



Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 13-48-OPO

DATE: July 26, 2013

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Organ Procurement Organizations (OPO) Agreements with Hospitals

Memorandum Summary

- **OPO Hospital Agreements:** Hospital regulations at 42CFR 482.45 (a)(1) require that all hospitals have written agreements in place with their OPO to notify them of an imminent death or of a death which has occurred. OPO regulations at §486.322 (a) require that OPOs have a written agreement in place with 95 percent of all participating Medicare and Medicaid hospitals and Critical Access Hospitals *that have both a ventilator and an operating room*. Historically, OPOs have not initiated agreements with hospitals without a ventilator and an operating room as donor maintenance cannot be accomplished in that setting.
- **OPO Agreements with Hospitals That Do Not Have a Ventilator and Operating Room:** While OPOs are not required to initiate agreements with hospitals that do not have a ventilator and an operating room, they are required at §486.303 (g) to enter into an agreement with any hospital that requests an agreement with them pursuant to the hospital regulations. However, for hospitals that do not have a ventilator and operating room, the agreement may be limited to notification of the OPO by the hospital of imminent death and/or death which has occurred in the facility.

Overview

Conditions of Participation for Hospitals at 42CFR 482.45 (a)(1) state that, “the hospital must have and implement written protocols that: Incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the hospital.”

Conditions for Coverage for Organ Procurement Organizations (OPO) at §486.322 (a) state, “An OPO must have a written agreement with 95 percent of the participating Medicare and Medicaid hospitals and critical access hospitals in its service area that have both a ventilator and an operating room and have not been granted a waiver to work with another OPO.”

Conditions for Coverage for Organ Procurement Organizations at §486.303 (g) state, “In order to be certified as a qualified organ procurement organization, an organ procurement organization must: Agree to enter into an agreement with any hospital or critical access hospital in the OPO’s service area, including a transplant hospital that requests an agreement.”

In a small percentage of hospitals (rehabilitation hospitals, psychiatric hospitals, long term care hospitals and small general hospitals without a ventilator and operating room) OPOs have not initiated agreements because there is no likelihood of organ recovery occurring at these hospitals; especially if these hospitals do not have a ventilator on premises. In most instances, these hospitals transfer patients, in the event their conditions become more complex or acute, to a higher level of care facility prior to the need for notification of imminent death. The OPO would then be notified of the imminent death by the higher level of care facility, with which the OPO would have an agreement in place.

Guidance

While the above practice is consistent with the OPO regulations, it does place a small percentage of hospitals in jeopardy of a deficiency citation by hospital surveyors. Unless and until revisions are made to the current hospital regulations, OPOs must agree to enter into an agreement with any hospital that requests such an agreement even though the hospital does not have a ventilator or operating room.

However, in cases where a hospital does not have a ventilator or operating room, the agreement may be limited to notification of the OPO by the hospital of an imminent death or a death which has occurred in the hospital. It is not required that the agreement, in these cases, include any provision for death record review, donor maintenance or the periodic provision of donation statistics to the hospital. The agreement may stipulate that the OPO staff will function as the Designated Requester for the hospital and thus no training will be required.

Effective Date: Immediately. This policy should be shared with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/

Thomas E. Hamilton

cc: Survey and Certification Regional Office Management