TRANSPANT C-SUITE SNAPSHOT SERIES
REGULATORY OVERSIGHT AND REQUIREMENTS

HOW DID TRANSPLANT BECOME SO REGULATED?
• The National Organ Transplantation Act (NOTA, 1984) created the Organ Procurement Transplantation Network (OPTN) with private contractors: the United Network for Organ Sharing (UNOS) and the Scientific Registry for Transplant Recipients (SRTR).
• CMS approved transplant centers beginning in 1986, but provided no regulatory oversight until 2006.
• CMS drafted and issued formal Conditions of Participation for Transplant Programs in 2006, which were designed with the intent to improve transplant patient outcomes.
• All transplant programs were required to submit a letter to CMS agreeing to abide by the COPs.
• Interpretive Guidelines were released by CMS in 2008.
• Transplant programs then needed to implement policies to address the separate and distinct requirements of both CMS and UNOS.

SITE SURVEYS
• Each state’s Department of Health began surveying transplant programs every three years, and initial findings revealed that not every program was following the CMS COPs as intended.
• When programs were deemed non-compliant with the CMS COPs, CMS imposed very costly Systems Improvement Agreements (SIAs) on the transplant program, which required the program to demonstrate changes to policies, procedures and oversight.
• Over the course of 10 years:
  ◦ 145 programs cited by CMS
  ◦ 83 improved within the 210-day period
  ◦ 45 received an SIA
  ◦ 17 programs terminated participation with CMS
• UNOS also began conducting site surveys based on policies and bylaws in 2000 every three years on transplant and living donor programs.

ASSESSING TRANSPLANT PROGRAM QUALITY
• CMS COPs state that transplant programs must have a Quality Program
  ◦ Most transplant programs have a dedicated Quality Manager/Director/Analyst/Coordinator
  ◦ Data integrity is a key element to ensure accuracy of outcomes
• COP 482.96 states transplant programs must have a written, comprehensive data-driven QAPI program that outlines and demonstrates:
  ◦ Collaboration with hospital QAPI
  ◦ Bidirectional flow of information between hospital and transplant QAPI
  ◦ Collaboration with hospital Risk
• Adverse events policy:
  ◦ Identification on thorough analysis of events.
  ◦ Programs have a separate Transplant Adverse Events Policy.

IDENTIFYING HOW DATA IS OBTAINED AND ANALYZED
• UNOS began collecting data in 1987 and implemented an electronic database, UNetSM, to facilitate submissions, in 1999.
• Per UNOS guidelines, data is required to be submitted in UNetSM within 90 days of due date.
• Initially the data collected was analyzed by UNOS but this is now managed by an external group: SRTR.
• SRTR began reporting outcomes to the public in 1999 per regulatory requirements.
• CMS and private insurers began close surveillance of outcomes released by SRTR.

WHAT C-SUITES NEED TO KNOW
• To help facilitate transplant program success, Hospital C-Suites should:
  ◦ Obtain updates on transplant programs’ quality and outcomes (QAPI reports).
  ◦ Provide adequate staffing and resources for the multidisciplinary team.
  ◦ Ensure readiness with regulatory survey protocol.

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