

CMS Regulation Update: F-155
Rights Regarding Treatment & Advance Directives
Effective Date: 11/30/12
Revised: 3/8/13

Legal Authority: the Federal Patient Self-Determination act contained in Public Law 101-508.

Intent:

- Each facility will establish & maintain policies and procedures regarding Treatment & Advance Directives.
- Each facility will inform and educate every resident [including resident's children and legal representative] about these rights and the facility's policies regarding exercising these rights. For example, a facility may have a policy that they perform CPR on everyone.
- Each facility will help every resident to exercise these rights, such as providing assistance with writing an advance directive.
- Each facility will incorporate the resident's choices regarding these rights into treatment, care, and services through vehicles such as physician orders and/or the resident's plan of care.
- *Applies only to adults unless State law has provisions governing the rights of parents/guardians to formulate advance directives for terminally ill or severely disabled children.*

New CMS Definitions:

- **Advance care planning:** process to identify & update the resident's preferences regarding care and treatment at a future time including a situation in which the resident subsequently lacks the capacity to do so.
- **Cardiopulmonary resuscitation:** refers to any medical intervention used to restore circulatory and/or respiratory functions that has ceased.
- **Durable Power of Attorney for Health Care:** a document delegating to an agent the authority to make health care decisions in case the individual delegating that authority subsequently becomes incapable of doing so.
- **Experimental Research:** *the development, testing, and use of a clinical treatment, such as an investigational drug or therapy that has not yet been approved by the FDA or medical community as effective and conforming to accepted medical practice.*
- **Health care decision-making:** Consent, refusal to consent, or withdrawn consent to health care, treatment, services, or a procedure to maintain, diagnose, or treat an individual's physical or mental condition.
- **Health care decision-making capacity:** possessing the ability [as defined by State Law] to make decisions regarding health care and related treatment choices.
- **Investigational or experimental drugs:** *new drugs that have not yet been approved by the FDA or approved drugs that have not yet been approved for a new use, and are in the process of being tested for safety and effectiveness.*
- **Life-sustaining treatment:** treatment that, based on reasonable medical judgment, sustains an individual's life and without which the individual will die; includes both life sustaining medications and interventions such as mechanical respiration, kidney dialysis, and artificial nutrition and hydration; does not include pain management, measures to enhance comfort, or medical care to alleviate pain.
- **Legal representative:** a person designated and authorized by an advance directive or by State law to make a treatment decision for another person in the event the other person becomes unable to make necessary health care decisions [agent, attorney in fact, proxy, substitute or surrogate decision-maker].

Each facility is required by 42CFR § 489.102-“Requirements for Providers” to provide, at admission, written information concerning the resident's rights to make decisions concerning medical care, including the right to refuse medical or surgical treatment, decline to participate in clinical research, and the right to formulate advance directives. The resident must also receive a written description of the facility's policies that govern the exercise of these rights.

Investigative Protocol
Regarding Treatment, Participation in Experimental Research, & Advance Directives
Effective Date: 11/30/12
Revised: 3/8/13

Purpose-to determine whether a facility has promoted the resident's right to accept or refuse treatment, *refuse to participate in experimental research*, and to formulate an advance directive.

Applies to residents who:

1. *Are the subject of complaints related to a resident's right to refuse medical or surgical treatment, participate in experimental research, formulate an advance directive, or related to a facility's failure to provide written information, policies and procedures related to advance directives.*
2. *All sampled residents identified with orders or a condition potentially related to provision of life-sustaining treatments such as artificial nutrition/hydration, ventilation, dialysis, blood transfusions, or cardiopulmonary resuscitation.*
3. Refused medical or surgical treatment.
4. *Are participating in an experimental research activity or project.*

Evidence:

1. **Observations:** Make observations of care and treatments provided during various shifts on various days to determine whether care and services are consistent with care plan, progress notes, and resident choices related to the following resident criteria:
 - a. *Participation in experimental research,*
 - b. Refusal of medical or surgical treatment, or
 - c. Provision of life-sustaining treatment
2. **Interviews:**
 - a. Resident and/or family members/decision makers about how the facility:
 - i. Determined the resident's choices regarding care & treatment at admission;
 - ii. Informed the resident/decision maker about resident's health condition and treatment options;
 - iii. Helped the resident/decision makers document the resident's choices [advance directives], *and*
 - iv. *Provided information prior to the start of the research project that sufficiently explained the research, risks/benefits, and informed the resident of his or her right to refuse to participate in the research project.*
 - b. Staff about how the facility:
 - i. Determines the resident's advance directive wishes;
 - ii. Trains staff regarding the initiation of advance directives;
 - iii. Assesses the resident's capacity to make decisions;
 - iv. Informs residents/decision makers about the resident's condition;
 - v. *Informs the resident/significant other about treatment options and the right to refuse medical, surgical, and research-based options;*
 - vi. Helps resident/decision maker formulate advance directives;
 - vii. Documents and communicates treatment decisions to the interdisciplinary team;
 - viii. *Monitors and safeguards the rights of the resident who participates in experimental research;*
 - ix. Informs staff about where to access advance directive information; and
 - x. Assures that practitioner orders and treatment decisions are consistent with resident advance directives.
 - c. Health care practitioners/professionals about how the facility:
 - i. Seeks, identifies, & documents resident's wishes regarding advance directives;
 - ii. Assures that medical orders and treatments reflect the resident's choices;
 - iii. Involves staff and practitioners in advising the resident about the right to refuse treatment and the consequences;
 - iv. Communicates residents' documented choices to the interdisciplinary team;

- v. *Obtains and documents informed consent of the resident who desires to participate in experimental research;*
 - vi. *Proceeds if the resident who is involved in experimental research is suffering adverse consequences related to the experimental treatment regimen;*
 - vii. Obtains timely access to the resident's advance directives and choices during routine, urgent, and emergent care; and
 - viii. Periodically reassesses the resident's condition and prognosis and determines the need to review advance directives with the resident when there is a decline or improvement in the resident's condition.
- d. **Record Review of:**
- i. Each sample resident for any information regarding initiating, continuing, withholding, or withdrawing treatment consent; refusing to participate in experimental research; formulate advance directives; and whether the care plan considers the resident's choices: determine whether:
 - 1. There is documentation of the rationale for recommendations and treatment decisions related to life-sustaining treatment options;
 - 2. *Orders are consistent with the resident's documented choices and goals [unless a physician needs more information about the residents decisional capacity, has a conscientious objection to the resident's decision or other aspects of the case in order to be comfortable writing orders that are consistent with the resident's expressed wishes];*
 - 3. *There is documentation of monitoring of the resident's response and adverse consequences to any experimental treatments, including frequency and scope of monitoring;*
 - 4. Treatments or interventions have been ordered [e.g. unplanned hospitalizations or placement of a feeding tube] that are inconsistent with the resident's documented treatment preferences or with any existing advance directives; and
 - 5. The resident's advance directives, if formulated, have been incorporated into his or her active record, including in medial orders, progress notes, the resident care plan, or other relevant means of communication to the interdisciplinary team.
 - ii. Facility processes related to determining and documenting resident advance care planning and implementation of medical orders that reflect a resident's wishes as revealed in:
 - 1. Policies and Procedures,
 - 2. Processes,
 - 3. In-service records, and
 - 4. Job descriptions, and
 - 5. Other facility documents.

CRITERIA FOR COMPLIANCE: the facility is in compliance if the facility has:

- 1. Implemented policies & procedures regarding the resident's right to formulate advance directives and to accept or decline treatments and interventions *and to decline to participate in experimental research;*
- 2. Educated and informed resident about these rights and the facility's policies regarding these rights;
- 3. Determined whether the resident has an advance directive in place, has offered the resident the opportunity to develop one, and assisted the resident in developing one;
- 4. Documented when it has been determined that a resident does not have decision-making capacity and the identity of the resident's legal representative;
- 5. Helped the resident to exercise these rights by explaining the risk and benefit of accepting or declining treatment, care, and services;

6. Incorporated the resident's choices into the medical record and orders related to treatment, care, and services;
7. Consistently maintained advance directives and resident treatment goals in the same section of the clinical record for easy retrieval by staff during routine, urgent, and emergent care situations;
8. Monitored care and services to assure they are consistent with the resident's documented choices and goals.

Level IV examples: The resident was transferred to the hospital for an acute change of condition and resuscitated against his or her documented wishes **or** the resident was found unconscious and was not resuscitated despite his or her documented wishes for resuscitation.

Level III example: The facility failed to identify practitioner orders that detailed the resident's wish to forgo diagnostics, treatment, and hydration for the resident's 7th episode of aspiration pneumonia and staff refused to allow the resident to attend his son's wedding, insisting that the resident remain so a chest x-ray and blood work could be done, against the resident's wishes.

Level II examples:

1. The facility failed to establish and implement policies and procedures regarding the right to decline treatment/interventions, the resident/decision maker was unaware of the opportunity to decline medical treatment/intervention, although no situation had yet arisen involving the use of life-sustaining treatment options.
2. The facility failed to obtain medical orders that were consistent with the resident's documented wishes, staff was unaware of the resident's wishes, although no situation had yet arisen involving the use of life-sustaining treatment options.

Level I example:

1. The facility failed to recognize and facilitate the exercising of the resident's right to refuse treatment and to formulate an advance directive; and
2. The facility failed to maintain written policies and procedures regarding the rights to refuse treatment and to formulate advance directives.