

F578

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§483.10(c)(6) The right to request, refuse, and/or discontinue treatment, to participate in or refuse to participate in experimental research, and to formulate an advance directive.

§483.10(c)(8) Nothing in this paragraph should be construed as the right of the resident to receive the provision of medical treatment or medical services deemed medically unnecessary or inappropriate.

§483.10(g)(12) The facility must comply with the requirements specified in 42 CFR part 489, subpart I (Advance Directives).

- (i) These requirements include provisions to inform and provide written information to all adult residents concerning the right to accept or refuse medical or surgical treatment and, at the resident's option, formulate an advance directive.**
- (ii) This includes a written description of the facility's policies to implement advance directives and applicable State law.**
- (iii) Facilities are permitted to contract with other entities to furnish this information but are still legally responsible for ensuring that the requirements of this section are met.**
- (iv) If an adult individual is incapacitated at the time of admission and is unable to receive information or articulate whether or not he or she has executed an advance directive, the facility may give advance directive information to the individual's resident representative in accordance with State law.**

- (v) **The facility is not relieved of its obligation to provide this information to the individual once he or she is able to receive such information. Follow-up procedures must be in place to provide the information to the individual directly at the appropriate time.**

DEFINITIONS §483.10(c)(6), (c)(8), (g)(12)

“Advance care planning” is a process of communication between individuals and their healthcare agents to understand, reflect on, discuss, and plan for future healthcare decisions for a time when individuals are not able to make their own healthcare decisions.

“Advance directive” is “a written instruction, such as a living will or durable power of attorney for health care, recognized under State law (whether statutory or as recognized by the courts of the State), relating to the provision of health care when the individual is incapacitated.” See §489.100.

“Physician Orders for Life-Sustaining Treatment (or POLST) paradigm form” is a form designed to improve patient care by creating a portable medical order form that records patients’ treatment wishes so that emergency personnel know what treatments the patient wants in the event of a medical emergency, taking the patient’s current medical condition into consideration. A POLST paradigm form is not an advance directive.

“Experimental research” refers to 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” refers to consent, refusal to consent, or withdrawal of consent to health care, treatment, service, or a procedure to maintain, diagnose, or treat a resident’s physical or mental condition.

“Health care decision-making capacity” refers to possessing the ability (as defined by State law) to make decisions regarding health care and related treatment choice.

GUIDANCE §483.10(c)(6), (c)(8), and (g)(12)

The resident has the right to request treatment; however, facility staff are not required to provide medical treatment or services if the requested treatment or services are medically unnecessary or inappropriate. While the resident also has the right to refuse any treatment or services, the resident’s refusal does not absolve facility staff from providing other care that allows him/her to attain or maintain his or her highest practicable physical, mental, and psychosocial well-being.

For example, facility staff would still be expected to provide appropriate measures for pressure injury prevention, even if a resident has refused food and fluids and is nearing death.

If a resident (directly or through an advance directive) declines treatment (such as refuses artificial nutrition or IV hydration, despite having lost considerable weight), the resident may not

be treated against his or her wishes. If a resident is unable to make a health care decision, a decision by the resident's legal representative to forego treatment may, subject to State requirements, be equally binding on the facility. A resident may not be transferred or discharged for refusing treatment unless the criteria for transfer or discharge are otherwise met. Facility staff should attempt to determine the reason for the refusal of care, including whether a resident who is unable verbalize their needs is refusing care for another reason (such as pain, fear of a staff member, etc.), and address the concern, if possible. Any services that would otherwise be required, but are refused, must be described in the comprehensive care plan. See F656, Comprehensive Care Plans, for further guidance.

The resident has the right to refuse to participate in experimental research. A resident being considered for participation in experimental research must be fully informed of the nature of the experimental research (for example, medication or other treatment) and the possible consequences of participating. The resident must provide informed consent prior to participation and initiation of experimental research. If the resident is incapable of understanding the situation and of realizing the risks and benefits of the proposed research, but a resident representative gives consent, facility staff have a responsibility to ensure that the consent is properly obtained and that essential measures are taken to protect the resident from harm or mistreatment. The resident (or his or her representative if the resident lacks health care decision-making capacity) must have the opportunity to refuse to participate both before and during the experimental research activity.

The ability of a dying person to control decisions about medical care and daily routines has been identified as one of the key elements of quality care at the end of life. The process of advance care planning is ongoing and affords the resident, family, and others on the resident's interdisciplinary health care team an opportunity to reassess the resident's goals and wishes as the resident's medical condition changes. Advance care planning is an integral aspect of the facility's comprehensive care planning process and assures re-evaluation of the resident's desires on a routine basis and when there is a significant change in the resident's condition. The process can help the resident, family and interdisciplinary team prepare for the time when a resident becomes unable to make decisions or is actively dying.

The facility is required to establish, maintain, and implement written policies and procedures regarding the residents' right to formulate an advance directive, *including the right to accept or refuse medical or surgical treatment*. In addition, the facility management is responsible for ensuring that staff follow those policies and procedures.

The facility's policies and procedures delineate the various steps necessary to promote and implement these rights, including, but not limited to:

- Determining on admission whether the resident has an advance directive and, if not, determining whether the resident wishes to formulate an advance directive;
- Providing information in a manner easily understood by the resident or resident representative about the right to refuse medical or surgical treatment and formulate an advanced directive. This includes a written description of the facility's policies to implement advance directives and applicable State law regarding advance directives.

- Determining if facility staff periodically assesses the resident for decision-making capacity and invokes health care agent or representative if the resident is determined not to have decision-making capacity;
- Identifying the primary decision-maker (assessing the resident's decision-making capacity and identifying or arranging for an appropriate representative for the resident assessed as unable to make relevant health care decisions);
- Defining and clarifying medical issues and presenting the information regarding relevant health care issues to the resident or his or her representative, as appropriate;
- Identifying, clarifying, and periodically reviewing, as part of the comprehensive care planning process, the existing care instructions and whether the resident wishes to change or continue these instructions;
- Identifying situations where health care decision-making is needed, such as a significant decline or improvement in the resident's condition;
- Establishing mechanisms for documenting and communicating the resident's choices to the interdisciplinary team and to staff responsible for the resident's care; and
- Identifying the process (as provided by State law) for handling situations in which the facility staff and/or physician do not believe that they can provide care in accordance with the resident's advance directives or other wishes on the basis of conscience.

If the resident or the resident's representative has executed one or more advance directive(s), or executes one upon admission, copies of these documents must be obtained and maintained in the same section of the resident's medical record readily retrievable by any facility staff. Facility staff must communicate the resident's wishes to the resident's direct care staff and physician.

If the resident does not have an advance directive, facility staff must inform the resident or resident representative of their right to establish one as set forth in the laws of the State and provide assistance if the resident wishes to execute one or more directive(s). Facility staff must document in the resident's medical record these discussions and any advance directive(s) that the resident executes.

The resident has the option to execute advance directives, but cannot be required to do so. As required by 42 C.F.R. §489.102(a)(3), the facility may not condition the provision of medical care or discriminate against a resident based on whether he or she has executed an advance directive. Facility staff are not required to provide care that conflicts with an advance directive. In addition, facility staff are not required to implement an advance directive if, as a matter of conscience, the provider cannot implement an advance directive and State law allows the provider to conscientiously object.

NOTE:Other directives a resident may choose to exercise may include, but are not limited to, a directive to the attending physician, a medical power of attorney, a pre-existing medical order for "do not resuscitate" (DNR), or another document that directs the resident's health care such as Do Not Hospitalize (DNH). Several States have adopted the use of a portable and enduring order form that documents the resident's choices related to life-sustaining treatments while some States recognize documented oral instruction.

Facility staff should periodically review with the resident and resident representative the decisions made regarding treatments, experimental research and any advance directive and its provisions, as preferences may change over time.

PROCEDURES §483.10(c)(6), (c)(8), (g)(12)

- Observe for efforts on the part of facility staff to inform residents or their representative of their rights and that information is communicated at times it would be most useful to them, such as when they are expressing concerns, or raising questions.
- Interview the resident, resident's representative and facility staff to determine if:
 - o Residents are informed in a manner they understand of their right to request or refuse treatment;
 - o A resident has an advance directive and if staff are aware of what this directive states;
 - o A resident does not have an advance directive and, if so, how the resident was informed of his or her right to develop one and was the resident provided assistance in doing so; and
 - o Staff periodically assess a resident's decision making capacity, how often and how and by whom is this done.
- Review the resident's medical record to determine if:
 - o The resident has an advance directive and a copy is located in the medical record; and
 - o The facility has policies and procedures to implement advance directives.

KEY ELEMENTS OF NONCOMPLIANCE §483.10(c)(6), (c)(8), (g)(12):

To cite deficient practice at F578, the surveyor's investigation will generally show that the facility failed to do one or more of the following:

- Provide information to the resident regarding their right to refuse medical or surgical treatment or to formulate an advance directive once the resident was able to receive the information; or
- Honor a resident's, their family, and/or their representative's decision to request, refuse, or discontinue experimental research; or
- Ensure that a current copy of a resident's advance directive was in the resident's medical record; or
- Have policies and procedures for implementing advance directives; or
- Follow policies to implement advance directives and applicable State laws regarding advance directives.

POTENTIAL TAGS FOR ADDITIONAL CONSIDERATION

Examples of some of the related requirements that may be considered when non-compliance has been identified include, but are not limited to, the following:

- 42 CFR §483.10(a)(3)-(7), F551 o For concerns regarding designation of resident representative.

- 42 CFR §483.10(c)(2)-(3), F553, Right to Participate in Planning Care o For concerns regarding the resident's right to participate in and be informed of his or her treatment.