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Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-10-16 -Transplant

DATE: **April 16, 2010**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Outcome Deficiencies in Medicare-Certified Transplant Program: Procedures for Citation

Memorandum Summary

- **How Outcomes are Measured:** Transplant programs participating in Medicare must meet the Conditions of Participation (CoPs) on a continuous basis. Compliance with the patient and graft survival outcome requirements are measured through risk-adjusted statistical reports released semi-annually by the Scientific Registry of Transplant Recipients (SRTR).

- **Enforcement of Outcomes Requirements:** This letter addresses the Centers for Medicare & Medicaid Services (CMS) review and enforcement activities for transplant programs that are Medicare-approved under the CoPs, but no longer meet Medicare's patient and/or graft survival outcome requirements.

A. Background

The Medicare CoPs establish a minimum set of requirements that transplant programs must meet on a continuous basis. For certain types of transplant programs, one of these minimum requirements includes that the actual patient and graft survival rates at 1-year post transplant may not fall significantly below the expected survival rates (based on the patient and donor's characteristics). These outcomes are calculated by the SRTR and published in the semi-annual Center Specific Outcomes report. Some transplant programs that previously had acceptable outcomes and met the other CoPs were granted Medicare approval, but now, based on the release of more recent outcomes information, no longer meet the CoPs. This letter addresses CMS' review and enforcement activities for these transplant programs.

Transplant programs subject to outcome requirements include:

- Adult Kidney-Only;
- Adult Heart-Only;
- Adult Lung-Only (include ages 12 and over);
- Adult Liver;
- Pediatric Kidney-Only (includes only 1-year graft survival);
- Pediatric Heart-Only;
- Pediatric Lung-Only (include ages 12 and over); and
- Pediatric Liver.

B. Identification of Transplant Programs

CMS Central Office (CO) will periodically distribute to the CMS Regional Offices (RO) a list of approved transplant programs that do not meet Medicare's outcome requirements at the Condition-level. An updated list will be distributed every six months. This list will be referred to as the "*Outcomes Non-Compliance Report*" and will outline the specific program, the expected and actual patient and graft survival rates, and the statistical significance of the difference between the expected and actual survival rates (i.e., the 1-sided p-value).

Within 30 calendar days of receipt of the Report, the CMS RO will:

1) Determine which of the following types of follow-up is required: a) offsite review; b) onsite complaint investigation, or c) full onsite re-approval survey. Enter the type of follow-up electronically into the *Outcomes Non-Compliance Report*. In certain unusual circumstances, CMS will indicate the need for an onsite survey.
2) Notify CO of the type of follow-up and timeframe for completing the survey by e-mailing the completed *Outcomes Non-Compliance Report* back to CMS CO. (Note, CMS CO may communicate with the CMS RO an alternative method if possible to reduce the e-mail administrative burden.)
3) Distribute the report to State Survey Agency (SA) to initiate follow-up activities; or
4) For those States where the surveys are conducted by the CMS National Contractor, the RO will initiate the follow-up activities by conducting the offsite survey or providing the survey shell to Contractor for the onsite surveys. If applicable, the Contractor will then make arrangements to conduct any onsite surveys.

For offsite complaint surveys, the RO or SA will complete the offsite complaint survey and issue the CMS-2567 to the provider within 75 calendar days of receipt of the Report. If an onsite survey is required, the survey must be completed within 120 days of receipt of the Report, and the CMS-2567 Form should be issued in accordance with standard operating policy (i.e., refer to Section 2062B of the State Operations Manual for a description of post-survey activities).

If unusual circumstances prevail, CMS CO may indicate a need for a different timeframe other than the one described above (e.g., another pending complaint). CMS CO will communicate this to the ROs in the distribution of the *Outcomes Non-Compliance Report*. Please note: CMS-2567 forms completed by the SA must still be reviewed by the CMS RO prior to release.

Generally, CMS CO will not include programs in the "Outcomes Non-Compliance Report" that have applied for approval based on mitigating factors, or have been granted Medicare approval based on the presence of mitigating factors, unless there is evidence that the circumstances leading to that decision have changed. For example, there may be programs where the outcomes continued to be lower than expected after they were supposed to have improved, according to the original mitigating factors decision.

C. Determine the Type of Follow-up Required

CMS RO will examine the information in the *Outcomes Non-Compliance Report*, and make a determination about the type of follow-up needed (unless CMS CO has already indicated a need for a particular type of follow-up). In determining the type of follow-up needed, CMS RO may want to consider the program's history of non-compliance, results of previous onsite surveys, and the timeframe for the re-approval survey, etc. The CMS RO will then inform the SA and CO of the type of follow-up required.

The types of follow-up may include:

1. **Offsite Complaint Survey** – Follow-up in most cases that involve only outcomes data may be accomplished through an offsite administrative review using the SRTR outcomes information described in the *Outcomes Non-Compliance Report*.

   Examples of considerations to determine that an offsite survey will be conducted:
   - The transplant program was in compliance with 42 CFR §482.96 (QAPI) at the most recent initial or re-approval survey, or was cited, but there was an onsite revisit to confirm that the issue has been addressed;
   - There have been no complaints; and/or
   - The program has received an onsite survey within the past 6 months.

2. **Onsite Complaint Survey** - In these cases, either State, federal, or contracted federal surveyors will go onsite to the transplant program, discuss the program's outcomes (42 CFR §482.82), and review the Quality Assessment and Performance Improvement (QAPI) program (42 CFR §482.96) to ensure that it is comprehensive, functioning effectively and can identify, analyze, and implement changes to address the outcome deficiencies. Surveyors may expand the scope of the survey to 1) other CoPs once onsite if the findings warrant such expansion; or 2) CoPs identified by the RO (e.g., based on review of the Transplant Program Quarterly Report, or complaint information).

   Examples of considerations where an onsite complaint survey may be particularly important:
   - The internal QAPI program was cited on the most recent survey;
   - The program has not met the outcomes requirements for several consecutive periods;

- There are questions about the extent to which the program has analyzed and is addressing the outcomes issues, or questions as to whether the center has implemented the QAPI program effectively: and/or
- There are questions about whether the hospital's governing body has fulfilled its obligations.

3. **Onsite Full Re-approval Survey** – In these cases, either State or contracted federal surveyors will review all CoPs through a re-approval survey. The complaint investigation for the outcomes CoP will become a part of the standard onsite re-approval survey. The surveyors would also review *all other* approved and new transplant programs that are due for re-approval at the hospital. Exceptions to inclusion of *all programs* on the survey may be made by the CMS RO on a case-by-case basis.

   Examples of considerations where an onsite full survey may be particularly important:
   - The internal QAPI program was cited on the most recent survey or the RO has questions about whether or not the program's QAPI program has been implemented effectively and operating continuously.
   - There are serious allegations or complaints that have been received related to other CoPs that have not already been investigated;
   - The program has not met the outcomes requirements for several consecutive periods; and/or
   - The periodic CMS re-approval survey is due within the next 6 months.

D. Process for Citing Non-Compliance with Medicare's Outcome Requirements

All outcome survey related information must be documented in the appropriate Automated Survey Processing Environment (ASPEN) database. The specific process for citing non-compliance and creating the CMS-2567 is determined by the type of follow-up required. For the offsite or onsite complaint survey, follow-up activities will be documented solely in the ASPEN Complaint Tracking System (ACTS). For the onsite full re-approval survey, the information would first be entered in the ASPEN Central Office (ACO), with a corresponding record then entered into ACTS. These steps are described in more detail below. The table in **Attachment A** provides additional information about which party is responsible for each of the activities.

1. **Offsite or Onsite Complaint Survey**
   a) Enter a new complaint intake into the ACTS System: The complaint intake should be identified with the following information:

Intake:	01 Complaint
Intake Subtype:	A Federal COPs, CfCs, RFPs, EMTALA, CLIA
Source:	CMS
Priority:	Priority C, non-IJ, medium
Start Date:	The date the SA or RO received the *Outcomes Non-Compliance Report*

b) Conduct the offsite or onsite review and draft the Form CMS-2567:
Please note, for onsite reviews performed by the Contractor, CMS RO sends the complaint survey shell to the Contractor for importing into the ASPEN Survey Explorer (ASE).

At a minimum, the CMS-2567 would cite the outcome deficiency ***at the Condition-level for non-compliance with 42 CFR §482.82*** (tags X041 and X045) and outline the deficiency statement and findings (see sample in **Attachment B**). If an onsite survey is conducted, there may also be deficiencies in QAPI or other CoPs. The date of the offsite survey is the date the review is actually performed by the RO or SA.

2. Onsite Full Re-approval Survey (ACO/ACTS Activities)

a) If a full re-approval survey is warranted, create a new re-certification kit in ACO, identify which program type(s) would be surveyed in the kit, and create a new survey. Please specify the type of survey as both "Re-certification" and "Complaint." This process creates an Event ID specific to the investigation in ACO.

b) Enter a complaint into the ACTS System: Create a new complaint intake in the ACTS system and link the intake with the Event ID created for the recertification kit in ACO. Specifically, the RO/SA selects that Event ID under the "Investigation" tab of the complaint intake form. The complaint intake should be identified with the following information:

Intake:	01 Complaint
Intake Subtype:	A Federal COPs, CfCs, RFPs, EMTALA, CLIA
Source:	CMS
Priority:	Priority C, non-IJ, medium
Start Date:	The date the SA or RO received the *Outcomes Non-Compliance Report*

c) Conduct the onsite review and draft the Form CMS-2567:
The SA, RO, and Contractor would follow the normal process for re-approval surveys outlined in the State Operations Manual, Section 2062 (e.g., requesting the Transplant Program Quarterly Report (TPQR), etc.). At a minimum, the CMS-2567 cites the outcome deficiency ***at the Condition-level for non-compliance with 42 CFR §482.82*** (tags X041 and X045) and outlines the deficiency statement and findings. If an onsite survey is conducted, there may be deficiencies cited elsewhere based on the findings.

An overview of the process described above can be found in **Attachment A**.

Attachment B is a sample *Outcomes Non-Compliance Report* and a corresponding CMS-2567 with the deficiency that would be cited at 42 CFR§482.82.

E. Provider Notification, Plans of Correction, and Requests for Consideration of Mitigating Factors

The provider must be notified with a cover letter and a copy of the CMS-2567 form. The SA and RO will use the standard model letter that has been used with other transplant providers for notification. If an offsite survey was conducted, revise the language accordingly.

The cover letter will notify the provider of:

1. The finding of non-compliance with the outcome requirement and any other compliance issues cited in the CMS-2567;
2. A prospective Medicare revocation date if the outcomes are not back in compliance within 210 days (and a prospective Medicare revocation within 90 days if other Condition-level deficiencies have not been corrected);
3. The requirement to submit a plan of correction; and
4. The option to request continued Medicare approval based on the consideration of mitigating factors.

Copies of all letters must be sent to the CMS RO and CO.

As referenced above, similar to the current process, transplant programs will have 210 days to come back into compliance with the outcome requirements and 90 days for other Condition-level deficiencies. Transplant programs will also be able to request that CMS review factors that the program believes mitigate the non-compliance with Medicare's requirements.

Additional information on the mitigating factors process can be found at: http://www.cms.hhs.gov/CertificationandComplianc/Downloads/ConsiderationofMitigatingFactors.pdf The transplant program should submit to CMS CO their initial request for consideration of mitigating factors within 10 days of receiving the CMS-2567 form and submit other supporting documentation within 30 days of receiving the CMS-2567.

In addition to any request for consideration of mitigating factors, the transplant programs must submit a Plan of Correction for the Condition-level deficiency to the SA or RO (as directed in the letter accompanying the CMS-2567).

F. Review for Compliance with the Condition of Participation:

Once a citation is made, CMS CO will review any subsequent Center-Specific Reports from the SRTR to verify whether or not the outcomes information is back in compliance, and will notify the CMS RO to communicate with the SA, as applicable.

If you have additional questions or concerns, please contact Karen Tritz (410-786-8021) or Karen.Tritz@cms.hhs.gov.

Effective Date: Immediately. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum.

Training: The information contained in this letter should be shared with all survey and certification staff, their managers, and the State/RO training coordinators.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

Enclosures

Attachment A

Summary of the Process for Citing Outcomes

1. CMS CO sends *Outcomes Noncompliance Report* to CMS RO periodically.

2. RO evaluates evidence and determines type of follow-up needed.

3. RO notifies CO and State Agency (SA) for states surveyed by SA within 30 days of receiving report.

4. For offsite surveys: Within 45 days after RO determines type of follow-up needed (and if applicable notifies SA), the following actions will occur
    a. SA or RO completes offsite complaint survey and CMS-2567 in ACTS
    b. RO reviews CMS-2567
    c. RO or SA mails cover letter and CMS-2567 to provider.

5. For onsite surveys: Within 120 days after RO determines type of follow-up needed (and if applicable notifies SA) the following actions will occur:
    a. SA or Contractor completes onsite survey and CMS-2567 in ACTS and for full re-approval surveys, ACO.
    b. RO reviews CMS-2567.
    c. If applicable, CO reviews Contractor's CMS-2567 concurrently with RO, and
    d. RO or SA mails cover letter and CMS-2567 to provider.

Table 1: Summary of RO, SA and Contractor Responsibilities

	Offsite Complaint		Onsite Complaint		Onsite Re-approval	
	States Surveyed by SA	**States where Contractor has onsite survey responsibility**	**States Surveyed by SA**	**States where Contractor has onsite survey responsibility**	**States Surveyed by SA**	**States where Contractor has onsite survey responsibility**
1. Enter in ACO	n/a	n/a	n/a	n/a	SA	RO
2. Enter complaint into ACTS	SA	RO	SA	RO	SA	RO
3. Create survey shell for importing into ASE	n/a	n/a	n/a	RO	n/a	RO
4. Conduct survey	SA	RO	SA	Contractor	SA	Contractor
5. Create 2567	SA	RO	SA	Contractor	SA	Contractor
6. Send 2567 to provider	SA (following RO review)	RO	SA (following RO review)	RO (concurrent CO review)	SA (following RO review)	RO (concurrent CO review)

Attachment B

Outcomes Non-Compliance Report and Corresponding CMS-2567

Outcomes Non-Compliance Report, July 2009 Outcomes from the Scientific Registry of Transplant Recipients

CCN	Hospital Name	OPTN Code	State	Program Type	Patient Cohort	Patient Deaths			Graft Failures			Comment	RO Determined Follow-Up Needed
						Actual	Expected	p-value	Actual	Expected	p-value		
509805	University of Wyoming	WYUV	WY	Adult Kidney-Only	1/1/2006-6/30/2008	11.00	4.44	0.006	11.00	4.37	0.005	Program does not meet Medicare's minimum outcome requirements for either patient or graft survival 1-year post transplant in the current SRTR report. In addition, the program had significantly lower than expected outcomes in 3 of the 4 prior SRTR reports (January 2009, July 2008, and July 2007).	

Sample CMS-2567 Citing Non-Compliances for Outcomes

X041:
This CONDITION is not met as evidenced by:

Based on review by the Centers for Medicare & Medicaid Services (CMS) of the July 2009 outcomes calculated by the Scientific Registry of Transplant Recipients (SRTR), the adult kidney transplant program failed to ensure that the CMS outcome requirements were met for the 1-year patient survival and 1-year graft survival rates.

Findings:

1. The Adult Kidney-Only (AKO) program's most recent outcomes data from the XX (Month,Year) Scientific Registry of Transplant Recipients (SRTR) Center Specific Report indicates that for patients receiving kidney transplants between 01/01/06 to 06/30/08, the observed patient death and graft failure rates were higher than expected and considered unacceptable as outlined in X045. See X045 for specific SRTR reported data results for patient death and graft failure rates.

X045:
This ELEMENT is not met as evidenced by:

Based on review of data from the XX (Month,Year) Scientific Registry of Transplant Recipients (SRTR) Center Specific Report, the AKO program did not meet the regulatory outcome requirements outlined in CFR 482.82(c)(3) for 1-year patient and graft survival rates.

Findings:

1. Review of the SRTR risk-adjusted outcomes report dated XX (Month,Year) revealed that the actual 1-year patient survival rate was significantly lower than expected for patients transplanted between January 1, 2006 and June 30, 2008. The expected number of patient deaths (based on patient and donor characteristics) was 4.44; the actual number of patient deaths was 11. This is a statistically significant difference (i.e., p-value is .006).
2. Review of the SRTR risk-adjusted outcomes report dated XX (Month,Year) revealed that the actual 1-year graft survival rate was significantly lower than expected for patients transplanted between January 1, 2006 and June 30, 2008. The expected number of graft failures (based on patient and donor characteristics) was 4.37; the actual number of graft failures was 11. This is a statistically significant difference (i.e., p-value is .005).