



**Center for Clinical Standards and Quality/Survey & Certification Group**

**Ref: S&C: 16-30-OPO/Transplant**

**DATE:** July 08, 2016

**TO:** State Survey Agency Directors

**FROM:** Director  
Survey and Certification Group

**SUBJECT:** Notice of Proposed Rulemaking (NPRM) for Organ Procurement Organizations (OPOs) and Transplant Centers

**Memorandum Summary**

- On July 6, 2016, the Centers for Medicare & Medicaid Services (CMS) released the Calendar Year (CY) 2017 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System policy changes, quality provisions, and payment rates proposed rule (CMS-1656-P). The NPRM includes sections related to changes for OPOs and Transplant Centers.
- To learn more about the proposed rule, please visit: <https://www.federalregister.gov/public-inspection>. CMS looks forward to feedback on the proposal and will accept comments until September 6, 2016.

**Summary of Provisions**

The OPPS NPRM includes changes to both OPOs and transplant centers and transplant enforcement. Changes to the OPO regulations include aligning the definition of “eligible death” and the aggregate donor yield metric in the OPO Conditions for Coverage (CfC) with those of the Organ Procurement and Transplantation Network (OPTN) and Scientific Registry of Transplant Recipients (SRTR), as well as revise the OPO CfC to reduce the amount of hard copy documentation that must be sent with the organ, as much of this information is now available to the transplant center electronically.

For transplant centers, the Medicare Conditions of Participation (CoPs) for Organ Transplant programs at 42 CFR sections 482.80 and 482.82 contain an outcome requirements standard for one-year patient and graft survival. A transplant program is out of compliance with this standard if all of the thresholds in the standard are crossed. One of the thresholds, the number of observed events divided by the number of expected events, is based on the program’s outcomes in relation to the risk-adjusted national average. Currently, that threshold, which was adopted in 2007, is 1.5. However, as national outcomes for organ transplants have improved over time, the margin for compliance and noncompliance has narrowed.

So, we are proposing to restore the CMS tolerance limit for patient and graft survival closer to the level allowed under the original 2007 rule by changing this threshold to 1.85. If the threshold is changed, transplant programs would not be out of compliance unless the number of observed events (one-year patient deaths or graft failures) divided by the number of expected events exceeds 1.85.

Additionally, we are also proposing several revisions to the “special procedures for approval and re-approval of organ transplant centers.” We are proposing to extend the time for organ transplant programs to notify CMS of their intent to request mitigating factors approval from 10 days to 14 calendar days; to clarify that the time period for submission of the mitigating factors information is calculated in calendar days; and to clarify CMS discretion regarding organ transplant Systems Improvement Agreements (SIAs).

**Contact:** The CY2017 Outpatient Perspective Payment System "OPPS" (CMS 1656-P) (PDF) is available at <https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-16098.pdf>. Comments may be submitted electronically through our e-Regulation website at: <https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Policies/eRulemaking/index.html> from July 14, 2016 until September 6, 2016.

**Effective Date:** Immediately. This memorandum should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/  
David R. Wright

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.*