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# **CMS Manual System**

## **Pub. 100-07 State Operations Provider Certification**

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Department of Health &  
Human Services (DHHS)  
Centers for Medicare &  
Medicaid Services (CMS)

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**Transmittal 149**

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**Date: October 9, 2015**

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**SUBJECT: State Operations Manual (SOM) for All Types of Providers and Suppliers  
Subject to Certification**

**I. SUMMARY OF CHANGES:** Clarification is being provided for all providers and suppliers subject to certification as to the meaning of the terms “marriage,” “spouse,” and other terms that implicate the spousal relationship wherever used in the appendices.

**NEW/REVISED MATERIAL - EFFECTIVE: October 9, 2015  
IMPLEMENTATION October 9, 2015**

*The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.*

**II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)  
(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)**

<b>R/N/D</b>	<b>CHAPTER/SECTION/SUBSECTION/TITLE</b>
<b>R</b>	<b>Appendix A/Survey Protocol, Regulations &amp; Interpretive Guidelines for Hospitals/ Regulations &amp; Interpretive Guidelines</b>
<b>R</b>	<b>Appendix AA/Psychiatric Hospitals – Interpretive Guidelines and Survey Procedures</b>
<b>R</b>	<b>Appendix M/Guidance to Surveyors: Hospice/ Part II – Interpretive Guidelines</b>
<b>R</b>	<b>Appendix PP/Guidance to Surveyors for Long Term Care Facilities</b>
<b>R</b>	<b>Appendix W/Survey Protocol, Regulations and Interpretive Guidelines for Critical Access Hospitals (CAHs) and Swing-Beds in CAHs/Regulations &amp; Interpretive Guidelines for CAHs</b>
<b>R</b>	<b>Appendix Y/Organ Procurement Organizations (OPO) Interpretive Guidance/ Regulation §486.302 Definitions</b>

**III. FUNDING:** No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 20xx operating budgets.

**IV. ATTACHMENTS:**

	<b>Business Requirements</b>
<b>X</b>	<b>Manual Instruction</b>
	<b>Confidential Requirements</b>
	<b>One-Time Notification</b>
	<b>Recurring Update Notification</b>

# State Operations Manual

## Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals

### *Regulations and Interpretive Guidelines*

*(Rev. 149, Issued: 10-09-15, Effective: 10-09-15, Implementation: 10-09-15)*

*NOTE: in the regulations or guidance which follow, in every instance where the following terms appear:*

- *“spouse” means an individual who is married to another individual as a result of marriage lawful where it was entered into, including a lawful same-sex marriage, regardless of whether the jurisdiction where the hospital is located, or in which the spouse lives, permits such marriages to occur or recognizes such marriages.*
- *“marriage” means a marriage lawful where entered into, including a lawful same-sex marriage, regardless of whether the jurisdiction where the hospital is located, or in which the spouse lives, permits such marriages to occur or recognizes such marriages;*
- *“family” includes, but is not limited to, an individual’s “spouse” (see above); and*
- *“relative” when used as a noun, includes, but is not limited to, an individual’s “spouse” (see above).*

*Furthermore, except where CMS regulations explicitly require an interpretation in accordance with State law, wherever the text of a regulation or associated guidance uses the above terms or includes a reference to a patient’s “representative,” “surrogate,” “support person,” “next-of-kin,” or similar term in such a manner as would normally implicitly or explicitly include a spouse, the terms are to be interpreted consistent with the guidance above.*

*A hospital is expected to recognize all lawful marriages and spouses for purposes of compliance with the Conditions of Participation, regardless of any laws to the contrary of the state or locality or other jurisdiction where the hospital is located or where the spouse lives.*

# **State Operations Manual**

## **Appendix AA - Psychiatric Hospitals – Interpretive Guidelines and Survey Procedures**

### **Part II - Interpretive Guidelines - Psychiatric Hospitals**

*(Rev. 149, Issued: 10-09-15, Effective: 10-09-15, Implementation: 10-09-15)*

*NOTE: in the regulations or guidance which follow, in every instance where the following terms appear:*

- “spouse” means an individual who is married to another individual as a result of marriage lawful where entered into, including a lawful same-sex marriage, regardless of whether the jurisdiction where the psychiatric hospital is located, or in which the spouse lives, permits such marriages to occur or recognizes such marriages.*
- “marriage” means a marriage lawful where entered into, including a lawful same-sex marriage, regardless of whether the jurisdiction where the psychiatric hospital is located, or in which the spouse lives, permits such marriages to occur or recognizes such marriages;*
- “family” includes, but is not limited to, an individual’s “spouse” (see above); and*
- “relative” when used as a noun, includes, but is not limited to, an individual’s “spouse” (see above).*

*Furthermore, except where CMS regulations explicitly require an interpretation in accordance with State law, wherever the text of a regulation or associated guidance uses the above terms or includes a reference to a patient’s “representative,” “surrogate,” “support person,” “next-of-kin,” or similar term in such a manner as would normally implicitly or explicitly include a spouse, the terms are to be interpreted consistent with the guidance above.*

*A psychiatric hospital is expected to recognize all lawful marriages and spouses for purposes of compliance with the Conditions of Participation, regardless of any laws to the contrary of the state or locality or other jurisdiction where the psychiatric hospital is located or where the spouse lives.*

# State Operations Manual

## Appendix M - Guidance to Surveyors: Hospice -

### Part II – Interpretive Guidelines

*(Rev. 149, Issued: 10-09-15, Effective: 10-09-15, Implementation: 10-09-15)*

*NOTE: in the regulations or guidance which follow, in every instance where the following terms appear:*

- *“spouse” means an individual who is married to another individual as a result of marriage lawful where entered into, including a lawful same-sex marriage, regardless of whether the jurisdiction where the hospice is located, or in which the spouse lives, permits such marriages to occur or recognizes such marriages.*
- *“marriage” means a marriage lawful where entered into, including a lawful same-sex marriage, regardless of whether the jurisdiction where the hospice is located, or in which the spouse lives, permits such marriages to occur or recognizes such marriages;*
- *“family” includes, but is not limited to, an individual’s “spouse” (see above); and*
- *“relative” when used as a noun, includes, but is not limited to, an individual’s “spouse” (see above).*

*Furthermore, except where CMS regulations explicitly require an interpretation in accordance with State law, wherever the text of a regulation or associated guidance uses the above terms or includes a reference to a patient’s “representative,” “surrogate,” “support person,” “next-of-kin,” or similar term in such a manner as would normally implicitly or explicitly include a spouse, the terms are to be interpreted consistent with the guidance above.*

*A hospice is expected to recognize all lawful marriages and spouses for purposes of compliance with the Conditions of Participation, regardless of any laws to the contrary of the state or locality or other jurisdiction where the hospice is located or where the spouse lives.*

# State Operations Manual

## Appendix PP - Guidance to Surveyors for Long Term Care Facilities

### *Regulations and Interpretive Guidelines*

*(Rev. 149, Issued: 10-09-15, Effective: 10-09-15, Implementation: 10-09-15)*

*NOTE: in the regulations or guidance which follow, in every instance where the following terms appear:*

- “spouse” means an individual who is married to another individual as a result of marriage lawful where it was entered into, including a lawful same-sex marriage, regardless of whether the jurisdiction where the nursing facility (SNF/NF) is located, or in which the spouse lives, permits such marriages to occur or recognizes such marriages.*
- “marriage” means a marriage lawful where it was entered into, including a lawful same-sex marriage, regardless of whether the jurisdiction where the nursing facility is located, or in which the spouse lives, permits such marriages to occur or recognizes such marriages;*
- “family” includes, but is not limited to, an individual’s “spouse” (see above); and*
- “relative” when used as a noun, includes, but is not limited to, an individual’s “spouse” (see above).*

*Furthermore, except where CMS regulations explicitly require an interpretation in accordance with State law, wherever the text of a regulation or associated guidance uses the above terms or includes a reference to a patient’s “representative,” “surrogate,” “support person,” “next-of-kin,” or similar term in such a manner as would normally implicitly or explicitly include a spouse, the terms are to be interpreted consistent with the guidance above.*

*A nursing facility is expected to recognize all lawful marriages and spouses for purposes of compliance with the Conditions of Participation, regardless of any laws to the contrary of the state or locality or other jurisdiction where the nursing facility is located or where the spouse lives.*

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## **Appendix W - Survey Protocol, Regulations and Interpretive Guidelines for Critical Access Hospitals (CAHs) and Swing-Beds in CAHs**

### **Regulations and Interpretive Guidelines for CAHs**

*(Rev. 149, Issued: 10-09-15, Effective: 10-09-15, Implementation: 10-09-15)*

*NOTE: in the regulations or guidance which follow, in every instance where the following terms appear:*

- *“spouse” means an individual who is married to another individual as a result of marriage lawful where it was entered into, including a lawful same-sex marriage, regardless of whether the jurisdiction where the hospital is located, or in which the spouse lives, permits such marriages to occur or recognizes such marriages.*
- *“marriage” means a marriage lawful where it was entered into, including a lawful same-sex marriage, regardless of whether the jurisdiction where the hospital is located, or in which the spouse lives, permits such marriages to occur or recognizes such marriages;*
- *“family” includes, but is not limited to, an individual’s “spouse” (see above); and*
- *“relative” when used as a noun, includes, but is not limited to, an individual’s “spouse” (see above).*

*Furthermore, except where CMS regulations explicitly require an interpretation in accordance with State law, wherever the text of a regulation or associated guidance uses the above terms or includes a reference to a patient’s “representative,” “surrogate,” “support person,” “next-of-kin,” or similar term in such a manner as would normally implicitly or explicitly include a spouse, the terms are to be interpreted consistent with the guidance above.*

*A CAH is expected to recognize all state-sanctioned marriages and spouses for purposes of compliance with the Conditions of Participation, regardless of any laws to the contrary of the state or locality where the CAH is located.*

# **State Operations Manual**

## **Appendix Y - Organ Procurement Organization (OPO)**

### **Interpretive Guidance**

#### **Regulation**

##### **§486.302 – Definitions.**

*(Rev. 149, Issued: 10-09-15, Effective: 10-09-15, Implementation: 10-09-15)*

As used in this subpart, the following definitions apply:

Adverse event means an untoward, undesirable, and usually unanticipated event that causes death or serious injury or the risk thereof. As applied to OPOs, adverse events include but are not limited to transmission of disease from a donor to a recipient, avoidable loss of a medically suitable potential donor for whom consent for donation has been obtained, or delivery to a transplant center of the wrong organ or an organ whose blood type does not match the blood type of the intended recipient.

Guidance: The unintended transmission of a disease through organ transplantation would be considered an adverse event. There are limited instances where disease transmission may occur with the knowledge of the recovery personnel and the recipient. (See 486.344 (b)(2)).

Instances where the donor has a transmissible disease (e.g., Human Immune Deficiency Virus ((HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV)) and the recovered organ is transplanted into a recipient with the same transmissible disease with the informed consent of the recipient, would not be considered an adverse event.

Agreement cycle refers to the time period of at least 4 years when an agreement is in effect between CMS and an OPO.

Certification means a CMS determination that an OPO meets the requirements for certification at §486.303.

Death record review means an assessment of the medical chart of a deceased patient to evaluate potential for organ donation.

Decertification means a CMS determination that an OPO no longer meets the requirements for certification at §486.303.

Designated requestor or effective requestor is an individual (generally employed by a hospital), who is trained to handle or participate in the donation consent process. The designated requestor may request consent for donation from the family of a potential donor or from the individual(s) responsible for making the donation decision in circumstances permitted under State law, provide information about donation to the family or decision-maker(s), or provide support to or collaborate with the OPO in the donation consent process.

Designation means CMS assignment of a geographic service area to an OPO. Once an OPO is certified and assigned a geographic service area, organ procurement costs of the OPO are eligible for Medicare and Medicaid payment under section 1138(b)(1)(F) of the Act.

Donation service area (DSA) means a geographical area of sufficient size to ensure maximum effectiveness in the procurement and equitable distribution of organs and that either includes an entire metropolitan statistical area or does not include any part of such an area and that meets the standards of this subpart.

Donor means a deceased individual from whom at least one vascularized organ (heart, liver, lung, kidney, pancreas, or intestine) is recovered for the purpose of transplantation.

Donor after cardiac death (DCD) means an individual who donates after his or her heart has irreversibly stopped beating. A donor after cardiac death may be termed a non-heart beating or asystolic donor.

Donor document is any documented indication of an individual's choice in regard to donation that meets the requirements of the governing state law.

Eligible death for organ donation means the death of a patient 70 years old or younger, who ultimately is legally declared brain dead according to hospital policy independent of family decision regarding donation or availability of next-of-kin, independent of medical examiner or coroner involvement in the case, and independent of local acceptance criteria or transplant center practice, who exhibits none of the following:

(1) Active infections (specific diagnoses).

(i) Bacterial:

(A) Tuberculosis.

(B) Gangrenous bowel or perforated bowel and/or intra-abdominal sepsis.

(ii) Viral:

(A) HIV infection by serologic or molecular detection.

(B) Rabies.

(C) Reactive Hepatitis B Surface Antigen.

(D) Retroviral infections including HTLV I/II.

(E) Viral Encephalitis or Meningitis.

(F) Active Herpes simplex, varicella zoster, or cytomegalovirus viremia or pneumonia.

(G) Acute Epstein Barr Virus (mononucleosis).

(H) West Nile Virus infection.

(I) Severe acute respiratory syndrome (SARS).

(iii) Fungal:

(A) Active infection with Cryptococcus, Aspergillus, Histoplasma, Coccidioides.

(B) Active candidemia or invasive yeast infection.



(iv) Parasites:

Active infection with Trypanosoma cruzi (Chagas'), Leishmania, Strongyloides, or Malaria (Plasmodium sp.).

(v) Prion: Creutzfeldt-Jacob Disease.

**(2) General:**

(i) Aplastic Anemia.

(ii) Agranulocytosis.

(iii) Extreme Immaturity (<500 grams or gestational age of <32 weeks).

(iv) Current malignant neoplasms except non-melanoma skin cancers such as basal cell and squamous cell cancer and primary CNS tumors without evident metastatic disease.

(v) Previous malignant neoplasms with current evident metastatic disease.

(vi) A history of melanoma.

(vii) Hematologic malignancies: Leukemia, Hodgkin's Disease, Lymphoma, Multiple Myeloma.

(viii) Multi-system organ failure (MSOF) due to overwhelming sepsis or MSOF without sepsis defined as 3 or more systems in simultaneous failure for a period of 24 hours or more without response to treatment or resuscitation.

(ix) Active Fungal, Parasitic, viral, or Bacterial Meningitis or encephalitis.

(3) The number of eligible deaths is the denominator for the donation rate outcome performance measure as described at §486.318(a)(1).

Eligible donor means any donor that meets the eligible death criteria. The number of eligible donors is the numerator of the donation rate outcome performance measure.

Entire metropolitan statistical area means a metropolitan statistical area (MSA), a consolidated metropolitan statistical area (CMSA), or a primary metropolitan statistical area (PMSA) listed in the State and Metropolitan Area Data Book published by the U.S. Bureau of the Census. CMS does not recognize a CMSA as a metropolitan area for the purposes of establishing a geographical area for an OPO.

Expected donation rate means the donation rate expected for an OPO based on the national experience for OPOs serving similar hospitals and donation service areas. This rate is adjusted for the following hospital characteristics: Level I or Level II trauma center, Metropolitan Statistical Area size, CMS Case Mix Index, total bed size, number of intensive care unit (ICU) beds, primary service, presence of a neurosurgery unit, and hospital control/ownership.

Observed donation rate is the number of donors meeting the eligibility criteria per 100 deaths.

Open area means an OPO service area for which CMS has notified the public that it is accepting applications for designation.

Organ means a human kidney, liver, heart, lung, pancreas, or intestine (or multivisceral organs when transplanted at the same time as an intestine).

Guidance: In Federal Register Notice Vol. 78, No. 128 published July 3, 2013 the U.S. Department of Health and Human Services announced that vascular composite allografts (VCAs) will be added to the definition of organs covered by federal regulation and legislation. This designation was effective July 3, 2013.

Organ procurement organization (OPO) means an organization that performs or coordinates the procurement, preservation, and transport of organs and maintains a system for locating prospective recipients for available organs.

Re-certification cycle means the 4-year cycle during which an OPO is certified.

Standard criteria donor (SCD) per §486.302 means a donor that meets the eligibility criteria for an eligible donor and does not meet the criteria to be a donor after cardiac death or expanded criteria donor. This definition differs from the OPTN definition of a standard criteria donor which is a donor that does not meet the criteria to be a donor after cardiac death or expanded criteria donor.

Transplant hospital means a hospital that provides organ transplants and other medical and surgical specialty services required for the care of transplant patients. There may be one or more types of organ transplant centers operating within the same transplant hospital.

Urgent need occurs when an OPO's non-compliance with one or more conditions for coverage has caused, or is likely to cause, serious injury, harm, impairment, or death to a potential or actual donor or an organ recipient.

Guidance: The term "Urgent Need" should be considered to be synonymous with the Survey and Certification definition of "Immediate Jeopardy." (See §489.3) Follow procedures in the State Operations Manual (Appendix Q) for notification of the OPO and termination procedures when urgent need is identified.

***NOTE: in the regulations or guidance which follow, in every instance where the following terms appear:***

- ***"spouse" means an individual who is married to another individual as a result of marriage lawful where it was entered into, including a lawful same-sex marriage, regardless of whether the jurisdiction where the OPO is located, or in which the spouse lives, permits such marriages to occur or recognizes such marriages.***
- ***"marriage" means a lawful marriage, including a lawful same-sex marriage, regardless of whether the jurisdiction where the OPO is located, or in which the spouse lives, permits such marriages to occur or recognizes such marriages;***
- ***"family" includes, but is not limited to, an individual's "spouse" (see above); and***

- *“relative” when used as a noun, includes, but is not limited to, an individual’s “spouse” (see above).*

*Furthermore, except where CMS regulations explicitly require an interpretation in accordance with State law, wherever the text of a regulation or associated guidance uses the above terms or includes a reference to a patient’s “representative,” “surrogate,” “support person,” “next-of-kin,” or similar term in such a manner as would normally implicitly or explicitly include a spouse, the terms are to be interpreted consistent with the guidance above.*

*An OPO is expected to recognize all lawful marriages and spouses for purposes of compliance with the Conditions of Participation, regardless of any laws to the contrary of the state or locality or other jurisdiction where the OPO is located or where the spouse lives.*