist to selection committee.	John Johnson	Intra-operative blood use	2/1/2008; 5/25/2008	2/5/2008	**In Development**	10%		
Peri-operative	Issues of hemodynamic instability preventable with better OR communication between Surgery and Anesthesia.	Improve visibility of OR monitors. Consider hiring additional 1.0 FTE Anesthesiologist.	Move OR monitors for better visibility. Revise call schedule to improve coverage by more experienced Anesthesiologists.	John Smith	Intra-operative blood use	2/1/2008; 3/3/2008	2/1/2008	**In Progress**	20%		

Post-transplant	Medication non-compliance preventable with additional coordination with Social Worker.	Include visit to Social Worker during post-transplant clinic.	Increased follow-up schedule with Social Worker from twice a month during initial 30-day post-transplant phase to once a week.	Jane Smith	Follow-up from Social Worker once a week during initial one-month post-transplant. Rate of Medication non- compliance.	12/1/2007; 1/3/2008	12/1/2007	**Completed**	100%	1/3/2008	

Root Case Category: Staffing

Phase of Transplant	Issue and Root Cause Description	Recommended Action	Action Plan	Team Members Required	Process/Outcome Measure	Target Start and End Dates	Start Date	Status	Progress	Completion Date	Comments
Pre-transplant	Medication non-compliance preventable with additional psychosocial workup. Need additional Social Worker.	Hire a properly credentialed and qualified Social Worker.	Post hiring criteria on recruiting web pages and actively recruit qualified personnel	Sally Thompson	Hire one qualified social worker. Rate of medication non-compliance.	1/15/2008; 3/1/2008	1/16/2008	**In Progress**	50% (Hired; on-boarding to occur on 3/15/2008)		
Pre-transplant	Potential for organ turndowns due to insufficient on-call Tx Surgeons.	Hire two additional full-time Transplant Surgeons. Revise call schedule.	Recruit and hire two FTE Transplant Surgeons	Sally Thompson	Two additional FTE Tx Surgeons on staff. Organ turndown rate.	11/1/2007; 2/20/2008	10/31/2007	**Completed**	100%	2/25/2008	

Appendix 4.4: Transplant SIA Comparative Effectiveness of Policies and Procedures Guide

Introduction

The Comparative Effectiveness Analysis of Policies and Protocols is an opportunity to identify and review select policies or protocols, compare them to industry best practices, and detail the rationale for modifying or retaining current practices. The purpose of the Comparative Effectiveness Analysis of Policies and Protocols Guide is to assist in the comprehensive analysis of selected policies and protocols including:

- Identification of policies and procedures for review and rationale for selection;
- Analysis of policies and protocols, including discussion of any internal analyses, comparison to programs with superior outcomes, and findings from literature review;
- Discussion of planned changes and the rationale for implementing the changes;
- Implementation strategy for planned changes;
- Metrics(s) for continuous monitoring of the outcomes of the change; and
- Mechanism for monitoring the progress of change implementation.

The Comparative Effectiveness Analysis should be evidence-based and should incorporate data analyses, including subgroup analyses, to make informed decisions about any changes to policies and protocols. A sample Comparative Effectiveness Analysis of Policies and Protocols is provided below.

I. Identify Policies and Protocols for Review

Select policies and protocols for analysis that are pertinent to current quality improvement efforts at the program. The assessment prepared by the independent peer review team, recommendations from the onsite consultant, and internal analyses should be used for identifying policies and protocols for review. Indicate the transplant phase and describe the rationale for selecting the policy or protocol for further analysis. The rationale should be evidence-based and include the findings of data analysis, as appropriate.

II. Analyze the Policies and Protocols

Identify sources of information used to analyze the program's policies and protocols. Select three to five organ transplant programs with superior patient outcomes based on the Scientific Registry of Transplant Recipients (SRTR) data. Compare the program's policies and protocols to those of the external programs and describe any similarities and differences. Additionally, complete a literature review and compare current practices to industry best practices.

III. Implement Changes

After completing the analysis, propose changes that address identified areas for improvement. Describe the rationale behind each proposed change. For each proposed change, list who is responsible for the change, the progress of implementation to date, and the completion date. If no changes are planned at this time, provide a rationale for maintaining current practices.

IV. Monitor Outcomes

For each proposed change, list the current indicator(s) at the facility, benchmark the indicators against industry best practices, identify the anticipated impact of the changes being made, and provide the quality monitoring strategy.

SAMPLE COMPARATIVE EFFECTIVENESS ANALYSIS OF POLICIES AND PROTOCOLS

Policies & Protocols Identification/Analysis **Change Implementation** **Outcomes**

Monitoring

Policy for Review/ Rationale	Similarities to Programs with Superior Outcomes	Differences to Programs with Superior Outcomes	Literature Review Findings	Changes Proposed/ Rationale	Responsible Party	Status	Completion Date	Benchmark of Initial Measures	Anticipated Impact of Revised Policy	Quality Monitoring Strategy	M
Psychosocial Evaluation: RCA identified that 30% of patient deaths post-transplant were attributed to non-compliance.	1. ABC University also requires annual psychosocial evaluations for waitlist patients. 2. DEF Medical Center also uses the PACT scoring tool. 3. Nephrology University also employs a full-time Social Worker	1. ABC University includes a Social Worker on multi-disciplinary selection committee. 2. DEF Medical Center conducts psychosocial evaluations twice yearly. 3. Nephrology University has no differences.	Programs with social services professionals as a part of their multi-disciplinary team have a better chance of including a psychosocial evaluation.	Hire a new Social Worker to include on the selection committee in order to increase occurrence of psychosocial evaluations.	John Johnson, Social Worker	**In Progress**: On 6/20/2012 received administrative approval to hire new Social Worker.		30% of patients are currently receiving a psychosocial evaluation. 100% of patients at industry best practice programs receive evaluation. 30% of patient deaths are due to non-compliance.	Decrease in patient deaths related to non-compliance	Monitor patient compliance	As pati eva of 20% dea
Immunosuppression: RCA identified an unacceptably high number of infectious disease related deaths.	1. ABC University uses Medication A regimen for immune-suppression. 2. DEF Medical Center has similar steroid-taper times.	1. ABC University has monthly biopsies extending one year post-transplant. 2. DEF Medical Center includes Infectious Disease Specialist on multi-disciplinary selection committee.	Data trends show that sepsis rates are lower for patients on Medication A based regimens than those on Medication B-based regimens.	Change Medication B-based immune-suppression regimen to Medication A-based regimen in order to decrease sepsis rates and prevent deaths or graft failures due to infectious disease complications.	Jake Jacobson, Medical Director	**In Progress**; Transition to new immune-suppression regimen started on 5/20/2012		20% of deaths are related to infectious diseases. Less than 10% of deaths are related to infectious diseases at programs with superior outcomes.	50% reduction in number of infections, 80% reduction in number of graft failures due to ID, 90% reduction in number of deaths due to ID, no significant increases in graft rejection.	Review patient charts.	The dea fail con si

Appendix 4.5: Transplant SIA Lessons Learned Teleconference Agenda Template

Transplant Program Name:	
Location:	
SIA Period:	
Determination:	

CALL-IN DETAILS

Date & Time:	
Call-in Number & Access Code:	

ATTENDEES

Transplant Program, the CMS, and CMS consultants

PURPOSE

- To discuss the provider's experiences with the Systems Improvement Agreement (SIA) and to share lessons learned.
- To discuss the SIA process and receive feedback on potential improvements to the process.

DISCUSSION TOPICS

Implementing the SIA

1. What were the key issues at the program that led to non-compliance?
2. What were the difficulties in implementing the SIA?

During the SIA

1. What factors did you consider when selecting the consultants?
2. Please describe your experience working with the consultants. When were the consultants most helpful? Were there any challenges?
3. Describe your experiences with the following SIA provisions, if applicable:
    - Patient Transfer Assistance
    - Engaging the Onsite Transplant Consultant
    - Conducting the Independent Peer Review Team Assessment
    - Developing the Action Plan
    - Quality Assessment and Performance Improvement (QAPI)
    - Clinical and Administrative Analyses
        - Comparative Effectiveness Analyses
        - Staffing Analysis
        - Scientific Registry of Transplant Recipients (SRTR) Data Analysis
    - Ongoing updates to the CMS and writing reports

- Other provisions not mentioned above

4. What resources were necessary to implement and monitor the SIA? What was the estimated level of effort?
5. What was the level of effort for the CMS reporting requirements (e.g. deaths and graft failures reporting, quarterly patient outcomes updates, selection criteria changes, monthly calls, final report of challenges and lessons learned)?
6. Were there new tools or processes that were implemented because of the SIA?

7. What changes were made to the Quality Assessment and Performance Improvement program during the SIA?

8. Did members of the media approach your facility with questions regarding the SIA? Were there any challenges related to this?

Completing the SIA

1. Which SIA provision(s) were the most helpful in your facility making significant quality improvements? Which were the least helpful?
2. Has anything changed since the completion of the SIA that you would like to share with us?
3. What feedback do you have for the CMS to improve the SIA process?

Appendix 4.6: Transplant SIA Lessons Learned Report Guide

Overview
The Lessons Learned Report, delivered at the completion of a Systems Improvement Agreement (SIA), serves as a review of experiences, challenges encountered, and lessons learned during the SIA process.

Introduction
Provide background information about the facility including mitigating factors at the program and the circumstances that led to a SIA.

Issues Identified and Changes Implemented
Describe the most significant issues identified and the changes implemented at the facility before and during the SIA. For each issue and resulting change, describe the following:

- Timeline of issue identification and change implementation
- Personnel involved
- Resources required
- Level of effort
- Method(s) for monitoring changes
- Measurable outcomes achieved/anticipated

Lessons Learned
Describe challenges encountered and lessons learned as a result of quality improvements implemented during the SIA. Discuss sustainable systemic improvements resulting from the SIA process, including the following:

- Leadership and Culture
- Resource Allocation and Institutional Commitment
- Communication
- Multidisciplinary Approach to Care
- Transplant Specific Policies and Protocols
- Quality Assessment and Performance Improvement
- Data Management and Analysis

Conclusion
Provide a brief summary of the program's overall experience with the SIA and quality improvement efforts, including interaction with the Centers for Medicare & Medicaid Services.

Summary of Lessons Learned

Summarize the lessons learned in the table below.

Issue Identified (include date)	Changes Implemented (include date)	Measurable Outcomes Achieved/Anticipated	Lessons Learned