

CMS Issues New Guidance Heightening Survey and Enforcement Risk for Donor Hospitals and OPOs

Insights

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On March 11, 2026, the Centers for Medicare & Medicaid Services (“CMS”) released [new guidance](#) reinforcing patient and family protections in the organ donation process and signaling an increase in survey and enforcement activity for donor hospitals and Organ Procurement Organizations (“OPOs”). Issued via memorandum to State Survey Agency Directors and updates to the [State Operations Manual](#), this guidance aligns with broader efforts by the U.S. Department of Health and Human Services (“HHS”) and Congress to bolster transparency and public trust in the organ transplant system.

CMS’s guidance reflects heightened federal scrutiny of organ donation practices, with recent enforcement activity and public reporting signaling increased attention to donation discussions, end of life decision making, and hospital–OPO interactions.

Highlights from the CMS Guidance

While the guidance largely reiterates existing regulatory requirements, CMS articulates those requirements in more explicit and prescriptive terms, emphasizing process, timing, and documentation. The following core expectations are highlighted:

- Hospitals and OPOs should maintain distinct responsibilities with respect to patient care throughout the process.
- Hospitals must ensure all patients receive full, life-saving treatment regardless of donor status.
- Donation discussions should not be rushed or perceived as coercive during moments of grief.
- OPOs must not influence end-of-life decisions, including withdrawal of life support or death declarations.
- Death must be declared in accordance with applicable law and accepted medical standards prior to beginning organ recovery activities.
- If signs of life are observed before or during recovery, OPOs should immediately stop procurement.

Notably, CMS emphasized that surveyors should formally cite noncompliance upon identification, even if the issue is corrected during the survey. This represents a significant departure from previous survey activities, and CMS identifies it as a purposeful component for transparency. As a result, consistent and well documented compliance practices remain critical.

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Practical Steps for Compliance

Hospitals, health systems, and OPOs should promptly evaluate their current practices and policies to ensure alignment with CMS's clarified expectations. Key areas for review include:

- **OPO–Hospital Agreements**
 - Ensure written agreements clearly define roles, responsibilities, and handoffs between hospitals and OPOs.
 - Address timing, consent processes, and communications with families in agreements.
 - Include procedures if signs of life are observed, including immediate reassessment and documentation.
- **Staff Training and Communication**
 - Reinforce training for all staff involved in organ donation discussions (clinicians, nurses, chaplains, social workers).
 - Emphasize appropriate language and conduct to avoid any appearance of pressure or urgency.
- **Medical Record Documentation**
 - Ensure records clearly reflect that all appropriate life-sustaining measures were provided prior to donation discussions.
 - Document clear separation between hospital decision-making and OPO involvement.
- **Withdrawal of Life Support Policies**
 - Review policies to confirm that OPO personnel are not involved—directly or indirectly—in withdrawal-of-life-support decisions.
 - Pay special attention to sedation, timing, and assessment protocols, which are identified as areas of concern by CMS, with the agency devoting new attention to donation after cardiac death (DCD).
- **Survey Preparedness**
 - Anticipate increased scrutiny of organ donation practices, including staff interviews and documentation review.
 - Be ready to demonstrate compliance through policies, training records, and consistent practice.

Heightened Scrutiny and the Upcoming OPO Recertification Cycle

Federal oversight of the organ donation and transplant system is intensifying, with the upcoming OPO recertification cycle expected to result in decertification or competition for service areas among OPOs. CMS [estimates](#) that approximately 10 of the 55 OPOs will be decertified and 16 will face competition for their donor service areas (DSAs). CMS [states](#) that transitions could begin as soon as January 2027.

This heightened scrutiny now extends to donor hospitals. As OPO service areas are reassigned, donor hospitals may find themselves working with a new OPO or needing to enter into new or updated agreements with an OPO—often under tight timelines and increased regulatory visibility. Hospitals should prepare for both closer survey attention and the operational impact of OPO transitions. CMS will publish 2026 OPO performance reports sometime this Spring, which will provide more context for any possible transitions by DSA.

Reflective of a harsher enforcement stance for OPO noncompliance, CMS notes that even one instance of noncompliance that is of serious threat to patient health and safety is sufficient to find condition-level noncompliance.

Key Takeaways

Increased oversight and scrutiny of the organ donation and transplant system likely will continue, with heightened and more explicit focus on donor hospitals alongside ongoing scrutiny of transplant hospitals. Organizations should consider:

- Reviewing and updating hospital-OPO agreements, policies, and protocols to reflect CMS's clarified expectations;
- Enhancing staff training and reinforcing appropriate communication practices;
- Ensuring robust documentation practices that clearly demonstrate compliance; and
- Anticipating and preparing for increased survey activity and possible OPO transitions.

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