

---

# CMS Manual System

## Pub. 100-07 State Operations Provider Certification

Department of Health &  
Human Services (DHHS)  
Centers for Medicare &  
Medicaid Services (CMS)

---

Transmittal 190

Date: June 14, 2019

---

**SUBJECT: Updates to the State Operations Manual (SOM) Chapters 2, 3 and 9 to add instructions for Organ Transplant Programs.**

**I. SUMMARY OF CHANGES:** There are new sections to the SOM outlining the instructions for Organ Transplant Programs in Chapter 2, sections §2060 through §2063, Chapter 3, section §3012.3, and Chapter 9 - Exhibits providing a template options letter for when a transplant program is inactive at 12 months.

**NEW/REVISED MATERIAL - EFFECTIVE DATE:** June 14, 2019

**IMPLEMENTATION DATE:** June 14, 2019

*Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.*

**II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)  
(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)**

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	2/Table of Contents
N	2/2060/Organ Transplant Programs
N	2/2060B/Definitions
N	2/2060C/Regulatory Background
N	2/2061/Request for Medicare Approval of an Organ Transplant Program
N	2/2062/Survey and Approval Procedures for Organ Transplant Programs
N	2/2062B/Types of Surveys and Related Guidance
N	2/2062C/ Determining Level of Deficiency for Clinical Experience (Volume) and Outcome Requirements Standards:
N	2/2062D/Post-Survey Activities
N	2/2062E/Transmission of Program Approval Information
N	2/2062F/Mitigating Factors
N	2/2063/Relationship Between the Transplant CoPs and Hospital CoPs
R	3/Table of Contents
N	3/3012.3/Termination of Organ Transplant Programs
R	9/Table of Contents
N	9/Exhibits/357-Options letter for transplant program inactive at 12 months

**III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.**

**IV. ATTACHMENTS:**

	<b>Business Requirements</b>
<b>X</b>	<b>Manual Instruction</b>
	<b>Confidential Requirements</b>
	<b>One-Time Notification</b>
	<b>Recurring Update Notification</b>

**\*Unless otherwise specified, the effective date is the date of service.**

# State Operations Manual

## Chapter 2 - The Certification Process

Table of Contents  
*(Rev. 190, Issued:06-14-19)*

### Transmittals for Chapter 2

#### *Organ Transplant Programs*

*2060 - Organ Transplant Programs*

*2060B – Definitions*

*2060C – Regulatory Background*

*2061 – Request for Medicare Approval of an Organ Transplant Program*

*2062 – Survey and Approval Procedures for Organ Transplant Programs*

*2062B – Types of Surveys and Related Guidance*

*2062C – Determining Level of Deficiency for Clinical Experience (Volume) and Outcome Requirements Standards:*

*2062D – Post-Survey Activities*

*2062E – Transmission of Program Approval Information*

*2062F – Mitigating Factors*

*2063 – Relationship Between the Transplant CoPs and Hospital CoPs*

## ***Organ Transplant Programs***

### ***2060 - Organ Transplant Programs***

***(Rev. 190, Issued:06-14-19, Effective: 06-14-19, Implementation: 06-14-19)***

#### ***2060A – Citations***

*The Conditions of Participation (CoPs) for Transplant Centers were established under several statutory authorities. Section 1102 of the Social Security Act (the Act) authorizes the Secretary to publish rules and regulations “necessary for the efficient administration of the functions” with which the Secretary is charged under the Act. Section 1871(a) of the Act authorizes the Secretary to “prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this title.” Section 1881(b)(1) of the Act contains specific authority for prescribing the health and safety requirements for facilities, including renal transplant centers, that furnish end stage renal disease (ESRD) care to beneficiaries. Section 1861(e)(9) of the Act authorizes developing standards necessary for the health and safety of individuals furnished services in hospitals. Organ transplant programs are required to be in compliance with the federal requirements set forth in the Medicare CoPs in order to be eligible to receive Medicare payment. In addition to meeting the CoPs for Transplant Centers in 42 CFR Part 482, Subpart E, transplant programs must also meet the Hospital CoPs specified in §§482.1 through 482.57.*

#### ***2060B – DEFINITIONS***

***(Rev. 190, Issued:06-14-19, Effective: 06-14-19, Implementation: 06-14-19)***

##### ***2060B-1 Organ Procurement and Transplantation Network (OPTN)***

*The OPTN is a public-private partnership that links all professionals involved in the donation and transplantation system. The OPTN operates the national network for organ procurement and allocation and works to promote organ donation. The OPTN was established by the National Organ Transplant Act of 1984 and is operated by United Network for Organ Sharing (UNOS) under a contract from the Health Resources and Services Administration (HRSA) in accordance with section 372 of the Public Health Service (PHS) Act. Through its policies, the OPTN works to increase the number of transplants, provide equity in access to transplants, improve outcomes for waitlisted patients, living donors and transplant recipients, and promote living donor and transplant recipient safety.*

##### ***2060B-2 Scientific Registry of Transplant Recipients (SRTR)***

*The SRTR, founded in 1987, is a national database of transplant statistics that provides analytic support for the ongoing evaluation of the scientific and clinical status of solid organ transplantation in the United States. It was established pursuant to section 373 of the PHS Act.*

**2060C - Regulatory Background**  
(Rev. 190, Issued:06-14-19, Effective: 06-14-19, Implementation: 06-14-19)

*The Conditions of Participation for transplant programs were published in the Federal Register on March 30, 2007 (72 FR 15198) and became effective 90 days after publication on June 28, 2007.*

**2061 – Request for Medicare Approval of an Organ Transplant Program**  
(Rev. 190, Issued:06-14-19, Effective: 06-14-19, Implementation: 06-14-19)

*Effective January 1, 2019, transplant programs seeking to participate in the Medicare program must submit a request for Medicare approval to the applicable State Survey Agency and not the CMS RO. The SA will provide a packet of information to the applicant including a list of documents that must be submitted to the SA.*

*The hospital in which the transplant center is located must submit a revised CMS-855A to its Medicare Administrative Contractor (MAC) to indicate the addition of a service.*

**2061A Programs Serving both Adult and Pediatric Populations**

*A transplant program can apply for and be approved for both an adult (age 18 and over) and a pediatric (under age 18) transplant program for the same organ type. They can apply to be approved separately, but are not required to do so.*

*If a transplant program is seeking separate approval of its adult and pediatric programs, the programs will be surveyed separately. If a program seeks a single approval for both age groups, the program must apply for the primary age group that it serves. That is, a program that provides more than 50 percent of its transplants in a 12-month period to pediatric patients must apply as a pediatric program. A program that provides more than 50 percent of its transplants in a 12-month period to adults must apply as an adult program.*

**2061B Organ Procurement and Transplantation Network Membership**

*Membership in the OPTN by the transplant hospital in which the transplant program is located is a requirement for Medicare approval.*

**2062 - Survey and Approval Procedures for Organ Transplant Programs**  
(Rev. 190, Issued:06-14-19, Effective: 06-14-19, Implementation: 06-14-19)

**2062A - The Transplant Program Quarterly Report (TPQR)**

*The TPQR is a pre-survey report generated by CMS. It conveys information from transplant program data received from the SRTR and the OPTN. The TPQR includes:*

- *Types of transplant programs;*
- *Program data including data submission, clinical experience (the number of transplants performed) and program outcomes for patient and graft survival.*

*During pre-survey, the survey team reviews the TPQR to determine the number of surveyors that will be indicated based upon the number of programs that will be reviewed. The team also identifies any non-compliance with the requirements of §482.80 and §482.82. Any non-compliance identified during the pre-survey will be communicated to the applicable program at the entrance conference of the survey. There is no additional survey activity required regarding the TPQR.*

*During the process of the transplant program survey, the surveyors review compliance with both the transplant program and general hospital regulations. If a deficiency with the hospital requirements is identified in the hospital in which the transplant program is located and that hospital is a deemed provider, the surveyor, (or their management) must contact the applicable CMS Regional Office for approval to investigate and cite the deficiency on a hospital survey report.*

## ***2062B Types of Surveys and Related Guidance***

***(Rev. 190, Issued:06-14-19, Effective: 06-14-19, Implementation: 06-14-19)***

### ***2062B.1 Initial Survey for Medicare Approval***

*Once the MAC notifies the SA/RO of its approval of the revised CMS-855A, a survey may be scheduled. Initial surveys are unannounced. If the applicant transplant program is found to be in compliance with the CoPs, it is assigned a CCN. The program will not be issued a separate provider agreement. Once transplant program approval is completed, the RO will forward a form CMS-2007 (Provider Tie-In Notice) to the MAC. In order for CMS to make a compliance determination with §482.80, the applicant must have submitted sufficient data to the SRTR for CMS to review.*

### ***2062B.2 Re-approval Surveys***

*Once a transplant program has been approved to participate, it will be periodically re-surveyed for compliance with the CoPs. Re-approval surveys are unannounced surveys and are performed at a frequency consistent with the CMS Mission and Priority Document (MPD).*

*A transplant program may voluntarily declare an “Inactive Status” with the CMS and may remain inactive and retain its Medicare approval for a period not exceeding 12 months under §488.61(e). The program must provide immediate written notification to its SA of the anticipated inactivity period. Notification to the SA and to the potential recipients must occur prior to the beginning of the planned inactivity period. During its*

*inactivity period, the program must continue to comply with all of the Medicare CoPs and routine surveys or complaint investigations should not be delayed based on an “Inactive Status.” During survey activity either during the inactive status or following an inactive status, the surveyor should determine that:*

- The patients on the waitlist during the period of inactivity were notified of the inactive status; and*
- The notifications were accomplished in a manner consistent with §482.102(c)(3).*

### ***2062B.3 Outcomes Non-Compliance***

### ***2062B.4 Clinical Experience***

*To be considered for an initial approval, a transplant program must generally perform 10 transplants over a 12 month period. If the program performs at least eight transplants over a 12 month period, it may be approved with an acceptable plan of correction.*

*Currently approved transplant programs must perform at least 10 transplants a year over the prior three years. Programs not meeting this standard should be cited for non-compliance at the Standard level. The program may be reapproved with an acceptable plan of correction if all other CoPs are in compliance.*

### ***2062B.4 Complaint Surveys***

*See SOM, Chapter 5, for a description of the general complaint investigation process.*

*For complaint investigations of a transplant program, the scope of survey activities is generally limited to the specific transplant CoPs associated with the allegation(s). If allegations are substantiated, the scope may be expanded to review any associated CoPs.*

*Complaints related to disease transmission via an organ from a deceased donor should be communicated to the RO for their determination of the need for an OPO complaint investigation.*

*\* There must be a formal arrangement between the hospital in which the transplant program is located and any other hospital which provides living donor services for the transplant program. It is the transplant program’s responsibility to ensure that the CoPs applicable to living donors are met by the associated hospital providing the living donor services. The medical record of the living donor must confirm that all the requirements of the CoPs were met.*

**2062C - Determining Level of Deficiency for Clinical Experience (Volume) and Outcome Requirements Standards:**

**(Rev. 190, Issued:06-14-19, Effective: 06-14-19, Implementation: 06-14-19)**

*Compliance with the clinical experience (volume) standards at 42 CFR §§482.80(b) and 482.82(b) and the outcome requirements standards at 42 CFR §§482.80(c) and 482.82(c) is determined by reviewing the program's performance compared to the objective standards outlined in the regulation. The goal of this section is to achieve consistency in determining the level of a deficiency citation, (i.e., condition level, or standard level) under these CoPs. The information outlined below will be provided to surveyors in the TPQR.*

***Determining the Level of the Deficiency for Non-Compliance with Clinical Experience Requirements:***

*A program's inactivation does not create an exception to the clinical experience requirement for the entire 3 year period.*

***Initial Approval of Transplant Programs under §482.80(b):***

*If the transplant program has not performed at least eight transplants in the past 12 months, a deficiency will be cited at the condition-level deficiency and it will not be approved for Medicare participation. If the program has performed at least eight but less than 10 transplants in that time period, a deficiency should be cited at the standard-level. The program may still be approved with a standard-level citation for Clinical Experience if an acceptable plan of correction is received and the program is in compliance with all remaining CoPs. Kidney programs that have not performed at least three transplants in a 12 month period may not be surveyed for initial approval.*

***Re-approval of Transplant Programs under §482.82(b):***

*If the transplant program has performed an average of less than 10 transplants per year over the re-approval period (three years), a deficiency should be cited at the standard-level. The program may be re-approved with a standard-level citation for Clinical Experience if an acceptable plan of correction is received and the program is determined to be in compliance with all remaining CoPs.*

*The determination of condition-level non-compliance is made based upon the extent of non-compliance findings with the standards within a Condition. A finding of non-compliance for the Clinical Experience standard alone with no other non-compliance within the Condition would generally not result in condition-level non-compliance at §482.80 or §482.82.*

***Determining the Level of the Deficiency for Non-Compliance with the Outcome Requirements at 42 CFR §482.80(c) and §482.82(c)***

*Compliance with outcome measures is assessed using data from the most recent Center-Specific Report from the SRTR. Surveyors must utilize the SRTR information reported in the TPQR that is provided by the CMS CO. The SRTR outcome measures reported in the TPQR are risk-adjusted, 1-year post transplant graft and patient survival measures. The SRTR*



*reports are released every six months and CMS compares the results for the programs' outcomes to the outcome requirements at 42 CFR §482.80(c) and §482.82(c) for transplants performed over a 2.5 year window (between one year prior and 3.5 years prior to the date the report is published) and enters the compliance determination onto the TPQR. The TPQR identifies the number of center- specific SRTR reports in that timeframe that failed to meet the outcome requirements. Surveyors do not conduct the statistical analysis to determine compliance nor may the program provide any information to the surveyor on-site to change the compliance determination.*

*The following transplant program types are subject to the outcome requirements:*

- *Adult Kidney-Only (AKO)*
- *Adult Heart-Only (AHO)*
- *Adult Lung-Only (ALO)*
- *Adult Liver-Only (ALI)*
- *Pediatric Kidney-Only (PKO) (includes only 1-year graft survival)*
- *Pediatric Heart-Only (PHO)*
- *Pediatric Lung-Only (PLO)*
- *Pediatric Liver-Only (PLI)*

*The following transplant program types are not subject to the outcome requirements:*

- *Adult Pancreas- (APA)*
- *Pediatric Pancreas- (PPA)*
- *Adult Intestine/Multivisceral- (AIM)*
- *Pediatric Intestine/Multivisceral- (PIM)*

***Standard*** – *If the most recent SRTR report shows that the program did not meet outcome requirements, but none of the four outcome reports prior to the most recent one show that the program was out of compliance, a deficiency should be cited at **the standard-level**.*

***Condition*** – *If the most recent SRTR report shows that the program has not met outcome requirements in two consecutive reports and there is either unchanged or a decline in outcome data, a deficiency should be cited at the **condition-level**.*

*Every six months, CMS CO receives a list of transplant programs that exceed the outcomes thresholds for patient and graft survival. When a program is identified to be out of compliance with the measures, CMS CO will notify the provider of its non-compliance. More current SRTR data will be reviewed by CMS to determine if the program is improving.*

*At the time of the next bi-annual SRTR report, if a program continues to exceed the acceptable patient and graft survival rate, with all thresholds crossed over, more recent SRTR data will again be requested and reviewed. If the more recent data indicates that the program's outcomes are not improving, CMS will consider the program to be non-compliant at a condition level and an on-site survey may be scheduled to review/identify associated process requirement concerns.*

*Deficiencies for non-compliance with the outcome requirements, as well as any additional deficiencies identified at the time of the on-site survey, will be cited upon completion of the survey. If an on-site survey is not conducted, the program will be notified of its non-compliance with the outcome requirements by letter that includes the form CMS-2567.*

*If a transplant program is cited at a condition-level for §482.82, include the following language in the letter accompanying the CMS-2567:*

*“The prospective termination date based on noncompliance determination with 42 CFR §482.82 will be set at 210 days. This deficiency must be corrected by [Date] in order for Medicare approval to continue for the program. The program has two options for a plan of correction for §482.82:*

- 1. The program may state that it expects to be back into compliance with §482.82 within 210 days; or*
- 2. The program will apply for mitigating factors review under §488.61(f).”*

### ***2062D - Post-Survey Activities***

***(Rev. 190, Issued:06-14-19, Effective: 06-14-19, Implementation: 06-14-19)***

*- Following the survey, the surveyor will complete the following forms:*

- 1) Organ Transplant Hospital Worksheet;*
- 2) CMS-670;*
- and*
- 3) CMS-2567.*

*Once the CMS-2567 is finalized, it will be forwarded to the hospital administrator with a request for a Plan of Correction (PoC) if substantial compliance with all the requirements was not found. The SA will review and accept or not accept the PoC. In the case of a finding of Immediate Jeopardy, see Section 3010B of the SOM for a description of the special procedures to be followed.*

### ***Plan of Correction Transplant Centers***

*The PoC should include plans for completion of corrective actions at a maximum of 90 days.*

*The PoC for all deficiency citations, with the exception of §482.80 or §482.82, must indicate projected correction within 90 days from the receipt of the notification of non-compliance. The plan of correction for §482.80 or §482.82 must indicate whether the provider intends to submit mitigating factors to CMS. Prior to the 90<sup>th</sup> day follow-up by the SA should occur. If the provider has not been determined to have achieved compliance with the CoPs (other than §482.80 or §482.82), the program approval must be terminated.*

## ***2062E - Transmission of Program Approval Information***

***(Rev. 190, Issued:06-14-19, Effective: 06-14-19, Implementation: 06-14-19)***

*The RO will assign one CMS Certification Number (CCN), within the 9800 series, to all transplant programs operating within a single hospital. The Medicare approval date for the individual program will be determined as follows:*

- When there are no deficiencies cited, the approval date is the last date of the survey.*
- When there are standard-level deficiencies cited, the approval date is the date on which an acceptable Plan of Correction was received by the SA.*
- When there are condition-level deficiencies cited, the approval date is the date on which the transplant program is determined to be back in compliance either through a revisit or, as determined by the CMS based on the approval of mitigating factors.*

## ***2062F - Mitigating Factors***

***(Rev. 190, Issued:06-14-19, Effective: 06-14-19, Implementation: 06-14-19)***

### ***2062F.1 Medicare Approval Based on Mitigating Factors***

*Under §488.61(f), a transplant program may request that CMS consider mitigating factors in the initial approval and re-approval of a transplant program that does not meet the CoPs at §482.80 or §482.82. Mitigating factors will not, however, be considered in situations of immediate jeopardy.*

*§488.61(f)(1) describes the general areas that will be reviewed in determining whether a program can be initially approved or re-approved based on mitigating factors. These areas include (but are not limited to):*

- 1. The extent to which outcome measures are not met or exceeded;*
- 2. The availability of Medicare-approved transplant centers in the area;*
- 3. Extenuating circumstances (such as natural disasters) that may have a temporary effect on the program;*
- 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 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 the Fontan procedure, where CMS finds that the innovative practices are supported by evidence-based, published research or nationally recognized standards or Institutional Review Board (IRB) approvals, and the SRTR risk-adjustment methodology does not take the relevant key factors into consideration; and*

- 6. If the program's performance, based on the 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.*

## **2062F.2 Mitigating Factors Application and Review Process**

### **A. Intent to Apply for Review of Mitigating Factors**

- 1. The program must state on the CMS-2567, which is submitted to the SA that it will apply for mitigating factors as its plan of correction (POC) for non-compliance with data submission, clinical experience, or outcomes noncompliance.*
- 2. Upon receipt of a POC that includes an intent to apply for mitigating factors by the provider, the SA will provide a copy of the POC to the CMS CO mailbox at [QSOG\\_TransplantTeam.cms.hhs.gov](mailto:QSOG_TransplantTeam.cms.hhs.gov) and the SA will refer the provider to 488.61(f) for the list of the information that should be submitted for the mitigating factors application.*

### **B. Applying for Mitigating Factors**

*All information necessary for consideration of mitigating factors must be received within 120 calendar days of receipt of the formal written notification of noncompliance at §482.80 or §482.82. Failure to submit a complete and timely application within 120 calendar days may be the basis for denial of mitigating factors. See 488.61(f) for the materials required for a mitigating factors application.*

*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.*

*The provider must submit the specific information requested by CMS for review. Information and documents submitted for mitigating factors review must have all Personally Identifiable Information (PII) removed prior to its submission.*

### **C. The CMS Process for Reviewing Requests for Approval Based on Mitigating Factors**

*The CMS CO reviews all requests for mitigating factors review. It will include analysis by CMS staff with programmatic and clinical expertise for each transplant*

*program and will be conducted on a case-by-case basis in accordance with §488.61.*

#### ***D. CMS Determination***

*According to §§488.61(g)(1)(i)-(iii), CMS has three options after considering applications for mitigating factors. CMS may:*

- 1. Approve or re-approve a program's request for approval based on the consideration of mitigating factors;*
- 2. Deny the program's request for approval or re-approval based on the consideration of mitigating factors; or*
- 3. Offer the program an opportunity to enter into a time-limited **Systems Improvement Agreement (SIA)** with CMS, under certain conditions.*

#### ***2062 F.3 Processing Medicare Approval based on Mitigating Factors***

*If a request for approval based on a mitigating factors application is approved, the condition-level non-compliance under §482.80 or §482.82 is rescinded and the prospective termination date is rescinded. Generally:*

- 1. The CO will send an approval letter for mitigating factors to the program with a copy to the SA and RO.*
- 2. The RO will send an approval letter (if it is an initial application) or a letter that removes the prospective termination date (if it is already a Medicare-approved transplant program).*
- 3. The SA/RO will enter an offsite revisit survey into ASPEN and the RO will document the program's approval based on the presence of mitigating factors.*
- 4. The approval based on mitigating factors does not carry forward to future re-certification periods, and CMS may remove approval based on mitigating factors at any time if improvements are not sustained, subject to prior notice to the program and an opportunity to reply.*

#### ***2062 F.4 Processing Denial of a Mitigating Factors Request***

*CMS will deny approval based on mitigating factors if it finds that a basis for approval consistent with §488.61(f) has not been adequately established by the transplant program.*

*If a mitigating factors request is denied, CMS CO will send a letter to the program communicating its denial of the mitigating factors request and copy of that letter will be sent to the SA and RO.*

## **2062 F.5 Systems Improvement Agreements (SIA)**

*When a transplant program has condition-level non-compliance with the CoP requirements at §482.80 or §482.82 triggering a pending termination date, CMS may extend the termination date and offer the hospital the opportunity to enter into a time-limited Systems Improvement Agreement (SIA) with CMS. A SIA is a binding agreement that may be offered by CMS pursuant to §488.61(h). The SIA is entered into voluntarily by the hospital. Under an SIA, CMS extends the prospective Medicare termination date and offers the program additional time to achieve compliance with the CoPs, contingent upon the hospital's agreement to participate in a structured regimen of quality improvement activities, to demonstrate improved outcomes, and to waive their right to appeal the noncompliance determination leading to the termination.*

*To be considered for a SIA, the program must demonstrate that it has developed, implemented, and evaluated interventions that are designed to address root causes that are institutionally supported by the hospital's governing body on a sustainable basis and has requested more time for further improvements or demonstrate compliance with the outcome requirements. SIAs include a mechanism for monitoring the program to ensure that the terms of the SIA are being met and program efforts to undertake targeted and systemic improvements to ensure ongoing and sustainable compliance with the regulatory requirements are occurring.*

*The SIA is signed by program individuals who have the authority to commit the hospital to the terms of the Agreement. The Agreement is between CMS and the transplant hospital.*

*In exchange for the additional time to initiate or continue activities to achieve compliance with the CoPs, the hospital must agree to a regimen of specified activities, including (but not limited to) all of the following:*

*(i) **Peer Review:** An external independent peer review team that conducts an onsite assessment of the program. The peer review must include—*

*(A) Review of policies, staffing, operations, relationship to hospital services, and factors that contribute to program outcomes;*

*(B) Both verbal and written feedback provided directly to the hospital;*

*(C); and*

*(D) Onsite review by a multidisciplinary team that includes a transplant surgeon with expertise in the relevant organ type(s), a transplant administrator, an individual with expertise in transplant QAPI systems, a social worker or psychologist or psychiatrist, and a specialty physician with expertise in conditions particularly relevant to the applicable organ types(s) such as a cardiologist, nephrologist, or hepatologist. 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.*

**(iii) Action Plan:** *An action plan that addresses systemic quality improvements and is updated after the onsite peer review;*

**(iv) Onsite Consultant:** *An onsite consultant whose qualifications are approved by CMS, and who provides services for eight (8) days per month on average for the duration of the agreement, except that CMS may permit a portion of the time to be spent offsite and may agree to fewer consultant days each month after the first three (3) months of the SIA. The function of the onsite consultant is established under the discretion of the program.*

**(v) Policy & Procedures Review:** *A comparative effectiveness analysis that compares policies, procedures, and protocols of the transplant program with those of other programs in areas of endeavor that are relevant to the center's current quality improvement needs;*

**(vi) Outcomes Data Proficiency:** *Development of increased proficiency, or demonstration of current proficiency, with patient-level data from the SRTR and the use of registry data to analyze outcomes and inform quality improvement efforts;*

**(vii) Staffing Review:** *A staffing analysis that examines the level, type, training, and skill of staff in order to inform transplant center efforts to ensure the engagement and appropriate training and credentialing of staff;*

**(viii) QAPI:** *Activities to strengthen performance of the QAPI program to ensure full compliance with the requirements of §482.96 and §482.21;*

**(ix) Monthly Dialogue:** *Monthly (unless otherwise specified) reporting with designated monitor regarding the status of programmatic improvements, results of the deliverables in the SIA, and the number of transplants, deaths, and graft failures that occur within one (1) year post-transplant; and*

**(x) Other:** *Additional or alternative requirements specified by CMS, tailored to the transplant program type and circumstances.*

*The content elements under (v), (vi), (vii), or (viii) above may be waived if CMS finds that the program has already adequately conducted the activity, the program is already proficient in the function, or the activity is clearly inapplicable to the deficiencies that led to the SIA.*

*When CMS has offered a SIA to a transplant program, and the program agrees to enter into it, the following occurs:*

- 1. CMS develops the initial draft of the proposed SIA, based on (i)-(x) above, and forwards the draft to the program for review and comment;*
- 2. CMS reviews the program's comments and provides feedback regarding any changes to the SIA;*
- 3. CMS and the program will negotiate the final SIA document.*

4. *CMS completes the final SIA and forwards it to the program for signature. The SIA becomes effective on the date CMS signs the agreement.*

***2063 - Relationship Between the Transplant CoPs and Hospital CoPs.  
(Rev. 190, Issued:06-14-19, Effective: 06-14-19, Implementation: 06-14-19)***

*The transplant program must be in compliance with all hospital CoPs as well as all transplant program CoPs. Certain hospital requirements are inherently included in the transplant program survey process. When hospital requirements are thought to be out of compliance and in need of investigation the transplant program survey team must contact their supervisor to consult with the CMS RO for further instructions on citing the hospital deficiencies and must notify the hospital administration of any such citation.*

*The transplant program and hospital survey findings are documented on separate CMS-2567 forms even though the surveys are conducted together.*



# State Operations Manual

## Chapter 3 - Additional Program Activities

Table of Contents  
*(Rev. 190, Issued:06-14-19)*

### Transmittals for Chapter 3

*3012.3 – Termination of Organ Transplant Programs*

**3012.3 – Termination of Organ Transplant Programs**  
**(Rev. 190, Issued:06-14-19, Effective: 06-14-19, Implementation: 06-14-19)**

*Transplant programs with one or more condition-level deficiencies other than 482.80 and 482.82 are placed on a 90 calendar-day termination track.*

*However, if the program is found to be out of compliance with CoPs 482.80 or 482.82 and submits a request for reconsideration based on mitigating factors, the program will be given 210 days to come into compliance with these conditions. The 90 day termination track is enforced if the program does not come back into compliance regardless of whether the program is also on a 210 day termination track.*

*Please note that the termination of the transplant program's Medicare approval does not affect the associated hospital's provider agreement for participation as a Medicare-certified hospital. However, condition level findings at the hospital CoPs, may affect the hospital's provider agreement if corrections are not made timely.*

*HRSA and, if applicable the ESRD Network for a kidney program, are notified by the applicable RO of either a voluntary or involuntary termination of Medicare participation.*

*“The Health Resources Administration (HRSA) (and if kidney program add ESRD Network) will be notified of this termination in order for them to provide assistance as indicated with potential recipient transfers to another Medicare-approved program.”*

# Medicare State Operations Manual

## Chapter 9 - Exhibits

### Exhibits

*(Rev. 190, Issued:06-14-19)*

*357 – Options Letter for Transplant Program Inactive at 12 Months.*

## ***Exhibit 357***

### ***Options Letter for a Transplant Program Inactive at 12 Months: Program is inactive at 12 months and must re-active, voluntarily withdraw or be terminated.***

*[Date]*

*Dear [Hospital ADM]:*

*We received notification that the [organ type] transplant program(s) at [Hospital] will become/became inactive as of [Date].*

*Pursuant to Transplant Center requirements at 42 CFR 488.61(e), a transplant program is permitted to be inactive for up to 12 months and retain its Medicare approval. The [Organ Type] transplant program at [Hospital] will reach the maximum 12-month period of inactivity on [Date]. CMS does not have the authority to provide an extension beyond this 12-month period and therefore the transplant program will be terminated unless it reactivates prior to the completion of the 12 month period.*

*We remind you that per §482.102(c)(3), the program must inform all patients on the waitlist of its inactivation and assist those patients who choose to transfer to the waitlist of another Medicare-approved transplant center without loss of time accrued on the waiting list.*

*If you have any questions please contact [x] at [phone], [e-mail].*

*Sincerely,*

*[Name, Title of Authorized Representative]*