

IS A HOSPITAL REQUIRED TO GRANT OPO EMPLOYEES ACCESS TO THE HOSPITAL OUTSIDE OF ITS STANDARD VENDOR/CONTRACT SERVICE PROVIDER CREDENTIALLING PROGRAM?

YES. *The CMS regulations mandate that OPOs perform specific duties related to the coordination of donation at the hospitals within the OPO's service area. The OPO is directly designated by the federal government to perform these duties, not as a vendor, business associate or contract service provider of the hospital. Hospitals are required under the Public Health Service Act authority and CMS regulations to work with the designated OPO by providing physical, EMR and family member access for OPO staff to facilitate organ, eye and tissue donation. Hospital credentialing programs for vendors, business associates or contract service providers are not applicable to OPO staff. Denying access to OPO staff on the basis of such a credentialing program is in violation of CMS regulations.*

1. OPOs are not vendors, business associates or contractor service providers of the hospital.

Under CMS regulation, hospitals are *required* to work with the OPO designated to them by CMS to facilitate all organ, eye and tissue donation. OPOs do not perform donation coordination services on behalf of the hospital but rather as the federally designated OPO for the region pursuant to CMS regulation and federal law; only federally designated OPOs can legally perform organ recovery for the purpose of transplantation. The CMS regulations require that OPOs and Hospitals enter into written agreements detailing the duties and responsibilities both parties have with regard to donation. Hospitals do not pay OPOs for this work. Rather, OPOs pay hospitals for services rendered by the hospital as requested by the OPO as part of coordinating donation.

See 42 CFR Section 482.45 (attached). See also the pre-amble to the HIPAA regulations where the federal government states that OPOs are not "business associates" of the hospitals based on the fact that OPOs are not performing services on behalf of the Covered Entity (the hospital). Fed. Reg. at 82462, 82688 Dec 28, 2000 (attached). This position has been re-iterated in a letter from the U.S. DHSS Office of General Counsel (OGC) in 2001. Although the letter is answering a different legal question, the DHHS OGC again states the federal government's position that (1) the relationship between hospitals and OPOs is not a business associate relationship and (2) OPOs are not health care providers.

The Joint Commission (TJC) provides clear direction that OPOs are not contracted services or patient care providers for the hospital and further clarify that Standard LD 04.03.09 and the entire HR Standard does not apply to OPOs. TJC encourages Hospitals to incorporate flexibility in their expectations for OPOs as these organizations are already subject to considerable oversight from CMS and other entities. See attachment The Joint Commission Perspectives, May 2014, Volume 34, Number 5.

2. Standard credentialing programs for vendors, business associates or contract service providers do not apply to OPO staff.

Because OPOs are not vendors, business associates or contract service providers of the hospitals they work with, a hospital's standard credentialing program for vendors, business associates or contract service providers does not apply to OPO staff who require access to the hospital facility and records for the purpose of facilitating transplantation of solid organs and tissues.

The CMS regulations on organ and tissue donation require that the OPO staff be "qualified and trained" as certified by the OPO. The CMS Interpretative Guidelines specifically clarify this point by stating that the hospital is "not required to perform credentialing reviews for, or grant privileges to, members of organ recovery teams as long as the OPO sends only 'qualified, trained individuals' to perform the organ recovery." See A-0371 CMS Interpretive Guidelines for 42 CFR Section 482.45 Conditions of participation: Organ, Tissue and Eye Procurement.

Hospitals can look to the OPO to confirm that the OPO staff, consistent with the CMS requirements, are "qualified and trained" to perform the OPO's responsibilities for coordinating donation including confirmation that OPO staff have complied with any mandated background checks or immunizations requirements. This approach has been consistent historically and is recognized by CMS and the Joint Commission as appropriate in other contexts when non-employed personnel are present in the hospital to perform other functions (e.g. personnel at the hospital from temporary staffing agencies).

3. Hospitals cannot deny OPO staff access.

Hospitals do not have the right to bar the designated OPO or its staff from performing their OPO Federal mandate in the hospital. It is reasonable that a hospital ensure through the CMS required agreement with the designated OPO that the OPO confirm its staff are qualified and trained and that it has taken steps to perform mandatory state and/or federally required background checks, or state and/or federally required immunizations. However, the CMS regulations do not provide a hospital the right to unilaterally determine that the *hospital* must perform or review these individual checks or perform or review these individual immunization records, or require an OPO to surrender an employee's entire Social Security number as an identifier if the OPO or employee objects.

OPOs provide services to sometimes hundreds of different hospitals in one service area and by necessity, given the 24/7 and unpredictable and time sensitive nature of donation events, it cannot always send the same staff to a particular hospital. The administrative burden and cost of each hospital performing or requiring its own individual review of every OPO staff record would be prohibitively burdensome and is not required or supported by the regulations.

Hospitals that bar OPO staff access to facilities or records on the basis of a vendor/contract service or provider credentialing program are interfering with the OPO's CMS mandated responsibilities in violation of federal law.

Further, the regulations require the OPOs and donor hospitals to work collaboratively to maximize organ, tissue and eye procurement for the purpose of transplantation.