DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality

Ref: QSO-26-05-[OPO & Transplant]

DATE: March 11, 2026

TO: State Survey Agency Directors

FROM: Director, Quality, Safety & Oversight Group (QSOG) and Survey & Operations Group (SOG)

SUBJECT: Organ Procurement Organizations (OPOs) and Donor Hospitals' Responsibilities

Memorandum Summary

- **This memorandum clarifies and reinforces the roles and responsibilities of** Organ Procurement Organizations (OPOs) and donor hospitals during the organ donation and procurement process.
- OPOs and hospitals are **required to approach potential donors and their families in a sensitive manner, which should be free of coercion or pressure.** Failure to follow the requirements constitutes noncompliance.
- **Noncompliance** related to this issue must be cited once identified, even if the deficiency has been corrected at the time of the survey.

Background:

Organ procurement and transplantation services are overseen by the Centers for Medicare & Medicaid Services (CMS) and the Health Resources & Services Administration (HRSA). Under HRSA's oversight, the Organ Procurement and Transplantation Network (OPTN) fulfills responsibilities outlined in the National Organ Transplant Act (1984), including the maintenance of a waitlist of individuals who need organs and a computer system to match those individuals with donated organs. OPTN member organizations include organ procurement organizations (OPOs), transplant hospitals, and histocompatibility laboratories. OPOs must comply with the Medicare Conditions for Coverage (CfCs) (42 CFR Part 486 Subpart G) for Medicare certification which include adhering to OPTN rules and requirements (§486.320). Donor hospitals[1] also must comply with CMS' Conditions of Participation (CoPs) for hospitals (42 CFR Part 482), including requirements related to organ, tissue and eye procurement (§482.45) which require hospitals to establish and implement written protocols for organ procurement. These entities are inspected for compliance by federal or state surveyors. Failure to comply with Medicare CfCs or CoPs can result in termination of an OPO's participation in the Medicare program, or for a hospital, termination of its participation in the Medicare and Medicaid programs.

[1] Donor Hospital: Hospitals that have the potential to admit patients who may become organ donors and are therefore responsible for identifying and referring potential donors to the designated Organ Procurement Organization (OPO).

OPOs and donor hospitals carry out complex, interactive, and complementary processes to facilitate the organ donation process and to increase opportunities to save lives through organ transplantation. Organ procurement occurs at a very difficult time for the potential donor's family. It is essential that the procurement process include sensitive and respectful discussions, avoiding families feeling rushed, pressured, or forced into premature decision-making.

Open and timely communication and collaboration between OPOs and donor hospitals maximizes donation opportunities and ensures a respectful and seamless process for potential donors and their families. At all times, it must be clear to all recovery participants (OPO and hospital staff) which organization is responsible for the care of the patient or potential donor, including following the declaration of the potential donor's death, until their remains are released to the funeral home selected by the family. Regardless of whether the patient is or is not a potential donor, they should be provided with the medical care due to all patients, consistent with current standards of practice and the expressed intent of the potential donor and/or family/legally authorized representative (LAR).

Discussion

OPOs and donor hospitals are required to develop and implement an agreement with specified organ procurement protocols to ensure that all involved individuals have clearly defined roles, responsibilities, and expectations for a successful donation process.

The OPO and hospital processes for organ procurement must include and effectively accomplish the following:

- Securing an agreement between the hospital and its designated OPO. The agreement should delineate the parameters for OPO interaction with the donor hospital staff and families or the LAR of patient/potential donors. Details about the agreement's contents are found in §486.322(a) for OPOs and §482.45(a)(1) for hospitals.
- Identifying a process for obtaining consent from the potential donor's family/LAR in the absence of first-person consent (the process should include details such as the timing of the contact, who makes the contact, their training, and the need for respect and sensitivity). Details about the information that must be provided to families are found in §486.342(a).
- Informing the family of every potential donor of the option to donate organs or decline to donate when first-person consent for donation is absent, in accordance with state and local laws. This request must be initiated by an organ procurement representative or a trained, designated requestor. Details about the qualifications for a designated requestor are found in §482.45(a)(3) and §486.322(b) and (c)(4).

Surveyor Tip #1: *During an OPO or hospital survey, surveyors must cite one or both entities if they fail to include the required elements in the OPO-hospital agreement or fail to comply with any of the applicable regulations noted above.*

OPO Role

Donor hospitals notify their designated OPO of deaths or imminent deaths based on criteria defined in their agreement with the OPO. This is commonly known as a "referral" or "patient

referral" between the hospital and OPO. Upon receiving this referral from the donor hospital, the OPO team rapidly goes onsite to determine the medical suitability of the potential donor. Determining the medical suitability of a potential donor to donate one or more organs is a complex and organ-specific process. This evaluation should be conducted in a manner that does not cause harm to the potential donor or disrupt their care as a patient.

Per §486.344, the OPO must establish a protocol for conducting evaluation and management (E&M) of the potential donor to determine medical suitability. This E&M protocol must meet current standards of practice and should address the following:

- Medical chart review.
- Laboratory testing (standard and additional as indicated).
- Other testing as indicated (echocardiogram, chest x-ray, etc.).
- Timeframes for donor protocol activities, including entering potential donor details into the national OPTN system.
- Documentation required (e.g., creation of a donor record by the OPO).
- OPO staff member interactions with family or LAR to collect information.
- OPO staff roles.

State Operations Manual (SOM) guidance for the requirements at §486.344 states that, "While the OPO may review the potential donor's hospital record without [patient, family or legally authorized representative] consent, in the absence of a donor document, consent from family or legally authorized representatives, or specific State law which allows invasive testing prior to consent, the OPO shall not conduct invasive testing prior to consent."

Surveyor Tip #2: *The OPO may review the potential donor's hospital record without consent; however, without consent, the OPO should not conduct invasive testing resulting in breaks in the skin or contact with the mucosa or internal body cavities beyond natural body orifices, unless allowed by state or local laws. This is consistent with national standards of practice and is stated in CMS SOM, Appendix Y guidance for the regulations at §486.344. The medical director is responsible for ensuring that potential donor evaluation and management protocols are implemented correctly and appropriately, including testing, in accordance with OPO policy and any corresponding requirements in the hospital agreement.*

Surveyor Tip #3: *Surveyors must ensure that the protocols adhere to the regulatory requirements referenced above, and that the OPO acts within that protocol. If an OPO recovers organs from donors after cardiac death, this includes having a protocol that addresses the criteria for declaration of death and the time that must elapse before the OPO can begin organ recovery. In the event of a potential donor's cardiac death, failure to wait the prescribed amount of time before recovering organs should be cited.*

The OPO is responsible for ensuring the recovery team is appropriately credentialed and may utilize hospital staff for some recovery roles. It must be clear which individuals are working for the OPO and which are working for the hospital, so their respective roles and responsibilities remain distinct during patient care and subsequent organ recovery. The OPO can prepare the patient for procurement, including draping the patient and monitoring the patient's status to protect organs for potential recovery; however, per OPTN Policy 2.15.F, no recovery staff should be present during the withdrawal of life support, but should be immediately available

following the declaration of death. After organ recovery, the OPO packages and transports the organ(s), according to the OPTN national allocation system, to the transplant program accepting on behalf of a patient awaiting transplant. The OPO should not seek to influence the timing of withdrawal of life support or take any action to hasten the declaration of death.

Hospital Role in Organ Procurement

In CMS's view, the primary responsibility of a hospital is to provide all medical care and set the patient on an optimal path to regain health and quality of life, regardless of whether they are a potential organ donor, in accordance with preferences for end-of-life health decision making, including as expressed in advance directives or health care powers of attorney, if any. A hospital's provisional identification of a patient as a potential organ donor should not affect the selection, quality, or urgency of the life-saving procedures that a patient receives when they are in critical condition. No action, other than those conducted to preserve life/regain health, should be taken until all life-saving measures have been exhausted.

Once the hospital care team has exhausted all appropriate life-sustaining measures and death is imminent (as specified in the OPO hospital agreement at 42 CFR 486.322), hospital clinicians and other appropriate hospital support personnel (such as chaplains, if requested) discuss withdrawing life support with the family, and notify the designated OPO. The OPO should not be involved in the decision to withdraw life support.

CMS is aware of concerns around the potential impact of sedatives used before or during withdrawal of life support and their effect on the clinical determination that the patient's death has occurred or is imminent. It is therefore critical that all hospital policies concerning the steps before organ recovery are followed, especially regarding the withdrawal or continuation of palliative sedation. Patient assessments should document the outcome of the assessment with consideration for any factors, such as sedatives, that could impact the accuracy of the assessment and the patient's ability to respond. See 42 CFR 482.24(c)(4)(vi) for medical records documentation requirements.

The discussion and decision to remove life support should be between the attending physician and the family/LAR, before any consideration of obtaining consent for organ donation. The family should be given every opportunity to grieve and come to terms with the loss of their loved one before being approached about organ donation. The process of the family deciding to allow withdrawal of life support could take minutes, hours, or days; the family must not be rushed.

Once a decision is made to pursue procurement, the hospital must continue to monitor the patient until death is pronounced and may continue to monitor after the declaration, depending on the specifications in the OPO-hospital agreement. It is desirable for hospital staff to continue to monitor the organ recovery process until organ recovery is completed. During procurement, the hospital team continues providing support under the guidance of the OPO to ensure optimal organ function.

Surveyor Tip #4: *Hospital regulations regarding organ donation at §482.45 largely mirror those for OPOs at §486.322. When feasible during the survey of a hospital or OPO, surveyors should interview relevant hospital staff about the OPO-hospital agreement, policies, and procedures for OPO-hospital interactions, including those prior to, during, and after the declaration of death, as outlined in the OPO-hospital agreement. Staff should clearly*

understand when the patient/potential donor is under the care of the hospital and when the patient/potential donor is under the care of the OPO, and this should be documented in the medical record. Interviews should assess staff training and awareness of the procedures, and inquire about any known departures from them, as well as how such instances were managed and resolved. During an OPO survey, this may require surveyors to request and review hospital policies and procedures pertaining to withdrawal of life support and organ recovery. If the surveyor finds that staff training did not occur or does not appear to be sufficient to fulfill their role in the donation process, they may cite §482.45(a)(5) if it's a hospital survey, or they may cite OPO requirements at §486.322(b) for the designated requestor, §486.326 for human resources, including having qualified staff; education, training, and supervision of staff; as well as medical director responsibilities for proper oversight of the clinical management of potential donors, and/or §486.344(a) for ensuring that the potential donor evaluation and management protocols are implemented correctly and appropriately.

Surveyor Tip #5: *To further investigate OPO actions or findings of OPO noncompliance, gather information from staff and medical records from the donor hospital that has an agreement with an OPO. Surveyors can also interview family, when appropriate, such as when there has been enough lapsed time since the death of a loved one that the family might be receptive to discussing their experience.*

Consent

A patient's status as a registered organ donor may be either known or unknown. For procurement and donation to proceed, the OPO must verify consent (when donor status is known) or obtain consent to donate organs. Consent may be obtained from the patient (when able) or by the family/LAR in the absence of first-person consent. See 42 CFR 486.342 for legal requirements.

- **Donation status is known**: In some cases, the patient's desire to become an organ donor after death is documented on a donor document, such as their driver's license, donor card, or donor registry. This is commonly referred to as first-person authorization or consent, which is the legal authority of OPOs and hospitals to uphold the individual's documented wish to donate. In cases where there is first-person consent but the family objects to the donation, the potential donor's wishes must be respected. Some state laws may impact this aspect of donation, including formal changes to the donor document, and these should be applied accordingly.

- **Donation status is unknown:** If there is no first-person consent in accordance with applicable state law and the patient does not have the mental capacity to understand the full implications of donation and make a reasoned decision, consent is obtained from an individual responsible for making medical decisions on behalf of the patient and consistent with applicable state laws. In these situations, the potential donor's family/LAR is approached to give consent (§486.342). Obtaining consent should be conducted only by individuals with appropriate training and must include sensitivity to the family/LAR situation (§482.45(a)(3)). For instance, family members may not agree about the donation, it may be contrary to their spiritual or cultural beliefs, or they may require additional time to grieve the apparent eventuality of their loved ones death. The timing and identification of the person to lead the donation conversation with the family

(who must be either an OPO representative or a trained designated requestor as described below) is specified in the OPO-hospital agreement and should take all of these factors into account. Where the family's decision is primary, their decision must be accepted and respected. At no time should there be forceful or repetitive requests (no pressure or harassment).

- **Family/LAR Rescinds Consent to Donate:** §482.13(a)(1) requires hospitals to inform each patient or their representative of the patient's rights, including the right to be free from all forms of abuse or harassment. Family/LAR who consent to donation (in the absence of first-person consent) may later rescind consent. This relieves the potential for pressuring, harassment, or coercion. Failure to provide these rights to the patient and their representative(s) can be cited for noncompliance at §482.45(a)(3)

Surveyor Tip #6: *When possible, surveyors should observe the OPO and hospital staff discussing organ donation with the family/LAR regarding the informed consent and the organ donation and recovery processes. If observation is not feasible due to the family's situation (distress with the loss of their loved one, etc.), the surveyor could interview (by phone if necessary) an individual who has had an experience with the OPO/hospital in the last six months (being mindful of the possibility of persistent grieving). Such a person could be identified using consents on file with the OPO or among designated requestor records. Inquire as to the family's/LAR's perspective in terms of not feeling rushed or pressured, harassed, or obligated to donate. Suggested inquiry: "Did you feel you received enough information and support during your time of loss and decision making about organ donation?" Refer to the SOM Appendix Y for other recommended questions and approach for this interview.*

OPOs and hospitals are both required to encourage discretion and sensitivity to the circumstances, views, and beliefs of the families of potential donors. (See §482.45(a)(4) for hospitals and §486.342 for OPOs). In general, this means assessing the family's understanding of the patient's medical condition and prognosis, providing information in a manner and format that is understandable to the family (e.g., consider limited literacy, including health literacy, limited English proficiency, use of translators when appropriate, etc.), providing opportunities for families to ask questions, understanding that this is a difficult time and decision for the family, and respecting the family's decision about donation, without placing pressure on the family when their decision is not to donate. Additionally, per §482.13(c)(3), hospitals are required to protect each patient's right to be free from all forms of abuse or harassment. Patient rights must be extended to the patient's family/LAR who are responsible for making decisions about the patient's care. Pressure to agree to a donation could constitute harassment. If so, hospitals could be cited for noncompliance with this requirement, regardless of which entity provided the pressure.

The family should not be approached regarding consent for donation by anyone other than an OPO representative or a designated requestor. A designated requestor is a staff member of either the OPO or the donor hospital (§482.45(a)(3)) who has completed all required training. Requestor training ***should not include*** content (formal or informal) that would encourage requestors to seek to influence or coerce families to donate organs but rather educate families and support their decision-making. Designated requestor training programs should include the following, as listed in CMS guidance in SOM Appendix Y:

- Communication with the appropriate hospital staff to discuss the approach to the family/LAR.
- Appropriate timing for approaching the family/LAR.
- Sensitivity to varying family or legally authorized representative situations.
- Support staff that should be included when the family or the LAR is approached to ensure they receive adequate information.
- Accepting decisions by the family/LAR to decline donation, in the absence of first-person consent verified in accordance with applicable state law.

Surveyor Tip #7*: Allegations of families feeling pressured or obligated to say "yes" to donation may indicate that the OPO (§486.342) or hospital (§482.45(a)(4)) has violated the requirements for discretion and sensitivity, or hospital patient's rights to be free from all forms of harassment (§482.13(c)(3)). Complaints against an OPO may be submitted through various channels, including CMS, the state survey agency, the Health Resources and Services Administration (HRSA), the OPO, or the hospital. Surveyors should investigate allegations of noncompliance with the federal requirements through staff and patient interviews with both OPO and hospital staff. This may require the surveyor to ask the hospital about complaints related to obtaining consent, withdrawing life support, or other organ donation matters. If noncompliance is found during an OPO or hospital survey, the surveyor must issue a citation, even if the OPO or hospital shows evidence that they implemented a corrective action after the noncompliance occurred.*

Declaration of Death

The decision to withdraw life support and the subsequent declaration of death, if death occurs, is solely the responsibility of the patient's attending physician or a hospital physician designee. Under §482.45, hospitals are required to have written protocols for organ, tissue, and eye donation. OPOs must verify that the pronouncement of death for potential donors adheres to applicable local, state and federal laws (§486.344(b)(1)), including in cases of Donation after Cardiac Death (also called Donation after Circulatory Death or DCD).

The OPO may not be involved in the decision or timing of withdrawal of life support or declaring death in any way. After the declaration and prior to beginning the organ recovery process, the OPO should confirm that death was pronounced and obtain a signed document confirming the date and time of the declaration of death.

Surveyor Tip #8*: During an OPO survey, surveyors should cite the OPO at §486.322(a) for failing to follow the OPO-Hospital agreement stipulations on initiating organ recovery, such as if the OPO is inappropriately involved or present in the operating room during withdrawal of life support or pronouncing death contrary to policies, and failure to adhere to the waiting period between the hospital's pronouncement of death and the OPO/surgical team's procurement of organs.*

Some potential organ donors have shown unexpected signs of life after being declared dead. The hospital should have clear and specific policies ensuring that the declaration of death and the organ procurement processes are transparent, that the protocols used to pronounce death, including pronouncing death in medically sedated patients, are based on accepted medical standards and are conducted with the utmost respect for the patient and their family, and that

staff are aware of and understand these policies. The OPO and hospital agreement should include procedures that must be followed if signs of life are observed at any time during the recovery process. This should include immediate reassessment and documentation of a patient's neurological and cardiac status to ensure patient safety and protocol adherence. If signs of life are observed before or during the recovery of an organ, OPOs are expected to immediately stop the procurement process. A prior declaration of death by the attending hospital physician does not permit OPOs to continue to pursue donation if signs of life are subsequently detected. Since in this situation the person is no longer a potential donor, the hospital should follow its plan for continued patient care and appropriate communication with the potential donor's family/LAR. Hospitals should work closely with the potential donor family/LAR and the OPO to determine the family/LAR wishes related to organ donation.

Surveyor Tip #9*: During a hospital survey, surveyors should interview hospital staff and review hospital protocols to ensure the assessment for declaring death is transparent and adheres to national standards of practice. Confirm that the hospital has relevant protocols in place and that staff are knowledgeable of their respective roles in the declaration of death. The protocol should address factors such as medications that may depress neurologic responsiveness and thereby impact the declaration of death. The protocol should also include what steps to take if a patient shows signs of life after death has been declared. (See Surveyor Tip #5 on hospital policy and procedures for declaration of death.)*

Closing Comments

OPOs and hospitals are required to engage potential donors (if they are responsive) and/or their families with discretion and sensitivity. Adhering to all federal regulations is critical for OPOs and hospitals to facilitate a successful organ donation process, honor the selfless decision of both the potential donor and their family and ensure public trust in the safety of the organ donation and transplantation system. If noncompliance with federal requirements is identified, it must be cited, even if the situation is subsequently addressed and corrected.

The Quality, Safety & Education Portal (QSEP) contains OPO and hospital survey process training materials as well as important resources to augment surveyors' understanding of the historical and current contexts surrounding the issues presented in this memo. Surveyors should access this site often to remain current on both OPO and donor hospital regulatory expectations.

Contact:
For questions or concerns relating to this memorandum, please contact QSOG_OPO@cms.hhs.gov.

Effective Date:
Immediately. Please communicate to all appropriate staff within 30 days.

Karen L. Tritz /s/ Melissa C. Daly
Director, Survey & Operations Group Acting Director, Quality, Safety & Oversight Group

Resources to Improve Quality of Care:
Check out CMS's new Quality in Focus interactive video series. The series of 10- to 15-minute videos are tailored to provider types and aim to reduce the deficiencies most commonly cited

during the CMS survey process, like infection control and accident prevention. Reducing these common deficiencies increases the quality of care for people with Medicare and Medicaid. Learn to:

- *Understand surveyor evaluation criteria*
- *Recognize deficiencies*
- *Incorporate solutions into your facility's standards of care*

See the Quality, Safety, & Education Portal Training Catalog, and select Quality in Focus

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