



The New Medicare Survey and Certification Process

What Transplant Centers Need to Know

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Today's Presentation

- History of CMS's Oversight of Transplant Centers
- Regulatory Requirements: Conditions of Participation for Transplant Centers
- Survey and Certification Process: What to Expect and Tips for Navigating
- 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.



42 C.F.R. §§482.80 and 482.82

- Data submission requirement
 - At least 95 percent of all required data submitted no later than 90 days after due date established by OPTN
- Clinical experience requirement
 - 10 transplants per year
 - Exceptions: heart-lung, pancreas, pediatric
- Outcome requirements
 - 1-year post transplant outcomes for patient death and graft failure below expectations, as specified by CMS
 - Exceptions: heart-lung, intestine, liver-intestine, multivisceral transplants, pancreas



42 C.F.R. §§482.80 and 482.82

Organ	Volume Requirements	Outcome Requirements (1-year post transplant)
Heart	10	<ul style="list-style-type: none"> Observed patient and graft survival rates are lower than expected <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> One-sided p-value < 0.05; # of observed deaths or graft failures minus # of expected > 3; and # of observed deaths or graft failures ÷ # of expected > 1.5
Lung	10	
Heart-lung*	N/A	
Intestine*	10	
Liver	10	
Pancreas*	N/A	
Kidney	3 (initial approval) 10 (re-approval)	

* Not required to comply with outcome requirements in certain circumstances.



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



Scope of Survey

- Effective date of CoPs is June 28, 2007
- Impact on review of care provided prior to that date
 - Clinical experience vs. outcome requirements
 - Process requirements
 - Review of medical records should be limited to practices and activities after June 28, 2007



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)



Complaint Survey Protocol

- Scope of survey limited to relevant CoPs outlined in the complaint
- Can expand once on site, if needed



Report of Survey Findings

- **No deficiencies**
 - Receive a letter from the CMS Regional Office (RO) (or State Agency) indicating Medicare approval of the transplant center
 - May also receive a “clean” CMS Form 2567
- **Deficiencies**
 - Receive CMS Form 2567 (Statement of Deficiencies and Plan of Correction)
 - Within 10 days of completion of the on-site survey
 - Indicates whether deficiency is “condition-level,” “standard-level” or “criteria-level”
 - ALL programs included on a single CMS Form 2567
 - Provider should be notified via telephone or email of condition-level deficiencies (per *draft* CMS State Operations Manual)
 - CMS Form 2567 is accompanied by a letter from the RO (or State Agency) which includes a date by which compliance must be achieved in order to avoid termination from the Medicare program



Written Notification of Termination

- **Revocation of Medicare payment approval**
 - Sent to hospital on **10th working day**
 - Clock starts on Day 1 (the date the RO considers the CMS Form 2567 ready to send to the hospital)
 - Upon review of CMS Form 2567 if survey by State Agency
 - Upon receipt of CMS Form 2567 if survey by National Contractor
 - Initial notice should indicate the effective date of revocation
 - Requires 30-day advance notification to patients waiting for transplants
- **Termination date triggers on Day 1 (NOT the date of the hospital's receipt of the CMS Form 2567)**
 - Immediate jeopardy: **23 days**
 - Condition-level deficiency NOT related to clinical experience or outcomes: **90 days**
 - Condition-level deficiency related to clinical experience or outcomes: **210 days**



Deficiencies

- **Standard-level**
 - Center may be approved for (or continue) participation in the Medicare program
 - Re-survey is not mandatory
 - Requires an “acceptable” Plan of Correction
 - Example: 8-9 transplants over 12-month period for **initial approval**
 - Example: most recent SRTR report shows failure to meet outcome requirements **BUT** none of 4 prior reports show noncompliance
- **Condition-level**
 - Center will not be approved for (or continue) participation in the Medicare program (if not corrected within allowable time period)
 - 210 days to come into compliance if center is currently approved for Medicare payment
 - Example: less than 8 transplants over 12-month period for **initial approval**
 - Example: most recent SRTR report shows failure to meet outcome requirements **AND** 1 or more of the 4 prior reports show noncompliance



Deficiencies (Re-approval)

- **Clinical experience**
 - **Standard-level**
 - average of 8 or more transplants per year over the re-approval period; AND
 - 4 transplants in the last 12 months
 - **Condition-level**
 - Average of less than 10 transplants per year over the re-approval period: AND
 - does not meet criteria for standard-level deficiency



Plan of Correction

- Due to CMS Regional Office within 10 calendar days of receipt of the CMS Form 2567 Statement of Deficiencies
- Response made directly on CMS Form 2567
- Must address each citation
 - specific steps to address the noncompliance
 - timeframes for completing each step
 - expected outcomes following implementation
- Plan to correct condition-level deficiencies requires root cause analysis



Plan of Correction

- Include a “credible allegation of compliance” in order to trigger a revisit
 - Statement or documentation that
 - Is realistic in terms of the possibility of the corrective action being accomplished between the exit conference and the date of the allegation
 - Indicates resolution of the deficiency
- Indicate whether a mitigating factors review has been requested
 - Plan of Correction must be submitted even if a mitigating factors review is requested



Plan of Correction

- Should not be used to refute the deficiencies cited in the CMS Form 2567
 - However, submission of a Plan of Correction does not indicate agreement with the deficiencies noted
 - Disclaimer appropriate? Effective?
- Plan of Correction is due regardless of agreement with contents of the CMS Form 2567



Mitigating Factors Review

- Separate from Plan of Correction
- Goes directly to CMS Central Office
 - NOT to the Regional Office
- Written request for approval based on mitigating factors must be submitted **within 10 calendar days** of receipt of CMS-2567 Statement of Deficiencies
 - Have 30 days to submit additional explanatory materials and rationale
- Conducted by national panel of CMS staff with programmatic and clinical expertise
- CMS will consider factors including (but not limited to)
 - Extent to which outcome measures are met or exceeded (if compliance failure is due to volume)
 - Availability of other Medicare-approved transplant centers in the area
 - Extenuating circumstances (e.g., natural disaster) that would have a **temporary** effect on the center's ability to meet the CoPs



Mitigating Factors Review

- Only available if no indication of immediate jeopardy to patient health and safety
 - May be requested for any CoP
- Must include information specified by CMS
- Does not impact appeal rights or timing of termination
- Case by case review
- CMS contacts center by telephone to discuss results of the mitigating factors review
- Approval of Medicare participation based on mitigating factors review does not automatically carry forward to subsequent request for re-approval



Satisfactory Compliance Following Implementation of Plan of Correction

- Must show successful implementation of Plan of Correction accepted by CMS
- Follow-up survey(s) may be required to show compliance with CoPs
 - Revisit required for most condition-level deficiencies
 - Revisit at the discretion of the surveyors for standard-level deficiency
 - Compliance determined off-site for criteria-level deficiencies



Revisit Surveys

- For condition-level deficiencies not due to failure to meet clinical experience or outcomes requirements
 - Revisit required to determine **compliance or acceptable progress**
 - Maximum of 2 revisits permitted
 - One revisit within 45 calendar days of Day 1
 - Second revisit between the 46th and 90th calendar days
 - Second revisit is not guaranteed; must be supported by the State Agency and the RO
- For condition-level deficiencies due to failure to meet clinical experience or outcomes requirements
 - Revisit is NOT required to determine compliance
 - On Day 180, **acceptable progress** is determined using the information from the most recent SRTR Center-specific Report and volume data reported by the transplant center



Continued Noncompliance

- RO (or State Agency) will certify noncompliance
 - Day 55 for deficiencies not related to clinical experience or outcomes
 - Day 185 for failure to meet clinical experience or outcomes
- Determination regarding whether survey findings support a determination of noncompliance with the CoPs
 - Day 65 for deficiencies not related to clinical experience or outcomes
 - Day 190 for failure to meet clinical experience or outcomes



Continued Noncompliance

- RO sends official termination notice to the hospital, the public, and the State Medicaid Agency (if applicable)
 - Must be sent at least 15 calendar days before effective date of termination
 - Day 70 for deficiencies not related to clinical experience or outcomes
 - Day 195 for failure to meet clinical experience or outcomes
- If compliance not achieved with all CoPs, **termination** takes effect **no later than**
 - Day 90 for deficiencies not related to clinical experience or outcomes
 - Day 210 for failure to meet clinical experience or outcomes
- Termination may occur earlier if all required procedures are completed and/or a SRTR Center-specific Report is available which confirms the transplant center's noncompliance with outcome measures (if applicable)



Appeals

- Request for CMS Reconsideration
 - Transplant center may request reconsideration of the survey agency's/Regional Office's decision to terminate its Medicare payment approval
- Hearing before an administrative law judge (ALJ) if reconsideration determination is adverse
- Appeal to HHS Departmental Appeals Board if ALJ determination is adverse



Tips for Navigating the Transplant Center Survey and Certification Process



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
 - Keep CMS updated with notifications of significant changes in the transplant program
- Cooperation with survey team
 - Provide requested information as quickly as possible
 - Survey “blueprint” was developed to streamline the survey process
 - Delays result in extended surveys during which additional concerns may surface
 - Ensure necessary staff is available and informed sufficiently to answer questions
- Request an entrance conference if survey team does not have one
- Request TPQR and review for accuracy



Post-survey Process

- Be on the lookout for the CMS Form 2567
 - Disseminate copies immediately upon receipt
 - Key program personnel
 - Transplant coordinator
 - General counsel's office or outside counsel
- Confirm that you have received approval or disapproval for each organ transplant program at the hospital
 - RO may send a single approval or disapproval letter for each organ transplant program within a hospital, or one letter listing all approved programs and a separate letter listing all disapproved programs



Plans of Correction

- Pay close attention to surveyors during the survey to identify concerns that may be cited as deficiencies
- Maximize utility of exit conference to address “on the fence” concerns and avoid inclusion in Statement of Deficiencies
- No need to wait until receipt of the CMS Form 2567 to begin drafting the Plan of Correction
- Be realistic with projected dates for compliance
 - Leave sufficient time for CMS to confirm compliance through revisits before 90-day (or 210-day) period lapses



Mitigating Factors Review Requests

- Meet established deadlines for submission and include all required information
 - Initial request within 10 calendar days
 - Name of the hospital, type of transplant program, name of contact person, and which CoPs are the subject of the mitigating factors review request
 - Final (additional) explanatory materials (i.e., supporting documentation) within 30 calendar days
 - Reason for requesting mitigating factors review
 - Supporting evidence
 - Internal program improvements achieved (for example, since last SRTR center-specific report)
 - Outcomes data for past 3 years (if applicable) since last SRTR center-specific report
 - OPTN review (if any) of program
- Use guidance provided by CMS to identify examples of the types of information and factors it will consider
- Use resources wisely
 - Responsibility for mitigating factors review request and establishment of Plan of Correction could be shared between more than one person



Where Do We Stand Today?

- As of February 26, 2009
 - 130 transplant centers (not hospitals) are operating under the CoPs
 - 551 currently approved transplant centers are still under NCDs
- Initial approval surveys prioritized by failure to meet clinical experience and outcomes requirements
 - CMS appears to be targeting outcome failures first
- No word from CMS on how it will prioritize or schedule re-approval surveys



Resources



CMS Resources

- CMS web site
 - <http://www.cms.hhs.gov/CertificationandCompliance/2010/Transplant.asp>
- CMS contacts
 - Karen Tritz, Center for Medicaid and State Operations/Survey & Certification Group
 - (410) 786-8021
 - Karen.Tritz@cms.hhs.gov



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