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Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 14-32-Transplant

DATE: **May 16, 2014**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: The CMS Mitigating Factors Process for Solid Organ Transplant Programs – Notice of Proposed Rule-Making (NPRM) - ***Informational Only***

Memorandum Summary

Publication of NPRM: CMS-1607-P was published on May 15, 2014. The proposed rule updates the Inpatient Prospective Payment System (IPPS) for hospitals. The NPRM also includes program updates for certain other acute care providers. This S&C memorandum summarizes only the proposals related to solid organ transplant programs.

Transplant Mitigating Factors Process: Current regulations permit a transplant program to apply for consideration of mitigating factors that, if approved, would permit the program to continue to participate in Medicare despite not fully meeting CMS requirements for patient or graft survival. This proposed rule would clarify the mitigating factors process, increase transparency, and explicitly recognize CMS willingness to consider program improvements and the use of innovative practices as part of the mitigating factors process.

A. Background - NPRM

On May 15 2014 CMS published in the Federal Register a Notice of Proposed Rule-Making for FY 2015 IPPS & Long Term Care Hospital PPS. The proposed rule updates the Inpatient Prospective Payment System (IPPS) for hospitals. The NPRM also includes program updates for certain other acute care providers. This S&C memorandum summarizes only the proposals related to solid organ transplant programs. The NPRM may be viewed at: http://www.gpo.gov/fdsys/pkg/FR-2014-05-15/pdf/2014-10067.pdf. Comments are invited within 60 days of the publication.

B. Background – Solid Organ Transplant Program – Mitigating Factors Process

CMS Conditions of Participation (CoPs) set forth explicit expectations for outcomes, patient safety, informed choice, and quality of transplantation services. In particular, §§ 482.80 and 482.82 specify that a transplant center's outcomes are not acceptable if, among other factors, the number of observed patient deaths or graft failures 1 year after receipt of a transplant exceeds the risk-adjusted expected number by 1.5 times, based on the most recent program-specific report from the Scientific Registry of Transplant Recipients (SRTR).

Current regulations for organ transplant centers permit CMS to consider mitigating factors as a circumstance before terminating Medicare participation for a transplant program that has not met CMS Conditions of Participation (§§ 488.61(a)(4) and (c)(4)). At this time, the regulations do not provide a full explanation of the process, criteria, and expectations for transplant programs requesting approval based on mitigating factors.

C. Proposed Changes – Mitigating Factors Process for Solid Organ Transplant Programs

Since the adoption of the organ transplant CoPs and corresponding enforcement regulations, we have expanded our knowledge regarding: (a) the factors and processes that promote improvement in transplant center outcomes; and (b) other mitigating factors that merit explicit recognition under CMS regulations.

The proposed changes would help transplant centers better understand the process and key factors that CMS applies in making decisions. The changes would also clarify the due dates for submission of mitigating factors applications and the timetable for CMS review.

Existing regulations do not limit the factors that CMS may consider, but describe only a few of the possible factors:

(1) The extent to which outcome measures are met or exceeded;
(2) The availability of Medicare-approved transplant centers in the area; and
(3) Extenuating circumstances that may have a temporary effect on a transplant center meeting the requirements under the CoPs, such as a natural disaster.

We have found few transplant programs that qualified for mitigating factors approval under the above examples currently listed in the regulation. For example, since 2007 only two programs were approved on the basis of natural disaster impediments. However, we have granted mitigating factors approval to other programs due primarily to substantial improvements they implemented or consideration of exceptional innovative practice. We therefore propose to add explicit recognition of such factors as examples within the regulation, specifically:

- ***Substantial Program Improvements and Supporting Data:*** Program improvements that substantially address root causes of graft failures or patient deaths and that have been implemented and institutionalized on a sustainable basis, and backed by recent data indicating compliance.
- ***Recent Outcomes Showing Compliance***: Recent patient and graft survival data to determine if there is sufficient clinical experience and survival for CMS to conclude that the program is in compliance with CMS requirements, except for the data lag inherent in the reports from the SRTR.
- ***Exceptional Innovation:*** 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 (proposed new paragraph (f)(1)(vi)).

We note that, since the June 28, 2007 effective date of the CMS CoPs, a considerable number of programs would have been terminated from Medicare participation (due to subpar patient or graft survival) if they had not benefitted from an extended period of time to make improvements under the terms of a Systems Improvement Agreement (SIA). Further, transplant centers under an SIA have substantially improved patient and graft survival in subsequent periods. A preliminary review adult kidney transplant programs engaged in an SIA, for example, found that, 2 years after the CMS onsite survey, patient deaths (one year after patients received a transplant) had improved from 2.4 times the risk-adjusted expected number to a level that is slightly better (but not statistically different from) the expected number.[1]

We therefore propose to incorporate (at 42 CFR §488.61(h)) and explain certain key SIA elements that have been important to the successful use of the SIA template. We define an SIA as a binding agreement, entered into voluntarily by the hospital and CMS, through which CMS extends the effective date of a prospectively-scheduled termination of the center's Medicare participation (thereby permitting the program additional time to achieve compliance with the CoPs), contingent on the hospital's agreement to participate in a structured regimen of quality improvement activities and subsequent demonstration of improved outcomes. An independent, onsite peer review and subsequent action plan represent two of the most important elements of that process.

D. Other Aspects (Beyond Transplants) of the Proposed Rule

Other important aspects of the IPPS rule that will be of interest to a larger audience include:

- ***Hospital Prospective Payment***: Revise the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals. These proposed changes would be applicable to discharges occurring on or after October 1, 2014
- ***LTCH Prospective Payment:*** Update the payment policies and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs) and to implement certain statutory changes to the LTCH PPS under the Affordable Care Act and the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 and the Protecting Access to Medicare Act of 2014.
- ***GME Payments:*** Make a number of changes relating to direct graduate medical education (GME) and indirect medical education (IME) payments.
- ***Quality Reporting:*** Establish new requirements or revise requirements for quality reporting by specific providers (acute care hospitals, PPS-exempt cancer hospitals, and LTCHs) that are participating in Medicare.
- ***Value-Based Purchasing:*** Update policies relating to the Hospital Value-Based Purchasing (VBP) Program, the Hospital Readmissions Reduction Program, and the Hospital-Acquired Condition (HAC) Reduction Program.
- ***Appeals:*** Make changes to the regulations governing provider administrative appeals and judicial review relating to appropriate claims in provider cost reports;

[1] Hamilton, Thomas E., *Regulatory Oversight in Transplantation: Are Patients Really Better Off*, Curr Opin Organ Transplant 2013, 18:203–209. Available at: at http://www.co-transplantation.com.

- ***Physician RCEs:*** Updates to the reasonable compensation equivalent (RCE) limits for services furnished by physicians to teaching hospitals excluded from the IPPS; and
- ***EHR Reporting:*** Align the reporting and submission timeline of the EHR Program for eligible hospitals and critical access hospitals (CAHs) with the reporting submission timeline for the Hospital IQR Program, and provide guidance on certain reporting criteria in the EHR Incentive Program for eligible hospitals and CAHs.

The full proposed rule, CMS-1607-P, published on May 15, 2104 and can be viewed at: http://www.gpo.gov/fdsys/pkg/FR-2014-05-15/pdf/2014-10067.pdf. Comments are invited within 60 days of the publication.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management