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Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 16-24-Hospitals

DATE: **May 13, 2016**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Solid Transplant Programs - Outcome Thresholds - Revised Guidelines

Memorandum Summary

- **Background on Organ Transplant Outcomes Standards:** Medicare Conditions of Participation (CoPs)[1] require that each solid organ transplant program maintain patient and graft survival rates that are within certain Centers for Medicare & Medicaid Services (CMS) tolerance limits. Specifically, when the total number of patient deaths or graft failures that occur within one year of transplant exceeds 150% of the risk-adjusted expected number (i.e., 1.5 times the expected number) for a 2.5-year period, and the result is both statistically significant ($p<.05$) and numerically meaningful ($O - E \geq 3$), then the program is not in compliance with CMS requirements.
- **Revisions to Interpretive Guidelines:** We are revising the CMS Survey & Certification interpretive guidelines to provide that such outcomes between 150% and 185% of the risk-adjusted expected number will generally constitute a "standard level" deficiency. A standard level deficiency requires improvement efforts but does not by itself put a program's Medicare participation at risk. One-year post-transplant patient deaths or graft failures that exceed 185% of the expected number will generally be classified at the more serious "condition-level" if such a finding occurs in more than one (SRTR) report.
- **Reasoning**: Since mid-2007 (the effective date of the CMS transplant regulations), national patient and graft survival rates have improved. Because individual programs are compared against the national risk-adjusted average, the national improvement has made the CMS outcomes standard increasingly stringent. We are concerned that transplant programs may avoid using certain available organs that they believe might adversely affect the program's outcome statistics. We expect that this revised policy, by lessening such concerns and augmenting the policy with other efforts, will promote more effective use of available organs and help more waitlisted individuals to benefit from a transplant, while continuing to promote high rates of patient and graft survival.

A. Background

The CMS (CoPs)[1] require that each solid organ transplant program maintain aggregate patient and graft survival rates (for a time period up to one-year post-transplant) that are within certain CMS tolerance limits, after adjusting for the particular risk profile of the program's recipients,

[1] See 42 CFR §§482.80(c)(2)(ii)(C) and 482.82(c)(2)(ii)(C)

donors, and organs involved. More specifically, when the total number of patient deaths or graft failures that occur within one year of transplant exceeds 150% of the risk-adjusted expected number (i.e., 1.5 times the expected number), and the result is both statistically significant ($p<.05$) and numerically meaningful[2], then the program is not in compliance with CMS requirements. CMS relies on the SRTR for the data and risk modeling. The registry supports the ongoing evaluation of the scientific and clinical status of solid organ transplantation, including kidney, heart, liver, lung, intestine, and pancreas. Solid organs subject to the CMS outcomes standard include kidney, heart, lung, and liver transplants.

CMS monitors the number of patient and graft (organ) failures that occur within one year of each person's receipt of a transplanted solid organ, as reported through the SRTR. The SRTR obtains detailed information from the Organ Procurement and Transplantation Network (OPTN)[3] regarding each (a) donor's characteristics (e.g., age, hypertension, diabetes, stroke, weight), (b) organ characteristics (e.g., both warm and cold ischemic time), and (c) recipient characteristics (e.g., age, race, gender, body mass index, hypertension status). More information on the SRTR is available at http://www.srtr.org.

The SRTR data (donor, organ, recipient) are used to construct a risk profile of each transplant program's organ transplants. The risk models allow the SRTR to calculate an expected survival rate for both patients and grafts (organs) over various periods of time. Every six months, the SRTR provides a report to each transplant program regarding the program's outcomes relative to the CMS outcomes standards. Each report covers a rolling, retrospective 2.5 year period. The reports provide the aggregate number of patient deaths and graft failures that occurred within one year after each transplant patient's receipt of an organ. The report allows a comparison between the actual number of such events and the risk-adjusted number that would be expected, and provides the resulting ratio (the number of observed events divided by the number of expected events). An "observed to expected (O/E)" ratio of 1.0, for example, means that the transplant program's outcomes were equal to the national outcomes for a patient, donor, and organ risk profile that reasonably matched the risk profile of that particular transplant program, for the time period under consideration. An O/E ratio of 1.5 means that the patient deaths or graft failures were 150% of the risk-adjusted expected number.

B. Policy Revision and Rationale

One-year post-transplant outcomes have improved for all organ types since 2007, when the CMS solid organ transplant regulation was first implemented. For adult kidneys, one-year graft survival increased nationally from 92.9% in CY 2007 to 94.8% in CY 2014, and one-year patient survival increased from 96.4% to 96.9%. One-year patient survival for heart recipients increased from 88.5% to 89.5%, for liver recipients from 87.7% to 90.8%, and for lung recipients from 80.4% to 85.7%[4].

Because individual programs are compared against the risk-adjusted national average, the national improvement has made the CMS outcomes standard increasingly stringent and made it

[2] That is, the difference between the number of observed patient death or graft failures and the expected number is greater than "3" ($O - E \geq 3$).
[3] https://optn.transplant.hrsa.gov/
[4] CMS analysis of SRTR data.

more difficult for individual transplant programs to maintain compliance with the outcomes standards in 42 CFR §§482.80 and 482.82. In 2007, for example, an adult kidney transplant program with a risk profile matching the national average was in compliance if there were no more than 10.7 graft losses, within one year, out of every 100 transplants. By 2014, that number had come down to 7.9, a 26% reduction in the number of graft losses that could occur and still allow the program to maintain compliance with the CMS standard. Similarly, among patients receiving a kidney transplant, the number of deaths that could occur, while still maintaining compliance with the standard, declined from 5.4 to 4.6 out of every 100 transplant recipients.

We are concerned that transplant programs may be avoiding use of certain available organs that they believe may adversely affect the program's outcome statistics. In CY 2015, a total of 3,159 adult kidneys were recovered from deceased donors but not used (out of a total of 16,410 deceased donor adult kidneys recovered for transplant). This was an increase from 2,889 such adult kidneys that were donated and recovered but not used for transplant in CY2014, and 2,632 in 2007 and 2,084 in 2004. Compared with kidney transplant recipients, individuals who remain on dialysis tend to have shorter lives and lower quality of life, with Medicare expenses that exceed the costs of organ transplantation after the first survived year.

We are therefore revising the CMS Survey & Certification interpretive guidelines to provide that Medicare approval will generally not be at risk solely due to noncompliance with the outcomes standards in 42 CFR §§482.80 and 482.82, so long as a transplant program's O/E ratio is within 185% of the risk-adjusted expected number. Outcomes that are above the 185% threshold will continue to be classified as "condition level" deficiencies when that threshold is crossed in more than one SRTR report (explained below in section C) and the outcomes are statistically significant ($p < .05$) and numerically meaningful ($O - E \geq 3$). A condition level deficiency means that the program may not receive, or continue to receive, Medicare approval after due advance notice and opportunity to appeal[5], except in the case where CMS finds that there are mitigating factors[6].

In the case of adult organ transplant programs, setting the classification for a condition level outcomes deficiency at 185% of the risk-adjusted expected number (instead of 150%) will generally allow adult kidney programs to avoid risk to Medicare participation if their only deficiency is due to outcomes and their patient and graft losses within one year of transplant do not exceed the approximate number allowed in 2007 for adult kidney patient survival, when national performance was not so high.

For example, using CY2014 national survival data, a threshold at 185% for a condition level deficiency means that up to 5.7 adult kidney patient deaths out of 100 transplants (within one year of transplant) would remain within the CMS range (compared to 5.4 in 2007 and 4.6 in 2015) for a program whose risk profile approximates that of the national average. Similarly, for adult kidneys, a condition level deficiency would be avoided for up to 9.7.graft losses out of 100 transplants (within one year of transplant), slightly fewer than the 10.7 allowed in 2007 but more than the 7.9 allowed in 2014).

While our concern regarding possible risk aversion in organ acceptance is primarily focused on

[5] Or, in the case of initial applications for approval, an opportunity to request reconsideration of a denial.
[6] The mitigating factors process and criteria are explained in 42 CFR §488.61(f),(g), and (h).

adult kidney transplants, it is also relevant to the other organ types to a lesser extent. National patient and graft survival for all other types of organs has also risen significantly since 2007. For this reason, for consistency, and to avoid unneeded complexity, we are applying the same 185% threshold for all organ types, and for both graft and patient survival.

Outcomes between 150% and 185% will still constitute a deficiency[7], since the 150% (an O/E ratio of 1.5) is defined in regulation. But we are generally reclassifying such a deficiency at the "standard level." A standard level deficiency requires improvement efforts but does not require a transplant program to file a plan of correction with CMS unless the deficiency is identified as part of an onsite survey. A standard level deficiency does not by itself put the program's Medicare participation at risk. Nor does a standard level deficiency require a transplant program to apply for, or receive, "mitigating factors" approval from CMS[8]. We note, however, that CMS reserves the right to examine any deficiency in light of the manner and degree of noncompliance, and other factors, and to classify any deficiency at the condition level, consistent with 42 CFR §488.26.

C. The Two-Flag Classification Policy for Condition Level Outcomes Deficiencies

We are retaining the "two-flag" method for distinguishing between a standard and condition level outcomes deficiency. If a program's outcomes exceed the 185% threshold in (a) the most recent SRTR report AND (b) one other SRTR report in the past 2.5 years, then CMS will classify the deficiency at the condition level. The "two-flag" classification method has been the CMS policy from the very beginning (when the Medicare regulations for organ transplantation were first implemented in 2007). In the case of a single flag (at either the 150% or 185% number) we assume that the peer review process of the Organ Procurement and Transplantation Network (OPTN) is reviewing the program. The "two-flag" method for classifying a deficiency at the condition level will apply using the 185% classification method (i.e., a single flag above 185% is a standard level deficiency; two SRTR reports in 2.5 years, with both above 185%, is classified as a condition level deficiency).

The two following charts offer a visual portrayal of the difference in how outcomes that exceed the regulatory thresholds are now classified, compared with the prior CMS classification system.

Chart 1 – Previous Classification System for
Standard and Condition Level Outcomes Deficiencies*

Number of SRTR Reports in Which Outcomes Exceed the Tolerance Limit ("Flags")	**Number of Deaths or Graft Failures within 1 Year of Transplant**
	More than 150% of the Risk-Adjusted Expected Number
Single Flag (Most Recent Report)	*Standard-Level Deficiency*
Two-Flags: Most Recent plus One Additional Rpt in 5 Reports (2.5 Years)	*Condition-Level Deficiency*

[7] If, in addition, the outcomes are statistically significant ($p < .05$) and numerically meaningful ($O - E \geq 3$).
[8] The mitigating factors process and criteria are explained in 42 CFR 488.61(f),(g), and (h).

Chart 2 – Revised Classification System for
Standard and Condition Level Outcomes Deficiencies*

Number of SRTR Reports in Which Outcomes Exceed the Tolerance Limit ("Flags")	Number of Deaths or Graft Failures within 1 Year of Transplant	
	Between 150% and 185% of the Risk-Adjusted Expected Number	More than 185% of the Risk-Adjusted Expected Number
Single Flag (Most Recent Report)	*Standard-Level Deficiency*	*Standard-Level Deficiency*
Two-Flags: Most Recent plus One Additional Rpt in 5 Reports (2.5 Years)	*Standard-Level Deficiency*	*Condition-Level Deficiency*

** Note: A deficiency is cited for substandard outcomes only if the results are also statistically significant ($p<.05$) and numerically meaningful (i.e. the number of observed patient deaths or graft failures exceeds the risk-adjusted expected number by 3 or more).*

We plan to communicate soon with any program that was cited for an outcomes deficiency at the condition level on the basis of the January 2016 SRTR report, but whose patient deaths or graft failures were fewer than, or equal to, 185% of the risk-adjusted expected number. We expect that any such program that has entered into a Systems Improvement Agreement (SIA) with CMS will complete the SIA process, but we will consider whether an expedited conclusion to the process is warranted.

We believe this change, when combined with transplant center and national initiatives to make more effective use of available organs, will redound to the advantage of individuals on the waitlists for organs while maintaining high standards of performance and accountability.

Contact: Should you have any questions about the information in this memo, please contact our solid organ transplant team at SCG_TransplantTeam@cms.hhs.gov.

Effective Date: Immediately. This policy has been communicated to the CMS National Contractor for solid organ transplant surveys. Since State Survey Agencies are not surveying solid organ transplant programs, we are communicating this guideline via S&C Memorandum for informational purposes and to ensure public transparency until the relevant portions of the State Operations Manual are revised.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

The contents of this letter support actions to improve patient safety and increase quality and reliability of care and promote better outcomes.