

# Clarifying Standards Applicability to Organ Procurement Organizations

Organ procurement organizations (OPOs) play a critical role in health care. The nation's 58 OPOs identify potential organ donors, coordinate the donation process, and are responsible for all organ recovery from deceased donors for transplantation. All OPOs are certified as meeting the Conditions for Coverage (CfCs) for OPOs,\* and the Centers for Medicare & Medicaid Services (CMS) designates one OPO per service area (which may include selected counties or entire states).

*The Joint Commission, which requires hospitals to have a written agreement with an OPO as part of its Transplant Safety (TS) Standard TS.01.01.01 (“The hospital, with the medical staff’s participation, develops and implements written policies and procedures for donating and procuring organs and tissues”), has received inquiries from hospitals about the applicability of certain other standards to OPOs.*

## Standard LD.04.03.09

One such standard is Leadership (LD) Standard LD.04.03.09 (“Care, treatment, and services provided through contractual agreement are provided safely and effectively”). Several hospitals have asked whether the services provided by OPOs are considered contracted services. Although hospitals and OPOs depend on one another to achieve the mutual goals of organ donation, recovery, and transplantation, their relationship is quite different from the traditional agreement between hospitals and contractors. The following unique organizational attributes distinguish OPOs from providers of contracted services:

**Federally Designated Entity.** One way OPOs differ from contractors is that they coordinate organ donation as federally designated entities and not on behalf of the hospital—that is, they are not paid by hospitals for their services. Instead, OPOs are required to meet performance-related standards in order to be reimbursed by CMS for the cost of their services.

**HIPAA Exemption.** In addition, OPOs are not considered business associates or vendors of the hospital as defined by the Health Insurance Portability and Accountability Act (HIPAA). HIPAA exemption 45 CFR 164.512(h) allows covered entities (hospitals) to use or disclose protected health information to OPOs without written patient consent or authorization for the purpose of facilitating organ, eye, or tissue donation and transplantation.

**Indirect Care.** Finally, although OPOs evaluate potential organ donors, notify the family of potential donors about the option to donate, and provide bereavement support for donor families, they do not provide direct care to living patients.

As stated in the Introduction to Standard LD.04.03.09, “This standard does not apply to contracted services that are not directly related to patient care.” Because the only contractual agreements subject to the requirements in LD.04.03.09 are for the provision of services provided to the hospital’s patients, the requirements for contracted services in Standard LD.04.03.09 do not apply to OPOs.

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## Human Resources (HR) Standards

Hospitals have also asked whether The Joint Commission HR standards apply to OPOs. Because the HR standards—like LD.04.03.09—focus on personnel providing patient care on behalf of the hospital, those requirements also are not applicable to OPOs.†

While the HR standards do not apply to OPOs, there are a number of federal regulations that address OPO staff qualifications and training. The CfCs require OPOs to ensure that all individuals who provide or supervise services are qualified to do so; therefore, OPOs maintain records for physicians and other practitioners who routinely recover organs to ensure that those individuals are qualified and trained.‡ Further, the Interpretive Guidelines for the CMS Hospital Condition of Participation regarding organ, tissue, and eye procurement state that hospitals are “not required to perform credentialing review for, or grant privileges to, members of organ recovery teams as long as the OPO sends only ‘qualified, trained individuals’ to perform organ recovery.”§

Though some hospitals choose to include personnel requirements in their hospital-OPO agreement, requirements specific to the HR and contracted services standards are unnecessary as those standards do not apply to OPOs. Hospitals are encouraged to incorporate flexibility in their expectations for OPOs as these organizations are already subject to considerable oversight from CMS and other entities.

† \* See 42 CFR 486, Subpart G, for more information.

Questions about this topic may be directed to the Standards Interpretation Group through its online question form at <http://www.jointcommission.org/Standards/OnlineQuestionsForm>

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† *Applicability to Contracted and Volunteer Personnel*” at [http://www.jointcommission.org/standards\\_information/jcfaqdetails.aspx?StandardsFAQId=344&StandardsFAQChapterId=66](http://www.jointcommission.org/standards_information/jcfaqdetails.aspx?StandardsFAQId=344&StandardsFAQChapterId=66).

§ See 42 CFR 486.326 for more information.

\*\* See A-0371 CMS Interpretive Guidelines for 42 CFR 482.45 for more information.

† See *Joint Commission Standards FAQ “Human Resources Standards*