# §483.10(b)(4) and (8) Rights Regarding Advance Directives, Treatment, and Experimental Research (F155)

Surveyor Training of Trainers:

Interpretive Guidance

Investigative Protocol

# Federal Regulatory Language

**§ 483.10(b)(4) – The resident has the right to refuse treatment, to refuse to participate in experimental research, and to formulate an advance directive as specified in paragraph (8) of this section; and**

## Federal Regulatory Language (cont'd.)

**§483.10(b)(8) – The facility must comply with the requirements specified in subpart I of part 489 of this chapter relating to maintaining written policies and procedures regarding advance directives. 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 individual's option, formulate an advance directive. This includes a written description of the facility's policies to implement advance directives and applicable State law.**

## Intent

The intent of this requirement is that the facility promotes these rights by:

- Establishing, maintaining and implement policies and procedures regarding these rights;

- Informing and educating the resident (family/responsible party) of these rights and the facility's policies regarding exercising these rights;

## **Intent** (cont'd.)

The intent of this requirement is that the facility promotes these rights by:

- Helping the resident to exercise these rights; and
- Incorporating the resident's choices regarding these rights into treatment, care and services.

## Definitions

**“Advance care planning”** is a process used to identify and 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; for example, when a situation arises in which life-sustaining treatments are a potential option for care and the resident is unable to make his or her choices known.

## Definitions (cont'd.)

**"Advance directive"** means, according to §489.100, 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. Some states also recognize a documented oral instruction.

## **Definitions** (cont'd.)

**"Cardiopulmonary resuscitation (CPR)"** refers to any medical intervention used to restore circulatory and/or respiratory function that has ceased.

## Definitions (cont'd.)

**"Durable Power of Attorney for Health Care" (a.k.a. "Medical Power of Attorney")** is 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.

## Definitions (cont'd.)

**"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 an individual's physical or mental condition.

## **Definitions** (cont'd.)

**"Health care decision-making capacity"** refers to possessing the ability (as defined by state law) to make decisions regarding health care and related treatment choices.

**"Investigational or experimental drugs"** refer to 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.

## Definitions (cont'd.)

**"Life-sustaining treatment"** is treatment that, based on reasonable medical judgment, sustains an individual's life and without which the individual will die. The term includes both life-sustaining medications and interventions such as mechanical ventilation, kidney dialysis, and artificial hydration and nutrition. The term does not include medical procedures related to enhancing comfort or medical care provided to alleviate pain.

# Interpretive Guidance

## **Definitions** (cont'd.)

**"Legal representative"** is 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.

***a.k.a.***

**"Agent"**

**"Attorney in fact"**

**"Proxy"**

**"Substitute decision-maker"**

**"Surrogate decision-maker"**

## Definitions (cont'd.)

**"Treatment"** refers to interventions provided for purposes of maintaining/restoring health and well-being, improving functional level, or relieving symptoms.

## Overview

In the United States, a broad legal and medical consensus has developed around issues of patient self-determination including an individual's rights to refuse treatment, to not participate in experimental research, and to determine, in advance, what treatments he or she wants or does not want.

This has influenced the standards of professional practice in health care facilities and promoted the implementation of approaches to obtaining and acting on patient/resident wishes.

## Establishing and Maintaining Policies and Procedures Regarding These Rights

The facility is required to establish, maintain, and implement written policies and procedures regarding the resident's right to:

- Formulate an advance directive;
- Refuse medical or surgical treatment; and
- Refuse to participate in experimental research.

## Establishing and Maintaining Policies and Procedures Regarding These Rights
(cont'd.)

Facility policies and procedures delineate the various steps necessary to promote and implement these rights. Such as:

- Identifying the primary decision-maker (resident and/or legal representative);
- Identifying situations where health care decision-making is needed; and
- Establishing mechanisms for communicating the resident's choices to the interdisciplinary team.

## Informing and Educating the Resident About These Rights

At admission, the facility is required to:

- Provide written information concerning the resident's rights in these areas; and
- Provide a written description of the facility's policies that govern the exercise of resident rights.

## Informing and Educating the Resident About These Rights
(cont'd.)

The facility must provide to the resident community:

- Education regarding the right to formulate an advance directive; and

- The facility's written policies and procedures regarding the implementation of this right.

## Establishing Advance Directives

At admission, the facility must determine if the resident has an advance directive. Examples of advance directives include:

- Living will
- Directive to the attending physician
- Durable power of attorney for health care
- Medical power of attorney
- Pre-existing physician's order for "do not resuscitate" (DNR)
- Portable order form re: life-sustaining treatment

## Establishing Advance Directives
(cont'd.)

If the resident does not have an advance directive (or other type of directive as per state law) the facility must advise the resident of the right to establish one and offer assistance should the resident wish to formulate one.

## Establishing Advance Directives
(cont'd.)

The facility is responsible for:

- Incorporating the information and discussions into the medical record; and

- Communicating the resident's wishes to the staff so that appropriate care may be provided.

## Advance Care Planning

is:

- An ongoing process that helps the resident exercise rights and make knowledgeable choices;
- A process by which the facility provides information to the resident or legal representative regarding: health status, treatment options, and expected outcomes; and
- A means by which resident choices are implemented and re-evaluated (both routinely and when the resident's condition changes significantly).

## Right to Refuse Treatment or to Participate in Experimental Research

- The resident may not receive treatment against his/her wishes (stated directly or through advance directive);
- A decision by the resident's legal representative may be equally binding by facility subject to state law; and
- The resident may not be transferred or discharged based solely on refusing treatment.

## Right to Refuse Treatment or to Participate in Experimental Research(cont'd.)

The facility is expected to:

- Determine what the resident is refusing;
- Assess reasons for the refusal;
- Advise about the consequences of refusal;
- Offer alternative treatments; and
- Continue to provide all other appropriate services.

## Experimental Research

- A resident being considered for participation in research must:
  - Be fully informed of the nature and possible consequences of participating; and
  - Give full informed consent to participate.
- The resident has the right to refuse to participate before and during research; and
- The facility has a process for approving and overseeing research.

## Objectives

To determine whether a facility has promoted the resident's right to refuse treatment, to refuse to participate in experimental research, and to formulate an advance directive by:

- Establishing, maintaining and implementing policies and procedures regarding these rights; and

- Informing and educating the resident about these rights and the facility's policies regarding these rights.

## **Objectives** (cont'd.)

To determine whether a facility has promoted the resident's right to refuse treatment, to refuse to participate in experimental research, and to formulate an advance directive by:

- Helping the resident exercise these rights; and
- Incorporating the resident's choices regarding these rights into treatment, care and services.

# Investigative Protocol

## Use

Use this protocol for:

- Complaints from residents, family members or other resident representatives concerning services related to a resident's right to refuse medical or surgical treatment, participate in experimental research, formulate an advance directive, or provide written information, policies and procedures related to advance directives;

# Investigative Protocol

## **Use** (cont'd.)

- All sampled residents identified with orders or a condition ( e.g., neuromuscular diseases, exacerbation of COPD, temporary swallowing or gastrointestinal tract issues) potentially related to provision of life-sustaining treatments such as artificial nutrition/hydration, artificial ventilation, dialysis, blood transfusions, or cardiopulmonary resuscitation. (NOTE: For the Quality Indicator Survey (QIS) process this review would be conducted during Stage 2 of the survey);

- Residents who refused medical or surgical treatment; or

- Is participating in an experimental research activity or project.

# Investigative Protocol

## Procedures

- Observations
- Interviews
- Record Reviews

## Observations

Observe the selected resident and care and treatments provided during various shifts.

Note whether the care and services related to participation in experimental research, refusal of treatment, and provision of life-sustaining treatment are consistent with the care plan and resident choices, if known.

## Interviews: Resident/Representative

Determine if the facility has informed the resident (or legal representative) of the rights provided in this regulation and helped the resident exercise these rights. For example, how did the facility:

- Determine the resident's choices regarding care and treatment?
- Make clear the risks and benefits of experimental research?

## Interviews: Facility Staff

Determine if the facility staff who inform the resident about treatment options and document the resident's wishes have promoted and implemented the rights provided in this regulation. For example, how did the staff:

- Assess the resident's health care decision making capacity?

- Help the resident document choices or formulate an advance directive?

## Interviews: Health Care Practitioners and Professionals

Determine if the practitioners and professionals, who possess appropriate training and knowledge of the resident, have promoted and implemented the rights provided in this regulation. For example, how did the facility:

- Ensure that medical orders and treatments reflect the resident's choice and goals?
- Periodically reassess the resident's status and existing advance directives?

## Record Review

Review the resident's record for evidence of whether (or how) the facility:

- Determined the resident's health care decision-making capacity;
- Provided written information regarding the rights provided in this regulation; and
- Determined, at admission, that the resident had an existing advance directive or offered to help the resident formulate one.

## **Record Review** (cont'd.)

Review the resident's record for any information regarding initiating, continuing, withholding or withdrawing treatment.

Note whether the care plan considers the resident's choices.

# Determination of Compliance

## Criteria for Compliance with F155

The facility is in compliance if the facility has:

- Established and implemented policies and procedures regarding the right to formulate advance directives, to decline treatment and other related interventions, and to decline to participate in experimental research;

- Informed and educated the resident about these rights, including the facility's policies regarding exercising these rights;

# Determination of Compliance

## Criteria for Compliance with F155 (cont'd.)

The facility is in compliance if the facility has:

- Determined whether the resident has an advance directive in place or has offered the resident the opportunity to develop an advance directive;

- Helped the resident exercise these rights based on determining the capacity of the resident to understand information and make treatment decisions, or through the input of the identified legal representative of the resident when the resident lacks sufficient decision-making capacity;

# Determination of Compliance

## **Criteria for Compliance with F155** (cont'd.)

The facility is in compliance if the facility has:

- Incorporated the resident's choices into the medical record and orders related to treatment, care and services; and

- Monitored the care and services given the resident to ensure that they were consistent with the resident's documented choices and goals.

## Noncompliance for F155

Noncompliance for F155 may include, but is not limited to, failure to do one or more of the following:

- Establish and implement policies and procedures regarding the right to establish advance directives, to decline treatment and other related interventions, and to decline to participate in experimental research;

# Determination of Compliance

## **Noncompliance for F155** (cont'd.)

Failure to:

- Inform and educate the resident about these rights, including the facility's policies regarding exercising these rights;

- Determine whether the resident has an advance directive in place or offer the resident the opportunity to formulate an advance directive;

# Determination of Compliance

## **Noncompliance for F155** (cont'd.)

Failure to:

- Help the resident exercise these rights based on determining the capacity of the resident to understand information and make treatment decisions or through the input of the identified legal representative of the resident who lacks sufficient decision-making capacity;

- Incorporate the resident's choices into decisions and orders related to treatment, care, and services;

# Determination of Compliance

## **Noncompliance for F155** (cont'd.)

Failure to:

- Monitor the care and services given the resident to ensure that they are consistent with the resident's documented choices and goals, as it relates to the right to refuse treatment including refusal to participate in experimental research; or

- Act in a timely and appropriate manner if the care and services are not consistent with the resident's documented wishes and goals, unless there is a clinically pertinent explanation for such failure to act.

## Deficiency Categorization
(Part IV, Appendix P)

The key elements for severity determination for F155 are:

- Presence of harm/negative outcome(s) or potential for negative outcomes;
- Degree of harm (actual or potential) related to the noncompliance;
- The immediacy of correction required.

## Presence of Harm/Negative Outcomes or Potential for Negative Outcomes

Actual or potential harm for F155 may include:

- The resident was resuscitated despite a DNR order included in the resident's record; or

- Resident suffered a life-threatening complication related to involvement in research activity in the absence of adequate consent of the resident or his/her legal representative.

## Degree of Harm (actual or potential) Related to the Noncompliance

How the facility practices caused, resulted in, allowed, or contributed to actual/potential harm:

- If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; and

- If harm has not yet occurred, determine how likely the potential is for serious injury, impairment, death, compromise or discomfort to occur to the resident.

# Deficiency Categorization

## Immediacy of Correction Required

Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

# Deficiency Categorization

## Severity Levels

Level 4: Immediate Jeopardy to Resident Health or Safety

Level 3: Actual Harm that is not Immediate Jeopardy

Level 2: No Actual Harm with Potential for More than Minimal Harm that is not Immediate Jeopardy

Level 1: No Actual Harm with Potential for Minimal Harm.

# Deficiency Categorization

## Severity Level 4: Immediate Jeopardy

Immediate jeopardy is a situation in which the facility's noncompliance with one or more requirements of participation:

- Has allowed, caused, or resulted in (or is likely to allow, cause, or result in) serious injury, harm, impairment or death to a resident; and

- Requires immediate correction as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.

# Deficiency Categorization

## Severity Level 4: Immediate Jeopardy

Severity Level 4 Example

As a result of the facility's failure to obtain the documented wishes of the resident related to life-sustaining treatments, the resident received treatments that were inconsistent with his/her advance directives or other documented wishes, including use of feeding tubes, artificial nutrition and hydration, and hospitalization.

# Deficiency Categorization

## Severity Level 3: Actual Harm that is not Immediate Jeopardy

The negative outcome can include, but may not be limited to: clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable well-being.

# Deficiency Categorization

## Severity Level 3: Actual Harm that is not Immediate Jeopardy

Severity Level 3 Example

The facility failed to identify the medical orders that detailed the resident's wishes to forego lab work, IV antibiotic treatment and IV hydration for the resident's 7th episode of aspiration pneumonia. Furthermore, the nurses refused to allow the resident to attend his son's wedding, insisting that the resident remain in the nursing home so that a chest x-ray and blood work be done, which went against the resident's expressed wishes. The resident suffered emotional harm.

# Deficiency Categorization

## Severity Level 2: No Actual Harm with Potential for More than Minimal Harm that is not Immediate Jeopardy

- Noncompliance that results in a resident outcome of no more than minimal discomfort and/or;
- Has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well being.

# Deficiency Categorization

## Severity Level 2: No Actual Harm with Potential for More than Minimal Harm that is not Immediate Jeopardy

Severity Level 2 Example

As a result of the facility's failure to obtain physician orders that were consistent with the resident's documented wishes, the direct care staff was unaware of the resident's wishes, although a situation involving life-sustaining treatment options had not yet arisen in the resident's care.

## Severity Level 1: No Actual Harm with Potential for Minimal Harm

The failure of the facility to recognize and facilitate the exercising of the resident's right to refuse treatment, to refuse to participate in experimental research and to formulate an advance directive; and to maintain written policies and procedures regarding these rights, places the resident at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.


# Questions?