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Transplant Center CMS Survey Process Part I: Preparing for Transplant Center Survey

August 25, 2009

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Today's Presentation

- Brief Review of CMS's Oversight of Transplant Centers
- Regulatory Requirements: Conditions of Participation for Transplant Centers
- How to Prepare for your Survey
- Lessons Learned
- Questions and Resources



History and Regulatory Background



History of CMS's Transplant Center Oversight

- **NCDs**
 - Outline conditions for Medicare payment approval for transplants performed at a Medicare-participating hospital

Organ	Date of NCD	Volume Requirement	Outcome Requirement (1-year survival)
Heart	1987	12	73 percent
Liver	1991	12	77 percent
Lung	1995	10	69 percent
Pancreas	1999 (with kidney) 2006 (isolated)	10	65 percent
Intestine	2001	10	65 percent



History of CMS's Transplant Center Oversight

- 2005-2006 inquiries by CMS regarding volume and outcome data
- Monitoring and enforcement of NCDs
 - Withdrawal of Medicare payment approval for some programs
 - Voluntary withdrawal from Medicare program
 - Corrective Action Plans



Shift to Conditions of Participation as Method of Oversight

- Town Hall Meeting in December 1999
- Revision of volume requirements in some NCDs (July 2000)
- Proposed Rule; 70 Fed. Reg. 6086 (Feb. 4, 2005)
- Final Rule; 72 Fed. Reg. 15198 (Mar. 30, 2007)



Shift to Conditions of Participation as Method of Oversight

- NCDs were no longer the appropriate mechanism for evaluating transplant centers
 - Transplantation no longer considered experimental
 - Survival standards in NCDs were too low
 - No mechanism for evaluating ongoing performance
- CoPs necessary to
 - Protect Medicare beneficiaries waiting for transplants
 - Establish quality and procedural standards for safety and efficiency
 - Reduce Medicare expenses by decreasing the likelihood that a transplant will fail



Transplant Center Conditions of Participation

- General requirements*
 - 42 C.F.R. §§ 482.72, 482.74 and 482.76
- Data submission, clinical experience and outcome requirements
 - 42 C.F.R. §§ 482.80 and 482.82
- Process requirements*
 - 42 C.F.R. §§ 482.90, 482.92, 482.94, 482.96, 482.98, 482.100 and 482.102
- Additional requirements for kidney transplant centers*
 - 42 C.F.R. §482.104

* For detailed information, please see handout.



Transplant Center Survey and Certification Process



Procedures for Initial Approval

- If already Medicare-approved as of June 28, 2007, submit request for initial approval under CoPs by December 26, 2007
 - Includes centers operating under a Corrective Action Plan pursuant to NCDs
- If not Medicare-approved as of June 28, 2007, submit request for initial approval at any time
 - Must include certain demographic information identified in the regulations
- **May be approved without a survey** if center meets the requirements of §482.80
- **Will be surveyed** for compliance if center does not meet the requirements of §482.80
- Initial approval is for a 3-year period



Survey Process

- Unannounced on-site surveys
- Performed by state agency or CMS national contractor
 - Usually 2 or 3 surveyors, but could be more
- Lasts from a few days to more than a week in some cases
 - Depends on number of programs to be surveyed
 - All of the hospital's organ transplant programs are surveyed during the same initial visit
- Surveys conducted in priority order set by CMS



Standard Survey Protocol

- Pre-survey preparation by survey team (off-site)
- **Entrance activities** (entrance conference)
 - Includes Program Director and all key personnel
 - Establish time frames for interviews, records production, etc.
- Orientation of survey team to transplant program areas
- Observations of care
- Sample selection
- **Patient interviews**
- **Review of medical records**
 - Transplant patients
 - Living donors
- **Staff interviews**
- Review of personnel records
- Administrative review
- Pre-exit activities
- **Exit conference**
- Post-survey activities (off-site)



How to Prepare for the Transplant Center Survey



Simplify the Survey Process

- Preparation
 - Make transplant center staff and physicians aware of process and what to expect
 - Update data frequently to show volume or other improvement
 - Mock surveys
 - Interview questions and document lists available on CMS website (and as a handout to this presentation)
 - Keep CMS updated with notifications of significant changes in the transplant program



Prepare Your Staff

- Anticipate that the reviewers will interview your staff extensively
- Educate all staff on the “new” requirements
- Train staff as to the appropriate way to answer questions during the survey
- Identify new hires within ninety days and prepare them for interview
- Anticipate that the reviewers will interview patients from each stage – pre-selection, selection, inpatient, and post transplant
- Provide a vacation day during survey for those employees who are resistant to the new regulations



Review of Documents

- Verify that ALL policies and procedures are consistent with the guidance
- Develop policies and procedures if none exists to address each aspect of the regulation
- Validate that clinical practice and your written policies and procedures are in sync
- Review personnel files and verify documentation of clinical competencies
- Verify that there is documentation of Quality Assurance activities consistent with the Quality Assurance and Performance Improvement requirements of the regulation



Audit & Monitor

- Audit medical record documentation for:
 - Consistency with internal requirements (policies and procedures)
 - Consistency with the regulatory requirements
- Focus on having complete documentation for ALL patients entering the program after the CoP became effective (June, 2007)



Lessons Learned



Where Do We Stand Today?

- As of July 21, 2009
 - 270 transplant centers (not hospitals) are operating under the CoPs
 - 408 currently approved transplant centers are still under NCDs
- Initial approval surveys prioritized by failure to meet clinical experience and outcomes requirements
 - CMS appears to have targeted outcome failures first
- According to CMS, only 2 facilities have been certified based on a mitigating factors review



Resources



CMS Resources

- CMS web site
 - http://www.cms.hhs.gov/CertificationandCompliance/20_Transplant.asp
- CMS contacts
 - Karen Tritz, Center for Medicaid and State Operations/Survey & Certification Group
 - karen.tritz@cms.hhs.gov
 - Linda O'Hara, Center for Medicaid and State Operations/Survey & Certification Group
 - linda.ohara@cms.hhs.gov



Upcoming Webinars

We hope that you will join us for Parts II and III of our Transplant Center CMS Survey Process Webinar Series:

- **Part II: Plan of Correction & Mitigating Factors of Review**
Wednesday, September 16, 2009
2:00-3:00 p.m. EDT
- **Part III: Tips for Ongoing Transplant Center Compliance**
Tuesday, September 29, 2009
2:00-3:00 p.m. EDT



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