STATE OF MICHIGAN

Department of Licensing and Regulatory Affairs
Bureau of Survey and Certification

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 transplant program in the preparation of a mitigating factors application. The completed checklist must be submitted with the application. All of the information described on this checklist is required as part of the mitigating factors application review.

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 organ transplant program's 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 the organ transplant program for which approval of mitigating factors is being 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 outcome requirements for initial approval of transplant centers; or §42 CFR 482.82 - Data submission, clinical experience and outcome requirements for re-approval of transplant centers	
(2d) A brief summary of the mitigating factors requested for consideration (template provided in Appendix 3.2).	

(2e) Rationale/Supporting Evidence: The rationale for requesting approval of a given organ transplant program based on mitigating factors and a description of the evidence the program believes supports its request for mitigating factors.	
(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 the following documentation relevant to the application process: (3a) Copy of the CMS **written notification of CoP deficiency.**	
(3b) Copy of the **Letter of Intent** sent to CMS 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 I-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.	
Section D - Root Cause Analysis Reports	

(6) **Root Cause Analysis of patient deaths and graft failures:** Root Cause Analysis report that includes the analyses of patient deaths and graft failures beginning from the most recent SRTR period under consideration to current. 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 or improvements that are planned."(42 CFR §§ 488.6l(f)(2)(v)(A) and (B). Note: 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 following guidelines: • A description of the key facts of the event in enough detail so that one can clearly understand the facts and chronology of what occurred, the severity of the event, and how the transplant candidate/recipient or potential LD/LD was affected. • A review of whether or not similar events have occurred in the past. • Gathering all of the information needed to identify factors throughout the system that may have caused or contributed to the outcome, directly or indirectly. • Analyzing the information for actual and potential vulnerabilities and opportunities to reduce risks and improve care. • Using the results of the analysis to design improvement actions addressing the factors that caused or contributed to the event's occurrence, including systems factors and processes. • Specifying the plan for implementing, evaluating and monitoring improvement actions (timeframes, responsible parties, measurement strategy to assess effectiveness, etc.).	
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 review you have requested.)*	

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**

Return form to: LARA-BSCSupport@Michigan.gov