DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 13-16-NH

DATE: **March 8, 2013**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: F tag 155-- Advance Directives- Revised Advance Copy

This memorandum replaces a previous version of S&C: 12-47-NH dated September 27, 2012.

Memorandum Summary

- **Revisions:** Additional revisions have been made to Surveyor Guidance at F tag 155 in Appendix PP of the State Operations Manual (SOM) and the associated training slides since the release of S&C 12-47 on September 27, 2012. The revisions include:
  - Removal of the term "right to accept" when referring to medical and surgical treatment.
  - Addition of guidance specific to experimental research.
  - Clarification that §483.10(b)(8) applies only to adult residents and not all residents regardless of age.
  - Addition of definition for "Investigational or experimental drugs."
  - Updating the Investigative Protocol.
  - Updating the Power Point training slides.
- **Advance Copy Interpretive Guidelines:** Revised advance copy of surveyor guidance is included in this memorandum.
- **Power Points:** The revised Power Point training material with speaker notes is provided.

Background

Since the release of S&C 12-47-NH, the Centers for Medicare & Medicaid Services (CMS) conducted a further review of the interpretive guidelines for F tag 155 in Appendix PP of the SOM. Based on additional internal and external stakeholder feedback this guidance and related training materials have been revised to provide additional clarification.

Revisions

The revisions have been highlighted in the Advance Copy Interpretive Guidelines and include:

- Removal of the term "right to accept" preceding language specific to medical and surgical treatment to correlate with the regulatory language at §483.10(b)(4).

- Language specific to experimental research has been added to the Interpretive Guidance (IG) and correlates with the Power Point training materials. A definition for investigational or experimental drugs has been added to the definitions sections of the IG.

- Clarification to specify that §483.10(b)(8) applies only to adult residents and not all residents regardless of age, as evidenced in the regulatory language.

- The Investigative Protocol has been updated to include guidelines specific to experimental research and record review considerations relative to a physician's basis for conscientious objection and/or need for additional information related to a resident's decisional capacity.

- The "Use" section of the Investigative Protocol has been revised secondary to burden reduction considerations. Surveyors will no longer use the protocol for all residents in the survey sample, only residents who meet the parameters listed in this section.

- Updated Power Point training slides to correlate with revisions made to the Surveyor Guidance at F tag 155. Revisions made to the training slides have a red font color.

Please note that the manual changes to Surveyor Guidance for F tag 155 will not be issued with highlights.

For questions on this memorandum, please contact Kathleen Johnson at 410-786-3295 or via email at Kathleen.Johnson@cms.hhs.gov.

Effective Date: This clarification is effective no later than 30 days after release of the memo. Please ensure that all appropriate staff is fully informed within 30 days of the date of this memorandum.

Training: The revised training materials should be distributed immediately to all SA training coordinators.

/s/
Thomas E. Hamilton

2 Attachments

Advance Copy Interpretive Guidelines
Power Point training slides with speaker notes

cc: Survey and Certification Regional Office Management

CMS Manual System

Pub. 100-07 State Operations Provider Certification

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

Transmittal- **Date: ----------**

SUBJECT: Revisions to Appendix PP – "Interpretive Guidelines for Long-Term Care Facilities F tag 155 (Advance Directives)"

I. SUMMARY OF CHANGES: This instruction revises Subsection §483.10(b)(8) by moving it from F156 and incorporating the regulatory language and interpretive guidance into F155.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: Upon Issuance
IMPLEMENTATION DATE: Upon Issuance

Disclaimer for manual changes only: 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.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix PP/F 155// §483.10(b)(4)
R	Appendix PP/F 156// §483.10(b)(8)

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

IV. ATTACHMENTS:

	Business Requirements
X	**Manual Instruction**
	Confidential Requirements
	One-Time Notification
	One-Time Notification -Confidential
	Recurring Update Notification

***Unless otherwise specified, the effective date is the date of service.**

(Rev.)

F155

§483.10(b)(4) and (8)

§ 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

§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: (F155) §483.10(b)(4) and (8) Rights Regarding Refusal of Treatment and Participation in Experimental Research and Advance Directives

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

- *Establishing and maintaining policies and procedures regarding these rights;*
- *Informing and educating the resident about these rights and the facility's policies regarding exercising these rights;*
- *Helping the resident to exercise these rights; and*
- *Incorporating the resident's choices regarding these rights into treatment, care and services.*

*NOTE: While the language of 42 C.F.R **§483.10(b)(8)** applies only to adults, states may have laws that govern the rights of parents or legal guardians of children to formulate an advance directive. The CMS believes that this is an important issue for the parents/guardians of terminally ill or severely disabled children. Therefore surveyors are encouraged to refer to state law in cases where concerns arise regarding advance directives in non-adult populations. The regulatory language found under 42 C.F.R. **§ 483.10(b)(4)** applies to all residents, regardless of age.*

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 capacity to do so. For example, when life-sustaining treatments are a potential option for care and the resident is unable to make his or her choices known.[1]

"Advance directive" *means, according to 42 C.F.R. §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.*

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

"Durable Power of Attorney for Health Care" (a.k.a. "Medical Power of Attorney") *is a document delegating authority to an agent to make health care decisions in case the individual delegating that authority subsequently becomes incapacitated.*

"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.*

"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.*

"Life-sustaining treatment" *is treatment that, based on reasonable medical judgment, sustains an individual's life and without it the individual will die. The term includes both life-sustaining medications and interventions (e.g. mechanical ventilation, kidney dialysis, and artificial hydration and nutrition). The term does not include the administration of pain medication or other pain management interventions, the performance of a medical procedure related to enhancing comfort, or any other medical care provided to alleviate a resident's pain.*[2]

"Legal representative" (e.g., "Agent," "Attorney in fact," "Proxy," "Substitute decision-maker," "Surrogate decision-maker") *is a person designated and authorized by an advance directive or State law to make a treatment decision for another person in the event the other person becomes unable to make necessary health care decisions.*

"Treatment" *refers to interventions provided to maintain or restore health and well-being, improve functional level, or relieve symptoms.*

OVERVIEW

Traditionally, questions of care were resolved at the bedside through decision-making by an individual, his or her family and health care practitioner. As technological advances have increased the ability of medicine to prolong life, questions have arisen concerning the use, withholding, or withdrawing of increasingly sophisticated medical interventions.

The Federal Patient Self - Determination Act contained in Public Law 101-508 is the authority on an individual's rights and facility responsibilities related to Advance Directives. The right of an individual to direct his or her own medical treatment, including withholding or withdrawing life-sustaining treatment, is grounded in common law (judge-made law), constitutional law, statutory law (law made by legislatures) and regulatory mandates governing care provided by facilities. Several landmark legal decisions have established an enduring judicial precedence for the legal principles of advance directives and the right to refuse or withhold treatment.[3,4,5,6]

These legal developments have influenced standards of professional practice in the care and treatment of individuals in health care facilities. Several decades of professional debate and discussion have simultaneously advanced the thinking on these matters and promoted implementation of pertinent approaches to obtaining and acting on patient/resident wishes.[7,8]

ESTABLISHING AND MAINTAINING POLICIES AND PROCEDURES REGARDING THESE RIGHTS

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

The facility's policies and procedures delineate the various steps necessary to promote and implement these rights, including, for example:

- *Determining on admission whether the resident has an advance directive and, if not, determining whether the resident wishes to formulate an advance directive;*
- *Determining if the facility periodically assesses the resident for decision-making capacity and invokes the health care agent or legal representative if the resident is determined not to have decision-making capacity.*
- *Identifying the primary decision-maker (e.g., assessing the resident's decision-making capacity and identifying or arranging for an appropriate legal 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/her legal 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;*

- *Reviewing the resident's condition and existing choices and continuing or modifying approaches, as appropriate;*

- *Establishing mechanisms for documenting and communicating the resident's choices to the interdisciplinary team; and*

- *Identifying the process (as provided by State law) for handling situations in which the facility 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.*

INFORMING AND EDUCATING THE RESIDENT ABOUT THESE RIGHTS

The facility is required (by 42 C.F.R. § 489.102 Requirements for Providers) to provide, at the time of a resident's 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 experimental 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.

ESTABLISHING ADVANCE DIRECTIVES

The facility must ensure compliance with Federal and State requirements regarding advance directives. At the time the resident is admitted to a nursing home, staff must determine whether the resident has executed an advance directive or has given other instructions to indicate what care he or she desires in case of subsequent incapacity. Such a directive or instructions could be a living will, a directive to the attending physician, a durable power of attorney for health care, 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. Several States have also adopted the use of a portable and enduring order form that documents the resident's choices related to life-sustaining treatments.[9]

If the resident or the resident's legal representative has executed one or more advance directive(s), or executes one upon admission, it is important that copies of these documents be obtained, incorporated and consistently maintained in the same section of the resident's medical record readily retrievable by any facility staff, and that the facility communicate the resident's wishes to the resident's direct care staff and physician. If the resident has not executed an advance directive, the facility is required to advise the resident and family of the right to establish an advance directive as set forth in the laws of the State; to offer assistance if the resident wishes to execute one or more directive(s); and to 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.

Advance Care Planning

In order for a resident to exercise his or her right to make knowledgeable choices about care and treatment or to decline treatment, the primary care provider and facility staff should provide information (in a language and terminology that the resident understands) to the resident and/or his/her legal representative regarding the resident's health status, treatment options, and expected outcomes. Whether or not the resident chooses to execute an advance directive, discussion and documentation of the resident's choices regarding future health care should take place during the development of the initial comprehensive assessment and care plan and periodically thereafter. The process of having such discussions, regardless of when they occur, is sometimes referred to as "advance care planning."

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 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. Advance care planning is a method to further a resident's control over his or her own medical treatment and choices. [10] *It also allows the decision-maker (whether it is the resident, family or other legal representative) to be better informed about the treatment alternatives available in a variety of circumstances.*

RIGHT TO REFUSE MEDICAL OR SURGICAL TREATMENT

If a resident (directly or through an advance directive) declines treatment (e.g., refuses artificial nutrition or IV hydration, despite having lost considerable weight), the resident may not be treated against his/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 facility may not transfer or discharge a resident for refusing treatment unless the criteria for transfer or discharge are otherwise met.

If a resident's refusal of treatment results in a significant change in condition, the facility should reassess the resident and modify the care plan as appropriate. The facility is expected to assess the resident for decision-making capacity and invoke the health care agent or legal representative if the resident is determined not to have decision-making capacity. Once the decision-making capacity is assessed, the facility is expected to determine and document what the resident is refusing, to assess the reasons for the resident's refusal, to advise the resident about the consequences of refusal, to offer pertinent alternative treatments, and to continue to provide all other appropriate services. The resident's refusal of treatment does not absolve a facility from providing other care that allows him/her to attain or maintain his/her highest practicable physical, mental and psychosocial well-being. For example, a facility would still be expected to provide appropriate measures for pressure ulcer prevention, even if a resident has refused food and fluids and is expected to die.

RIGHT TO DECLINE TO PARTICIPATE IN EXPERIMENTAL RESEARCH

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 (e.g., medication, other treatment) and the possible consequences of participating. The resident must give informed consent in order to participate. If the resident is incapable of understanding the situation and of realizing the risks and benefits of the proposed research, but a legal representative gives proxy consent, the facility has a responsibility to ensure that the proxy consent is properly obtained and that essential measures are taken to protect the individual from harm or mistreatment. The resident (or his/her legal 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.

A facility participating in any experimental research involving residents must have a process for committee (e.g., an Institutional Review Board) approval of this research and mechanisms in place for its oversight. In this regard, §483.75(c), Relationship to Other HHS Regulations, applies (i.e., research conducted at a facility must adhere to 45 CFR Part 46, Protection of Human Subjects of Research).

ENDNOTES

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[1] *Adapted from: Emanuel, L.L., Danis, M., Pearlman, R.A., Singer, P.A. (1995). Advance care planning as a process: structuring the discussions in practice. Journal of the American Geriatric Society, 43, 440-6.*

[2] *TX Health and Safety Code Title 2, §166.002: Definitions – Advance Directives Act. Available from: www.statutes.legis.state.tx.us; Accessed on December 3, 2010.*

[3] *Thomas, K.R. (Updated September 19, 2005). The Right to Die: Constitutional and Statutory Analysis. Congressional Research Service Report for Congress, 907-244A. (http://www.policyarchive.org/handle/10207/bitstreams/363.pdf)*

[4] *Quinlan. (1976). 70 N.J. 10, 355 A.2d 647. (http://www.libraryindex.com/pages/582/Court-End-Life-RIGHT-PRIVACY-KAREN-ANN-QUINLAN.html">Court)*

[5] *Bartling v. Superior Court. (1984). Dec 27:209:220-7. (http://www.ncbi.nlm.nih.gov/pubmed/11648164)*

[6] *Cruzan v. Director, Missouri Department of Health. (1990). 497 U.S. 261. (http://www.oyez.org/cases/1980-1989/1989/1989_88_1503)*

[7] *Atmore, C. & Naksook, C. (2007). Respecting Patient Choices – Literature Review. Prepared by Health Issues Centre for the Respecting Patient Choices Project, Austin Health, La Trobe University, VIC, Australia. (http://www.healthissuescentre.org.au/documents/items/2008/04/205853-upload-00001.pdf)*

[8] *Emanuel, L.L., von Gunten, C.F., Ferris, F.D. (1991). Education for Physicians at the End of Life (EPEC) Participant's Handbook -- Plenary 2, Legal Issues. Robert Wood Johnson Foundation. (http://endoflife.northwestern.edu/legal_issues/module15.pdf)*

[9] *POLST Physician Orders for Life Sustaining Treatment Paradigm (http://www.ohsu.edu/polst/)*

[11] *Teno, J.M., Casey, V.A., Welch, L.C., Edgman – Levitan, S. (2001). Patient-Focused, Family-Centered End-of-Life Medical Care: Views of the Guidelines and Bereaved Family Members. Journal of Pain and Symptom Management, Vol. 22 No. 3.*

INVESTIGATIVE PROTOCOL

§483.10(b)(4) AND (8) RIGHTS REGARDING REFUSAL OF MEDICAL OR SURGICAL TREATMENT, PARTICIPATION IN EXPERIMENTAL RESEARCH AND ADVANCE DIRECTIVES

Objectives

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

- *Establishing and maintaining policies and procedures regarding these rights;*
- *Informing and educating the resident about these rights and the facility's policies regarding these rights;*
- *Helping the resident exercise these rights; and*
- *Incorporating the resident's choices regarding these rights into treatment, care and services.*

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;*
- *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.*

Procedures

Briefly review the resident's record to determine if the resident has an advance directive, is participating in experimental research, refused medical or surgical treatment, received or is

currently receiving life sustaining treatments. The surveyor(s) should conduct the following observations, interviews and record reviews.

Observations

Observe the selected resident care and treatments provided during various shifts. Note whether the care and services related to participation in experimental research, refusal of medical or surgical treatment, or provision of life-sustaining treatment are consistent with the care plan, progress notes and resident choices.

Interviews

Resident/Representative

Interview the resident and/or the resident's legal representative, as appropriate, regarding the following:

- *What the facility has done to determine the resident's choices regarding care and treatment;*
- *What the staff and practitioner have done to inform the resident or the resident's legal representative about the resident's medical condition and relevant health care issues;*
- *What the staff and practitioner have done to inform the resident or the resident's legal representative about treatment options and the relevance of those options to the resident's goals, wishes, medical condition and prognosis;*
- *What the staff and practitioner have done to help the resident or the resident's legal representative document treatment choices (e.g., advance directives or another format consistent with State and Federal law and regulation); and*
- *If the resident is participating in research, did the resident or the resident's legal representative receive information prior to the start of the project that: sufficiently explained the research for which he/she was being asked to give consent; made clear the risks and benefits of the research; and informed him/her of the right to refuse to participate?*

Facility staff

Interview staff who are involved in informing residents about treatment options and documenting resident wishes to determine:

- *How the facility determines whether the resident has an advance directive or other existing documentation related to life-sustaining treatment;*
- *What training staff receive regarding advance directives and their initiation;*

- *How the facility assessed the resident's capacity to make health care decisions and consent to participate in experimental research;*

- *How the practitioner and facility inform the resident or legal representative about his or her medical condition and relevant health care issues;*

- *How the practitioner and facility inform and educate the resident or legal representative about treatment options and the resident's right to refuse medical or surgical treatment, to formulate an advance directive and to refuse to participate in experimental research;*

- *How staff helps the resident or legal representative document treatment choices and formulate an advance directive;*

- *How documented choices and treatment decisions are communicated to the interdisciplinary team;*

- *How the practitioner and staff monitor and safeguarded the rights of the resident involved in experimental research;*

- *How staff know where to access the documented information on the resident's treatment choices and advance directives in the medical record, during both routine care and in an urgent or emergent situation; and*

- *How the facility ensures that practitioner orders and treatment decisions are consistent with the resident's documented choices and goals.*

Health care practitioners and professionals

Interview one or more health care practitioners and professionals as necessary (e.g., physician, nurse practitioners, physician assistants, charge nurse, director of nursing, social worker) who, by virtue of training and knowledge of the resident, should be able to provide information regarding:

- *How the facility seeks, identifies, and documents the resident's wishes regarding advance care planning and life-sustaining treatments;*

- *How the facility ensures that medical orders and treatments reflect the resident's choices and goals;*

- *The process by which the staff and practitioners are involved in advising the resident and the resident's legal representative about the right to refuse treatment (including life-sustaining treatments);*

- *How documented choices and treatment decisions are communicated to the interdisciplinary team;*

- *How the staff and practitioner obtain and document informed consent of the resident who is participating in experimental research;*

- *How the staff and practitioners proceed if the resident who is involved in experimental research is suspected of, or identified as, suffering adverse consequences related to his/her participation;*

- *How staff know where to access the documented information on the resident's treatment choices and advance directives in the medical record, during both routine care and in an urgent or emergent situation; and*

- *How the staff and practitioner periodically reassess the resident's condition and prognosis to identify whether existing advance directives remain pertinent and/or whether there is a need to review or possibly modify them.*

During the course of the review, the surveyor should consider contacting the attending physician or health care practitioner regarding questions related to the treatment regimen. It is recommended that the facility's staff have the opportunity to provide the necessary information about the resident and the concerns to the physician or health care practitioner for his/her review prior to responding to the surveyor's inquiries. If the attending physician or health care practitioner is unavailable, interview the medical director as appropriate.

Record Review

Depending on the issue of concern, review the resident's records for evidence of whether and how the facility determines the resident's capacity to understand and make decisions regarding the right to refuse treatment, to formulate an advance directive and/or refuse to participate in experimental research. Review whether information was provided in writing regarding these rights. Review whether the facility determined at admission if the resident had an existing advance directive and, if the resident did not have one, whether the facility offered the resident the option to formulate an advance directive. Review for any information regarding initiating, continuing, withholding, or withdrawing treatment. Note whether the care plan considers the resident's choices.

Depending on the issue of concern, review information such as medical orders and interdisciplinary progress notes to determine:

- *Whether there is documentation of the rationale for recommendations and treatment decisions related to life-sustaining treatment options;*

- *Whether the practitioner's orders are consistent with the resident's documented choices and goals. Unless, in rare circumstances, where a physician needs more information about the residents decisional capacity, has a conscientious objection to the residents decision or other aspects of the case in order to be comfortable writing orders that are consistent with the resident's expressed wishes;*

- *The frequency and scope of monitoring the resident who is participating in experimental research activities for responses to and adverse consequences of any experimental treatments;*

- *Whether any 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*

- *Whether the resident's advance directive, if formulated, has been incorporated into his or her active record, including in medical orders, progress notes, the resident care plan or other relevant means of communication to the interdisciplinary team.*

Review of Facility Practices

Depending on the issue of concern, the assigned surveyor should review, as indicated, the facility's policies, procedures, records related to determining and documenting resident wishes regarding advance care planning and implementing medical orders that reflect a resident's wishes. Related concerns may have been identified that would suggest the need for further review of facility practices. Examples of such activities may include a review of policies, staffing, staff training and/or functional responsibilities.

DETERMINATION OF COMPLIANCE

Criteria for Compliance

The facility is in compliance with 42 §CFR 483.10 (b)(4) and (8), if the facility has:

- *Established and implemented policies and procedures regarding the right to formulate advance directives, refuse medical and surgical 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;*

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

- *Documented when the resident is determined not to have decision-making capacity and therefore decision-making is transferred to the health care agent or legal representative;*

- *Helped the resident to exercise these rights based on explaining risk and benefits of declining treatment;*

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

- *Consistently maintained advance directives and resident goals and in the same section of the clinical record or other document filing system for all appropriate residents, where those documents are easily retrievable by staff during both routine and urgent or emergent situations; and*

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

If not, cite at F155.

IV. DEFICIENCY CATEGORIZATION (PART IV, APPENDIX P)

Once the team has completed its investigation, analyzed the data, reviewed the regulatory requirements, and determined that noncompliance exists, the team must determine the severity of each deficiency, based on the harm or potential for harm to the resident.

The key elements for severity determination for F155 are as follows:

1. ***Presence of harm/negative outcome(s) or potential for negative outcomes** because of lack of appropriate care and services or lack of implementation of resident's right to refuse medical or surgical treatment, refuse to participate in experimental research and/or formulate an advance directive. Actual or potential harm/negative outcomes for F155 may include, but are not limited to:*

    - *Resident was resuscitated despite a DNR order included in the resident's record;*

    - *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;*

    - *Resident was hospitalized contrary to his/her wishes; and*

    - *Resident received treatment based on the consent of an individual who was not the resident or his/her representative, in accordance with State Law.*

2. ***Degree of harm (actual or potential) related to the noncompliance.*** *Identify how the facility practices caused, resulted in, allowed, or contributed to the actual or potential for 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.*

3. ***The 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.*

The survey team must evaluate the harm or potential for harm based upon the following levels of severity. First, the team must rule out whether Severity Level 4 (immediate jeopardy to a resident's health or safety) exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q, Determining Immediate Jeopardy.)

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety

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.*

NOTE*: The death or transfer of a resident, who was harmed as a result of facility practices, does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to correct the deficient practices which allowed or caused the immediate jeopardy.*

Examples of avoidable actual or potential resident outcomes that demonstrate severity at Level 4 may include, but are not limited to:

- *As a result of the facility's failure to obtain and implement medical orders related to life-sustaining treatments, after the resident had documented choices, the resident was transferred to the hospital for an acute change of condition against his wishes, where he was resuscitated against his documented wishes, despite the facility's knowledge that the intervention was against the resident's wishes.*

***NOTE**: If Severity Level 4 (immediate jeopardy) has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at Severity Level 3 or the potential for more than minimal harm at Severity Level 2 exists.*

Severity Level 3 Considerations: Actual Harm that is Not Immediate Jeopardy

Severity Level 3 indicates noncompliance that resulted in 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.

Examples of avoidable resident outcomes that demonstrate severity at Level 3 may include, but are not limited to:

- *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.*

***NOTE:** If Severity Level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether Severity Level 2 (no actual harm with the potential for more than minimal harm) exists.*

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

Severity Level 2 indicates noncompliance that resulted in a resident outcome of no more than minimal discomfort and/or had the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well being. The potential exists for greater harm to occur if interventions are not provided.

Examples of avoidable outcomes at Severity Level 2 include, but are not limited to:

- *As a result of the facility's failure to establish and implement policies and procedures regarding the rights to decline treatment and other related interventions, the resident and/or the resident's legal representative was unaware of the opportunities to decline medical treatment, although a situation involving the use of life-sustaining treatment options had not yet arisen in the resident's care; or*

- *As a result of the facility's failure to obtain medical 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 medical or surgical 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

§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.

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;

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.

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.

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;

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.

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.

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.

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.

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.

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.

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.

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.

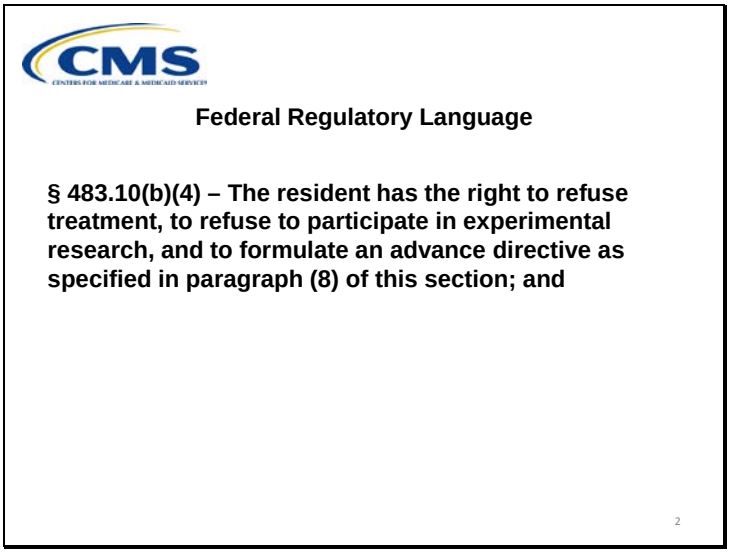
Questions?

Slide 1

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

Surveyor Training of Trainers:
Interpretive Guidance
Investigative Protocol

Slide 2


CMS
Federal Regulatory Language
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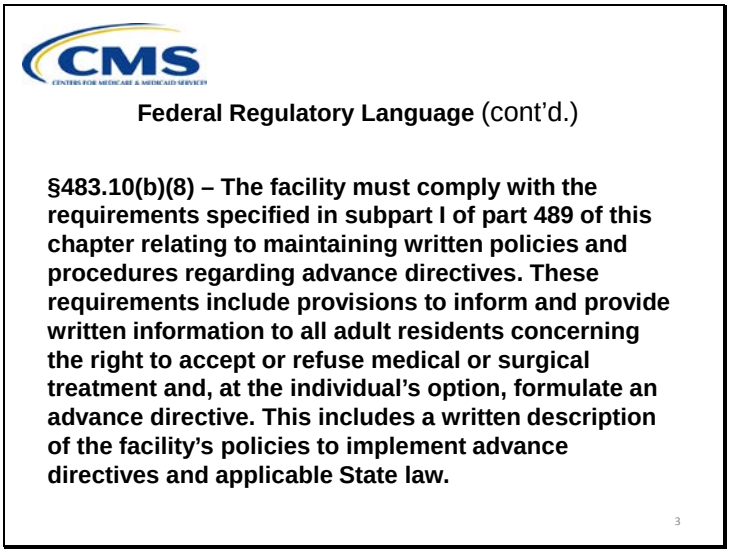
Slide 3



Discussion re: why subsection (b)(8) from F156 if being combined with F155.

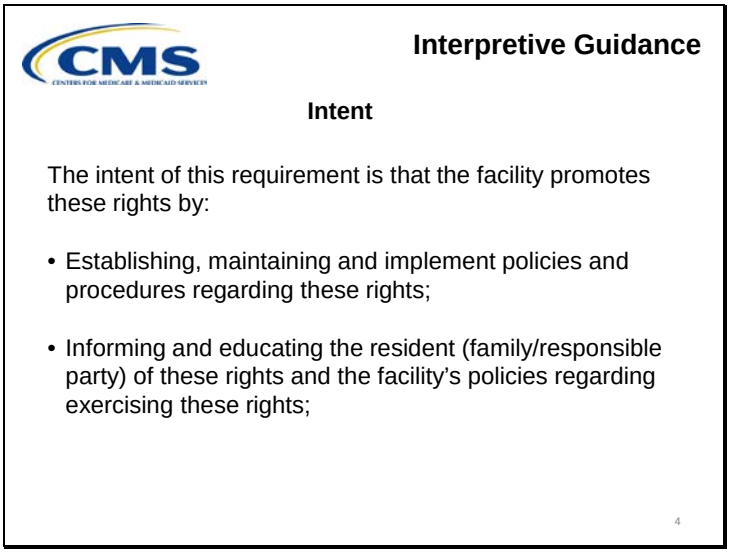
This instruction combines F155 [§483.10(b)(4)] with subsection (b)(8) formerly at F156.

F155 discusses the resident's rights to refuse treatment, formulate and advance directive, and refuse to participate in experimental research.

Subsection (b)(8), formerly addressed in F156, discusses facility requirements for informing the resident of the federal right regarding refusal of treatment and formulation of advance directives – as well as applicable state law regarding advance directives. The requirements under §483.10(b)(8) apply to adult residents.

By combining these regulations under F155, all guidance to surveyors related to advance directives is in one location.

Slide 4


Interpretive Guidance
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;
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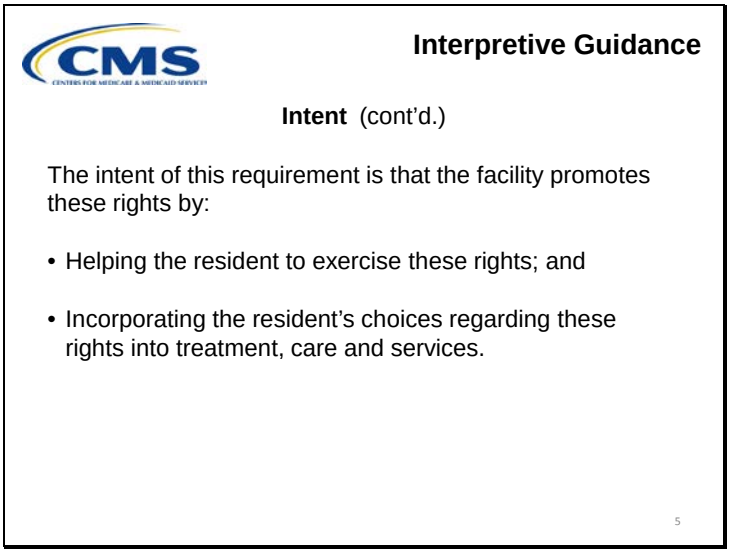
Slide 5

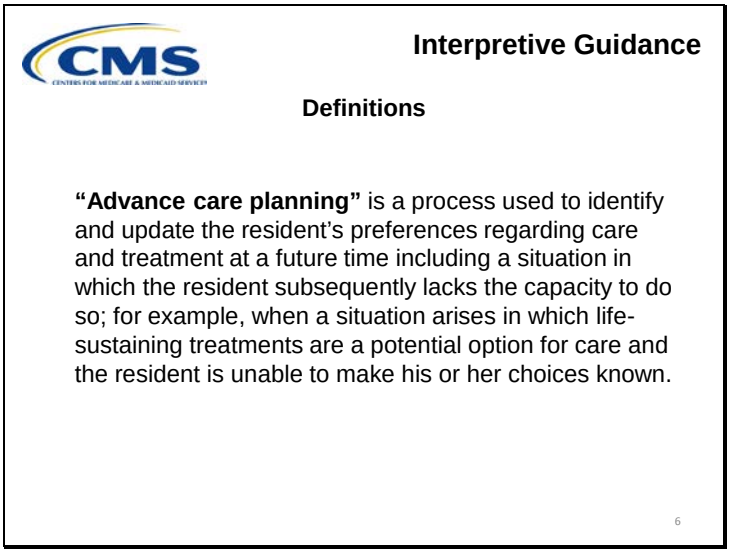


Discussion re: these bullets:

Bullet #1: NOTE: The facility is responsible for providing information and resources to the resident as he or she may require to exercise these rights, but does not directly participate in or influence the resident's decisions.

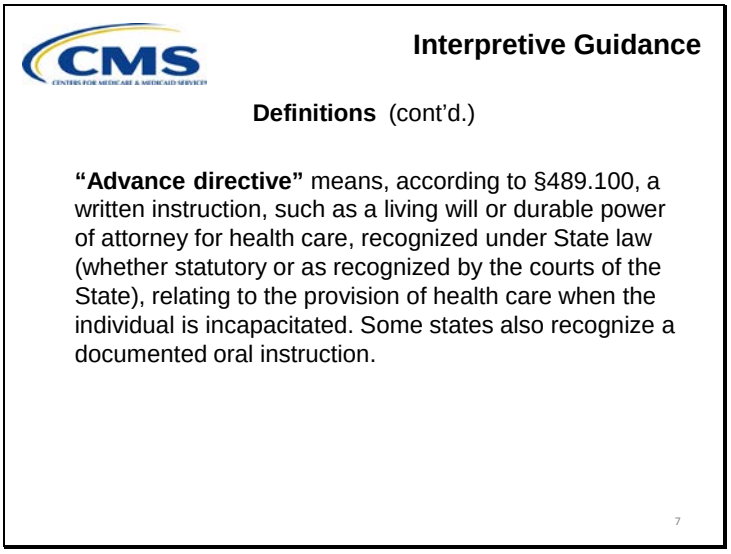
Bullet #2: NOTE: See §483.25 Quality of Care (F309) for failure to implement these rights into the resident's treatment, care and services.

Slide 6



Advance care planning will be discussed later in the presentation.

Slide 7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Definitions (cont'd.)
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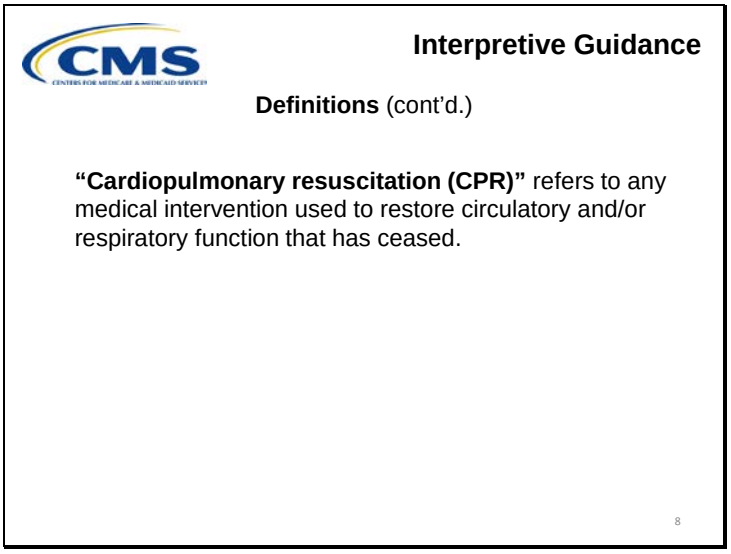
Slide 8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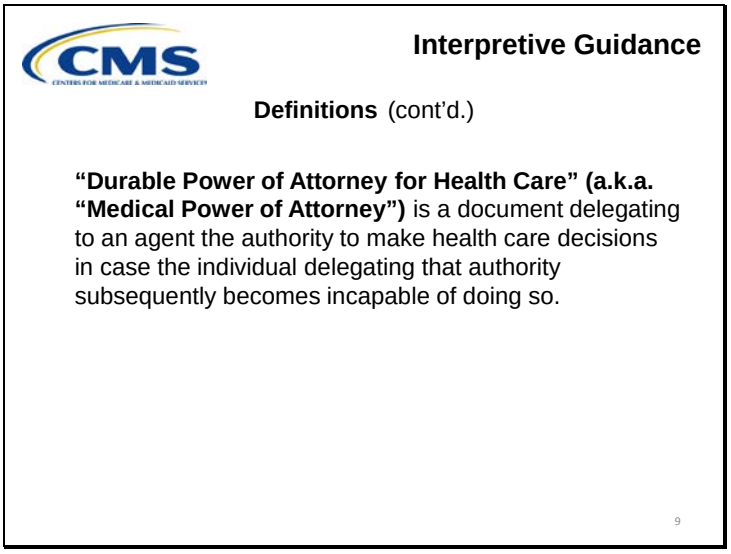
8

Slide 9


Interpretive Guidance
Definitions (cont'd.)
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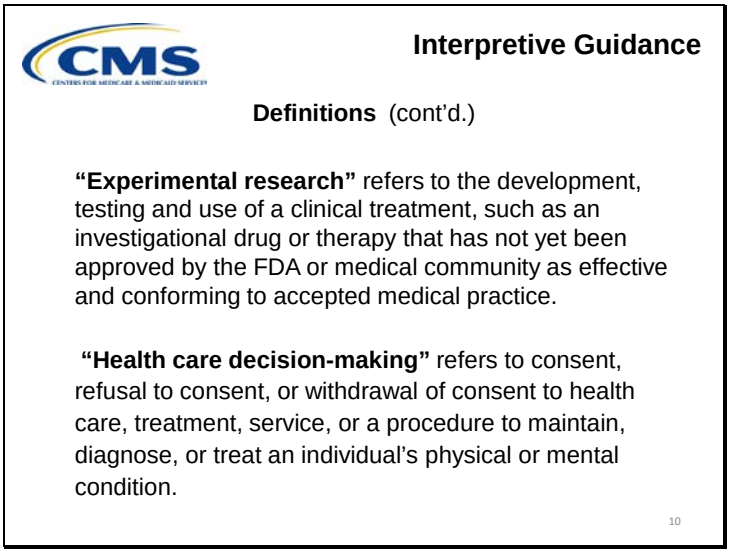
9

Slide 10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Definitions (cont'd.)
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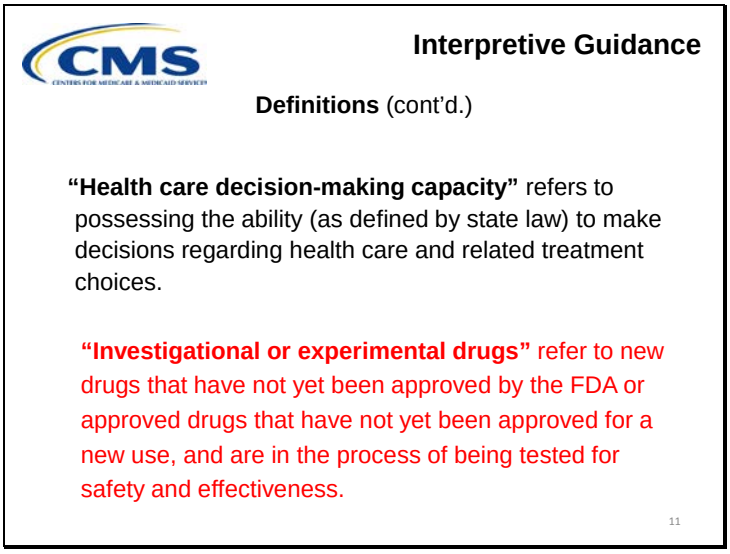
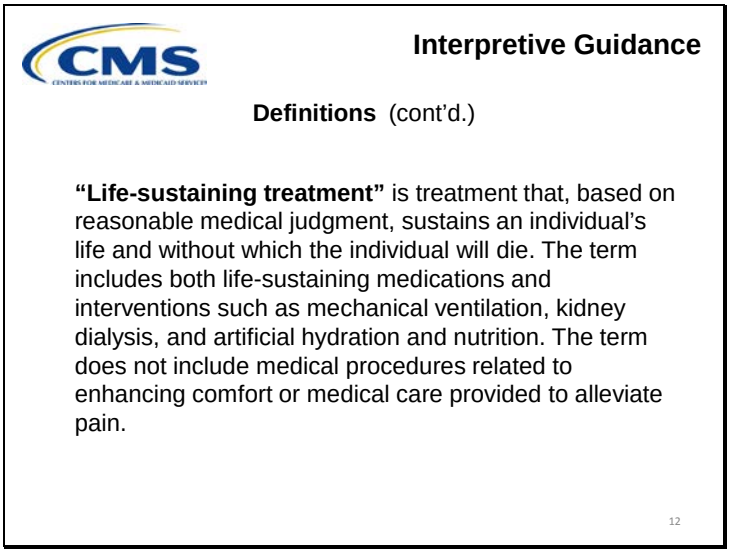
10

Slide 11



Investigational or experimental drugs has been added to the definitions list secondary to the additional of experimental research interpretive guidelines.

Slide 12


Interpretive Guidance
Definitions (cont'd.)
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Slide 13

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"

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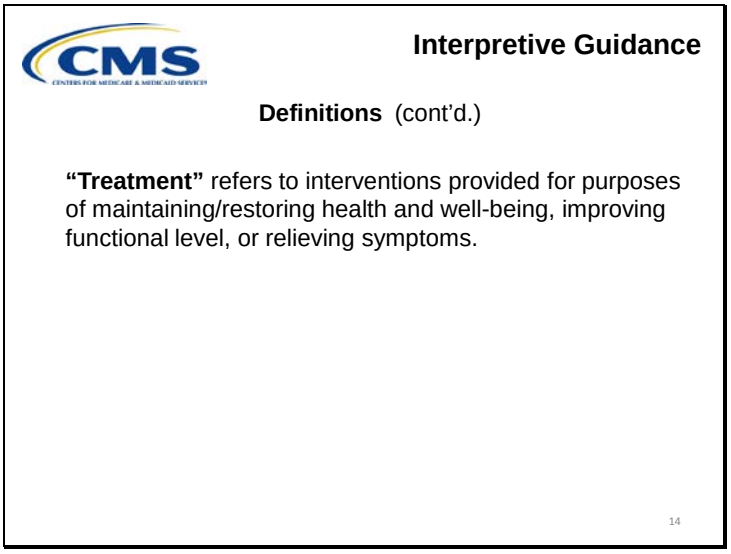
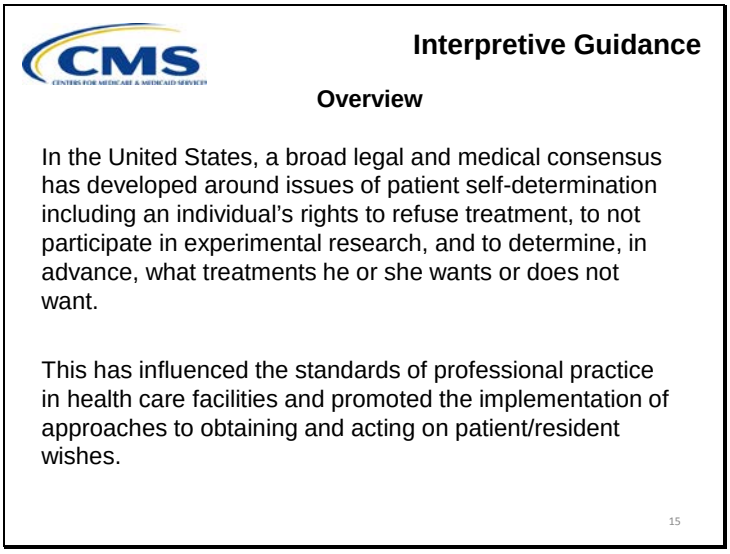
Slide 14


Interpretive Guidance
Definitions (cont'd.)
"Treatment" refers to interventions provided for purposes of maintaining/restoring health and well-being, improving functional level, or relieving symptoms.
14

Slide 15



The legal basis for the use of an advance directive in health care today is based on a citizen's right of self-determination and the federal Patient Self- Determination Act (effective December 1, 1991).

The right of an individual to direct his or her own medical treatment, including withholding or withdrawing life-sustaining treatment, is grounded in common law (judge-made law), constitutional law, statutory law (law made by legislatures) and regulatory mandates governing care provided by facilities.

The F155 Interpretive Guidance Endnotes refer to a summary analysis of constitutional and statutory law regarding the "right to die."
[Thomas, K.R. (Updated September 19, 2005). The Right to Die: Constitutional and Statutory Analysis. Congressional Research Service Report for Congress, 907-244A. (http://www.policyarchive.org/handle/10207/bitstreams/363.pdf)]

Several landmark legal decisions have established an enduring judicial precedence for the legal principles of advance directives and the right to accept or refuse or withhold treatment. The F155 Interpretive Guidance Endnotes refer to:

1) Quinlan. (1976). 70 N.J. 10, 355 A.2d 647. (http://www.libraryindex.com/pages/582/Court-End-Life-RIGHT-PRIVACY-KAREN-ANN-QUINLAN.html">Court)

2) Bartling v. Superior Court. (1984). Dec 27:209:220-7. (http://www.ncbi.nlm.nih.gov/pubmed/11648164)

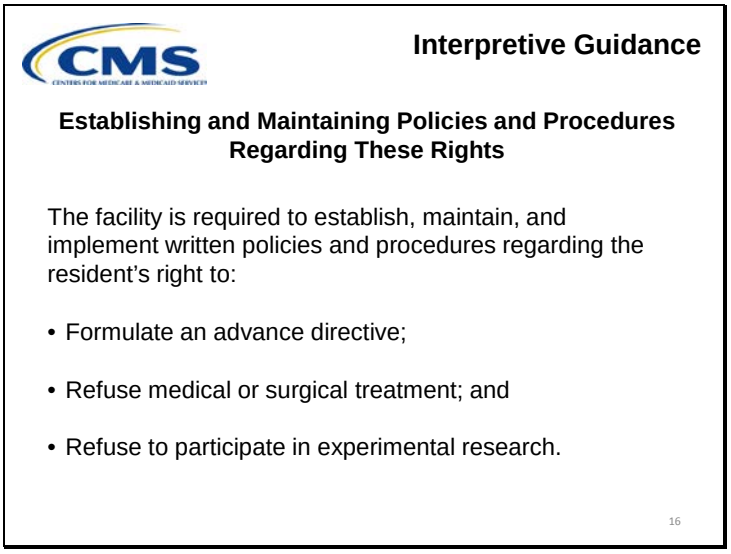
3) Cruzan v. Director, Missouri Department of Health. (1990). 497 U.S. 261. (http://www.oyez.org/cases/1980-1989/1989/1989_88_1503)

For additional information regarding standards of professional practice and the implementation of patient rights, refer to the F155 Interpretive Guidance Endnotes:

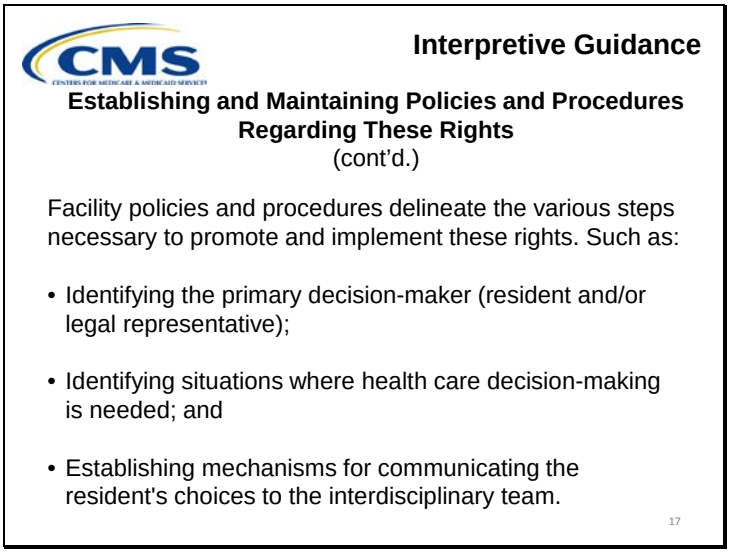
Atmore, C. & Naksook, C. (2007). Respecting Patient Choices – Literature Review. Prepared by Health Issues Centre for the Respecting Patient Choices Project, Austin Health, La Trobe University, VIC, Australia. (http://www.healthissuescentre.org.au/documents/items/2008/04/205853-upload-00001.pdf)

Emanuel, L.L., von Gunten, C.F., Ferris, F.D. (1991). Education for Physicians at the End of Life (EPEC) Participant's Handbook -- Plenary 2, Legal Issues. Robert Wood Johnson Foundation. (http://endoflife.northwestern.edu/legal_issues/module15.pdf)

Slide 16


Interpretive Guidance
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.
16

Slide 17



Discussion -- A more extensive list of some facility policies and procedures (and additional information for those listed on this slide) include:

Determining on admission whether the resident has an advance directive and, if not, determining whether the resident wishes to formulate an advance directive;

Identifying the primary decision-maker (e.g., assessing the resident's decision-making capacity and identifying the appropriate legal 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/her legal 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 in the resident's condition;

Reviewing the resident's condition and existing choices and continuing or modifying approaches, as appropriate;

Establishing mechanisms for communicating the resident's choices to the interdisciplinary team; and

Identifying the process (as provided by State law) for handling situations in which the facility and/or physician do not feel that they can provide care in accordance with the resident's advance directives or other wishes.

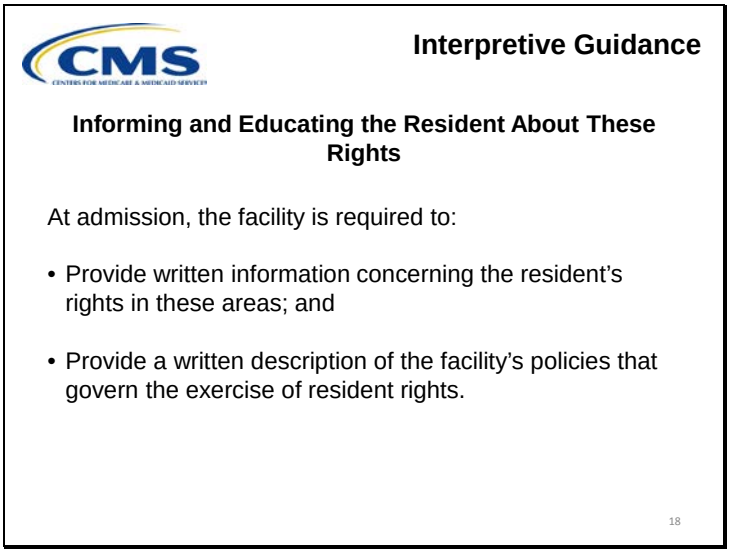
Refer to following F155 definitions:

"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.

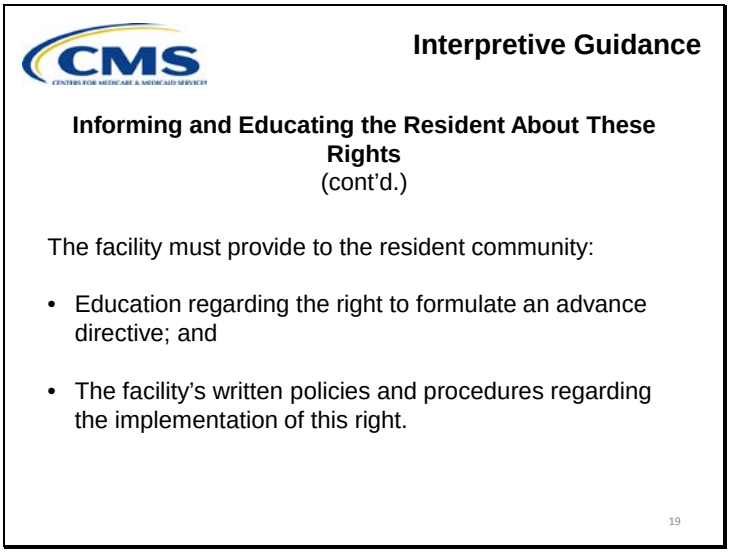
"Health care decision-making capacity" refers to possessing the ability (as defined by state law) to make decisions regarding health care and related treatment choices.

“Legal representative” (e.g., “Agent,” “Attorney in fact,” Proxy,” “Substitute decision-maker,” “Surrogate decision-maker”) 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.

Slide 18


Interpretive Guidance
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.
18

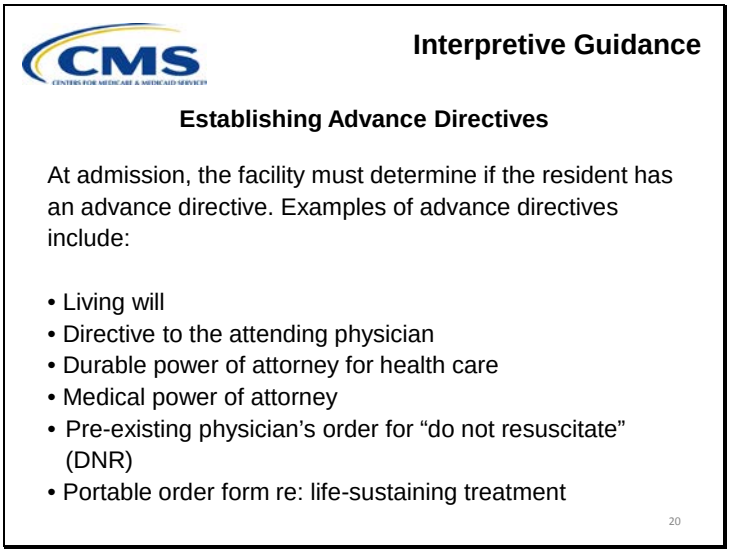
Slide 19



Bullet #1: The sum total of these educational efforts must include: the rights of the resident to formulate advance directives, a summary of the State law with regard to the right and the facility's implementation policies regarding advance directives. Various formats (e.g., written materials, video and audio tapes) may be used to provide such education.

Bullet #2: Written policies should include any limitations the facility may have with respect to implementing this right on the basis of conscientious objection as provided by state law.

Slide 20



Discussion regarding "Portable order form re: life-sustaining treatments"

Some states have adopted the use of a "portable and enduring form that documents the resident's choices related to life-sustaining treatments."

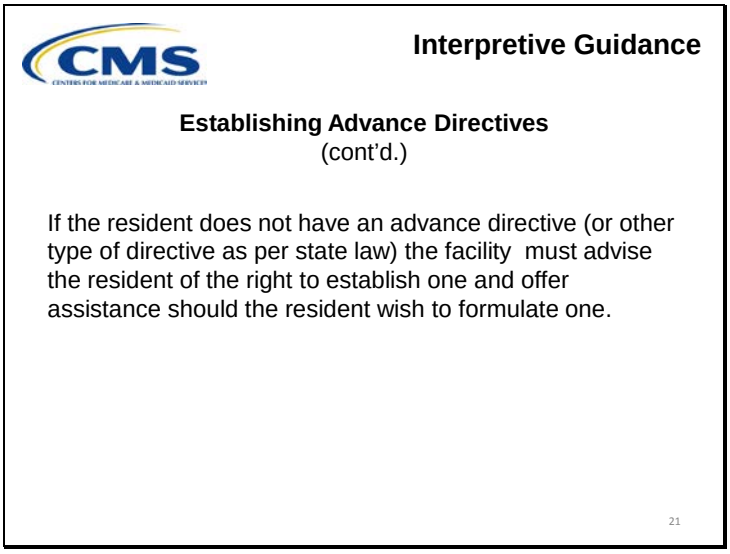
States have given them different names – "Physician Orders for Life Sustaining Treatment" (POLST) is common. New York State calls them Medical Orders for Life Sustaining Treatment" (MOLST). One tool for researching what each state may have is to refer to: www.POLST.org.

Refer to F155 Definition:

"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.

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

Slide 21



NOTE: The facility is responsible for providing information and resources to the resident as he or she may require to exercise these rights, but does not directly participate in or influence the resident's decisions. The facility must assist the resident if they wish to formulate an advance directive.

Slide 22

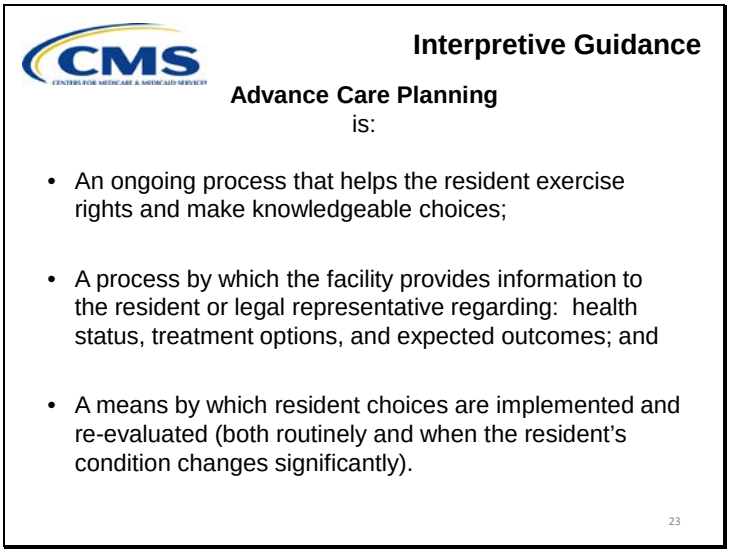
Interpretive Guidance

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.

Slide 23



Additional discussion re: the bullets:

Bullet #1: Discussions should occur during the development of the initial comprehensive assessment and care plan and periodically thereafter.
Bullet #2: This information should be provided in language and terms understandable to the resident and/or legal representative.
Bullet #3: Facility policies and procedures define when and how this implementation and reevaluation should be addressed.

Advance care planning (ACP) helps to further a resident's control over his/her medical treatment and choices. The process affords the resident, family and interdisciplinary care team the opportunity to reassess the resident's goals and wishes. It also helps the resident and family prepare for the time when the resident becomes more incapacitated or is actively dying.

Example for discussion re: the usefulness of establishing and understanding the resident's choices through the ACP process:

With the help of the staff and practitioner, the decision maker may need to tailor a resident's general wishes to specific circumstances. For example, a resident's advance directive states "do not hospitalize." This is a general statement that may be intended for terminal illness, or it may have been meant to cover every situation. The advance directive cannot anticipate every possible circumstance. What if the resident develops an acute illness unrelated to the terminal illness and would benefit from being hospitalized. The advance directive doesn't always distinguish between situations for which it was intended to be in effect and those for which it was not. Nevertheless, it represents the closest we can come to the wishes of someone who can no longer make such choices.

Example for discussion re: the need to reevaluate and possibly update the resident's documented choices through the ACP process:

A resident has a stroke, is hospitalized and is suffering from relocation trauma and is not eating. The hospital physician states that the resident will require a feeding tube if he/she doesn't eat. The advance directive at the facility states the resident did not want artificial nutrition and hydration. However, the family agrees to place the feeding tube and the resident returns to the facility with a feeding tube and without advisement or notification from the hospital.

- Did the resident verbally revoke the advance directive while in the hospital?
- If so, the resident's advance directive should be reevaluated and revised.
- If not, the resident's documented choices should be reviewed and the resident's preferred treatment implemented.

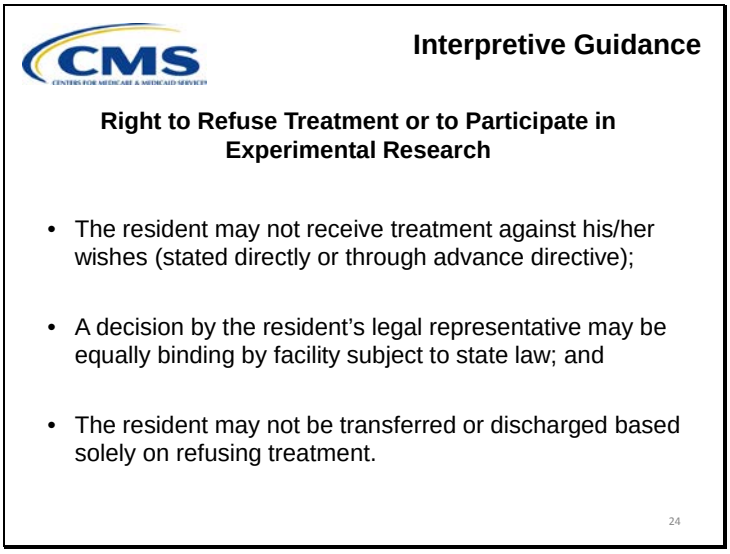
NOTE: Assessing the reasons why another facility may have placed a feeding tube and whether it continues to be necessary is discussed in the revised feeding tube guidance F322.

Refer to F155 definition:

"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.

"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 the administration of pain medication or other pain management interventions, the performance of a medical procedure related to enhancing comfort, or any other medical care provided to alleviate a resident's pain.

Slide 24



Additional discussion re: bullets:

Bullet #1 Discussion Example: Despite having lost considerable weight due to an underlying cause that is not readily corrected, the resident still has the right to decline artificial nutrition or IV hydration.

Bullet #2: Refer to state law.

Bullet #3: Refer to the criteria for transfer or discharge (§483.12(a) Transfer, and Discharge).

Refer to F155 Definitions:

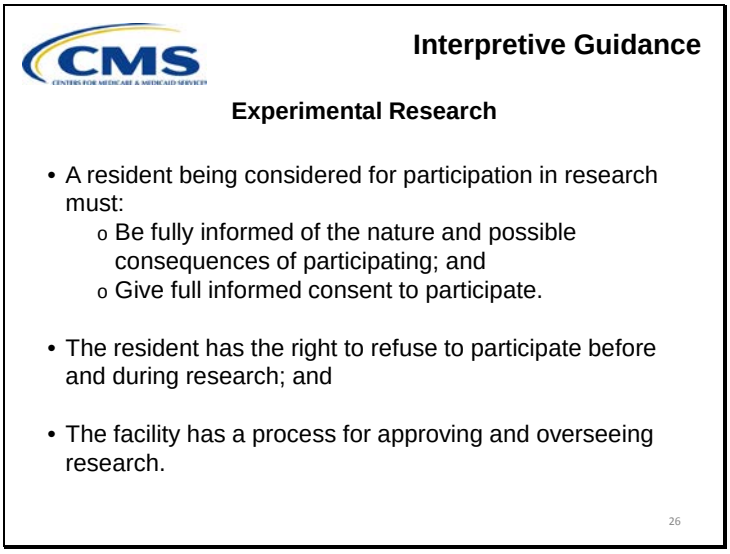
"Treatment" refers to interventions provided for purposes of maintaining/restoring health and well-being, improving functional level, or relieving symptoms.

Slide 25

It is important to note that the Quality of Care regulation (F309) states: "Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care."

The resident's refusal of treatment does not absolve a facility from providing other care and services that allow him/her to attain or maintain this highest practicable level of well-being – even though it is considered in the context of making that refusal of treatment and its implications for the resident's prognosis.

Slide 26



Additional Discussion:

Re: Bullet #1 -- If the resident is incapable of understanding the situation and of realizing the risks and benefits of the proposed research, but a legal representative gives proxy consent, the facility has a responsibility to ensure that the proxy consent is properly obtained and that essential measures are taken to protect the vulnerable individual from harm during the project.

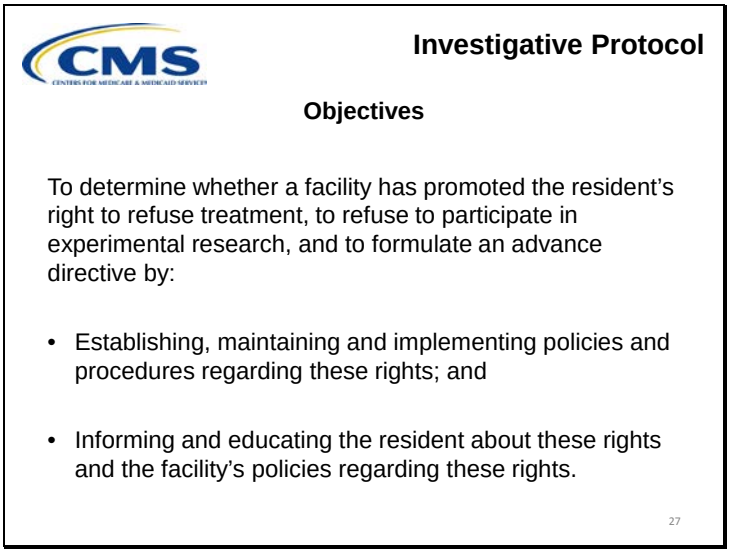
Re: Bullet #3 -- A facility participating in any experimental research involving residents has a process for committee approval of this research and mechanisms in place for its oversight.

Note: §483.75(c), Relationship to Other HHS Regulations, applies (i.e., research conducted at a facility must adhere to 45 CFR Part 46, Protection of Human Subjects of Research)

Refer to F155 Definition:

"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.

Slide 27


Investigative Protocol
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.
27

Slide 28

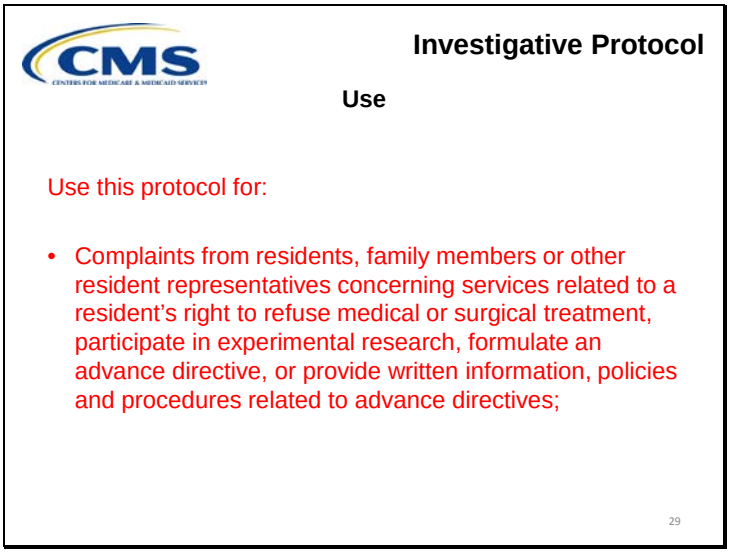
Investigative Protocol

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.

Slide 29



The investigative protocol use has been revised to apply only to residents that meet the criteria listed (training slides and investigative protocol).

Surveyors are <u>not</u> required to use this protocol for <u>all</u> residents in the survey sample.

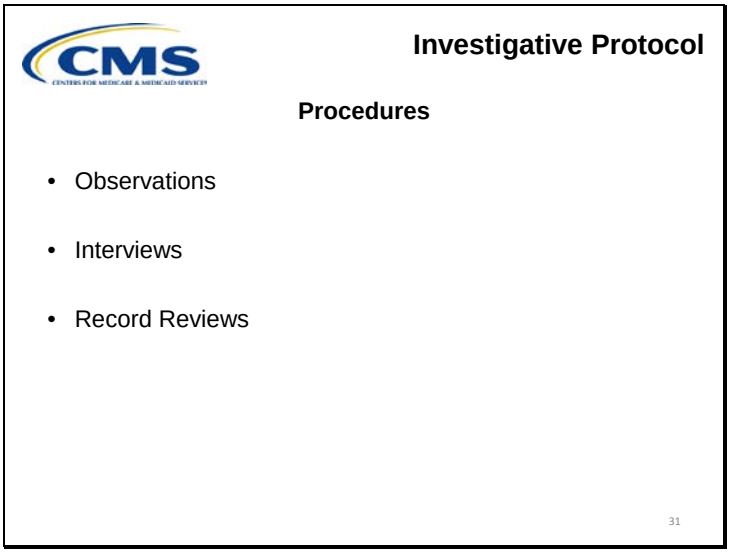
Slide 30

Investigative Protocol

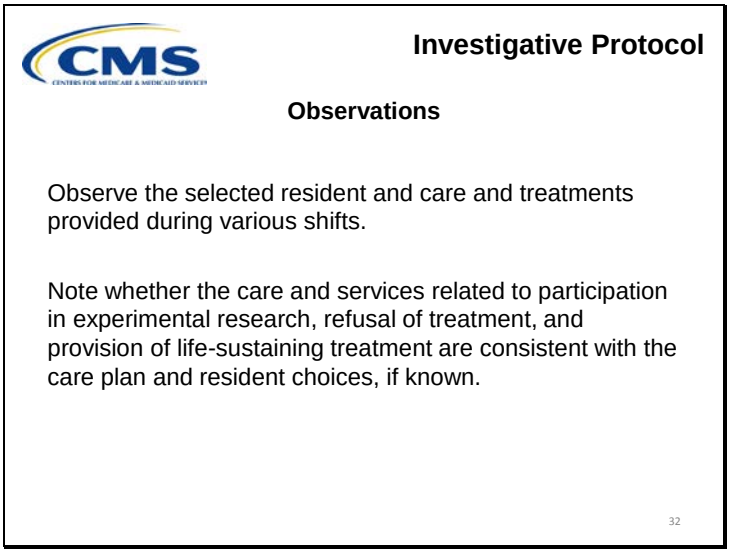
Use (cont'd.)

- 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.

Slide 31

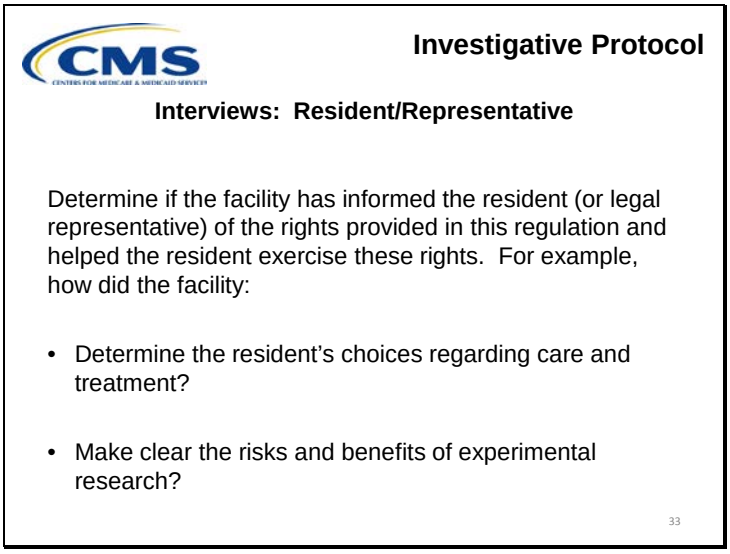

Investigative Protocol
Procedures
• Observations
• Interviews
• Record Reviews
31

Slide 32



Note: In some cases the observations on various shifts apply to all applicable shifts, depending on the observation being made.

Slide 33



Additional interview questions for discussion:

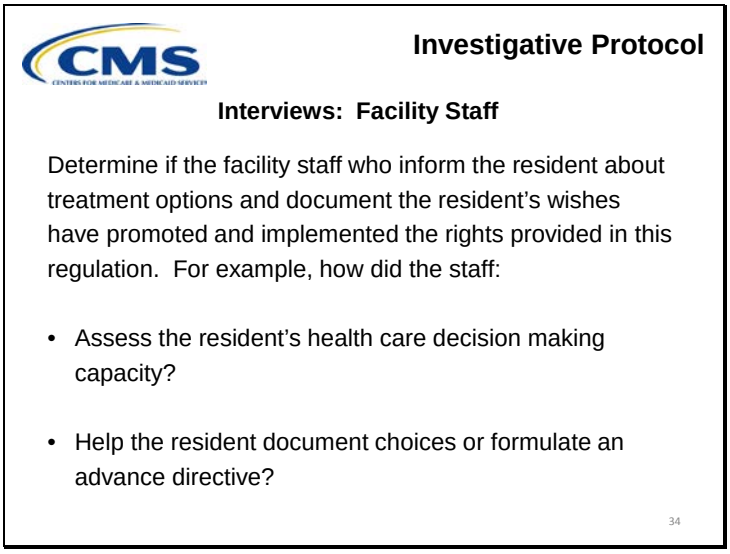
What have the staff and practitioner done to inform the resident or the resident's legal representative about the resident's medical condition and relevant health care issues;

What have the staff and practitioner done to inform the resident or the resident's legal representative about treatment options and the relevance of those options to the resident's goals, wishes, medical condition and prognosis;

What have the staff and practitioner done to help the resident or the resident's legal representative document treatment choices (e.g., in the form of advance directives or another format consistent with state and federal law and regulation); and

If the resident is participating in research, did the resident or the resident's legal representative receive information prior to the start of the project that: sufficiently explained the research for which he/she was being asked to give consent; and informed him/her of the right to refuse to participate?

Slide 34



Additional interview questions for discussion:

What training did staff receive regarding advance directives and their initiation?

How did the facility ensure that practitioner orders and treatment decisions were consistent with the resident's identified condition, prognosis, and documented choices and goals?

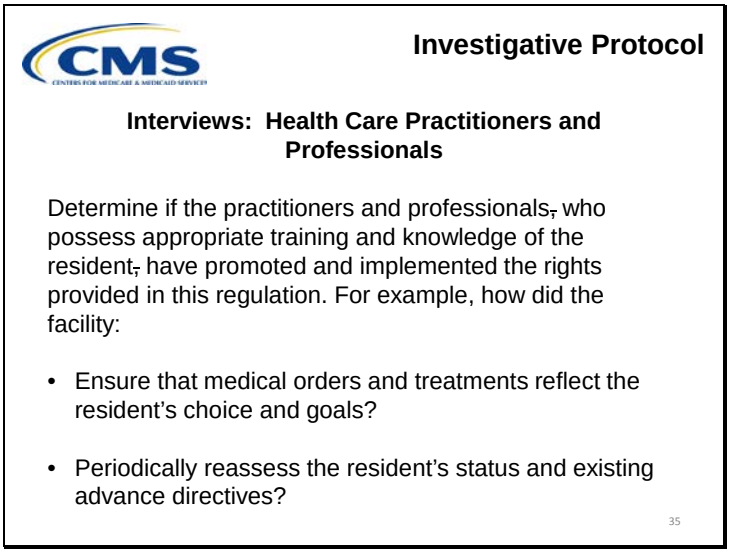
How did the practitioner and staff monitor and safeguard the rights of the resident involved in experimental research?

How did the practitioner and facility inform the resident or legal representative about his or her medical condition and relevant health care issues?

How did the facility determine whether the resident has an advance directive or other existing documentation related to life-sustaining treatment?

Did staff know how to access the information to determine the resident's choice?

Slide 35



Additional interview questions for discussion:

How does the facility seek, identify, and document the resident's wishes regarding advance care planning and life-sustaining treatments?

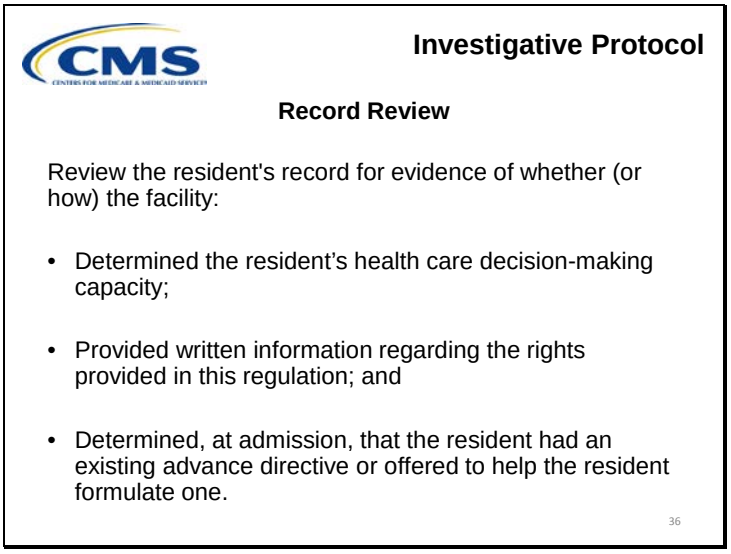
What is the process by which the staff and practitioners are involved in advising the resident and the resident's legal representative about the rights to refuse treatment (including life-sustaining treatments)?

How does the staff and practitioner periodically reassess the resident's condition and prognosis to identify whether existing advance directives remain pertinent and/or whether there is a need to initiate or expand such discussions?

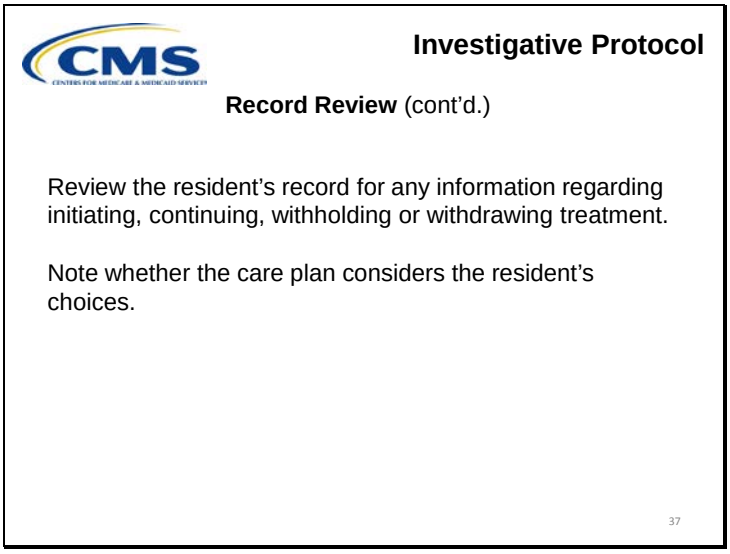
How does the staff and practitioner obtain and document informed consent of the resident who is participating in experimental research?

How does the staff and practitioner proceed if the resident who is involved in experimental research is suspected of, or identified as, suffering adverse consequences related to his/her participation?

Slide 36


Investigative Protocol
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.
36

Slide 37



Discussion examples -- Review information such as physician orders and interdisciplinary progress notes to determine:

Whether there is documentation of the medical rationale for recommendations and treatment decisions related to life-sustaining treatment options;

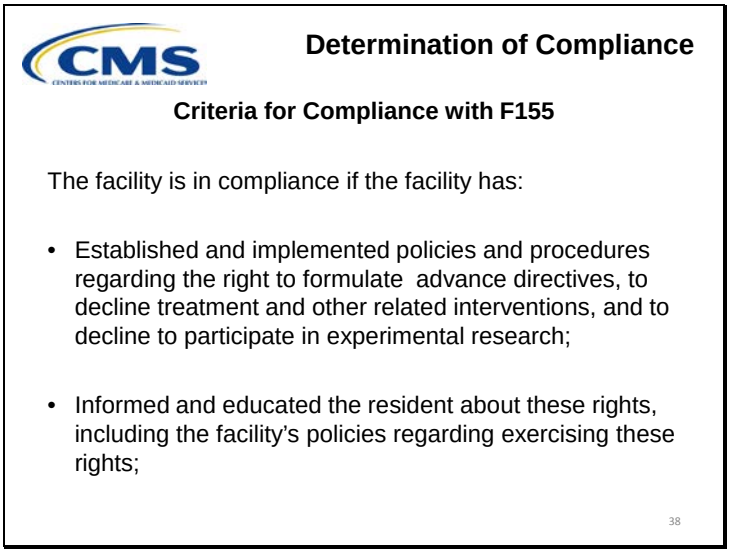
Whether the practitioner's orders are consistent with the resident's documented choices and goals (unless the physician needs further information about decision making capacity of the resident or has a conscientious objection);

Whether any treatments or interventions have been ordered (e.g., unplanned hospitalizations or placement of a feeding tube) that are inconsistent with the resident's documented acceptance or refusal of treatment or with any existing advance directives;

Whether the resident's advance directive, if formulated, has been incorporated into his or her active record; and

The frequency and scope of monitoring the resident who is participating in experimental research activities for responses to and adverse consequences of any experimental treatments.

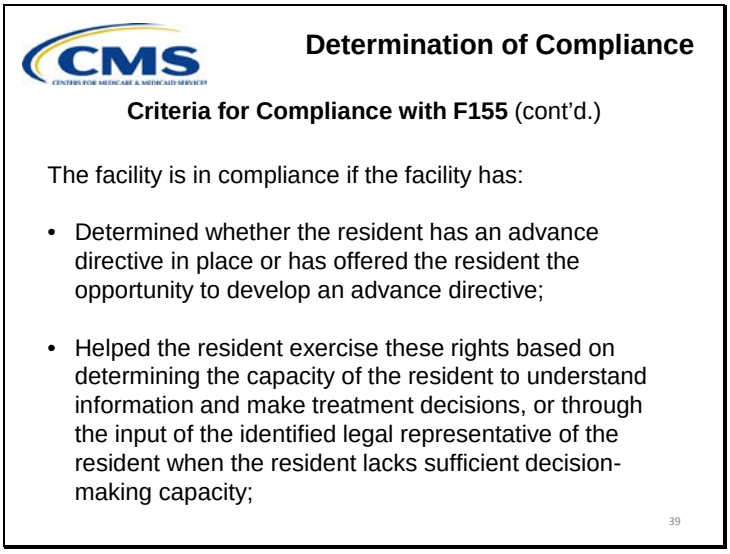
Slide 38



Note: Compliance with these criteria assures that the resident receives the appropriate care and treatment in accordance with their choices.

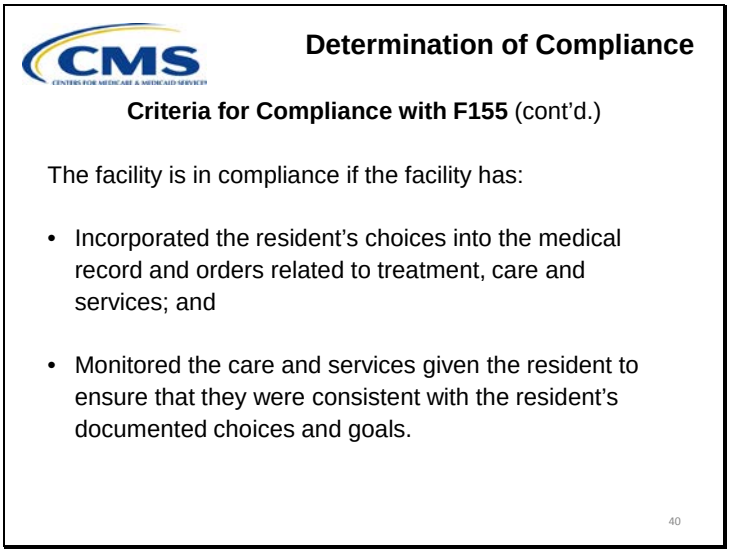
Conscientious Objection: A practitioner's refusal to do, or seeking exemption from, acts that threaten a person's sense of integrity or conscience. Patients as well as physicians and nurses may appeal to conscience in refusing treatment or procedures.

Slide 39



Note: Compliance with these criteria assures that the resident receives the appropriate care and treatment in accordance with their choices.

Slide 40



Note: Compliance with these criteria (slide 39-41) assures that the resident receives the appropriate care and treatment in accordance with their choices.

Slide 41

Determination of Compliance

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;

Slide 42

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;

Slide 43

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;

Slide 44

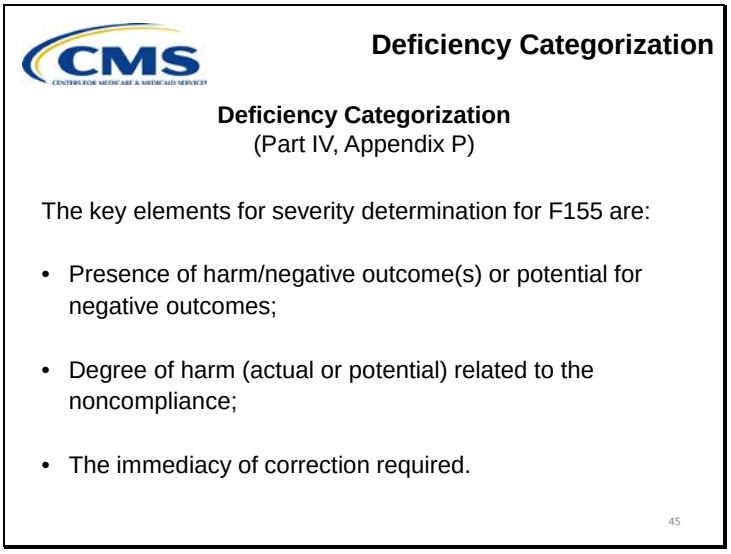
Determination of Compliance

Noncompliance for F155 (cont'd.)

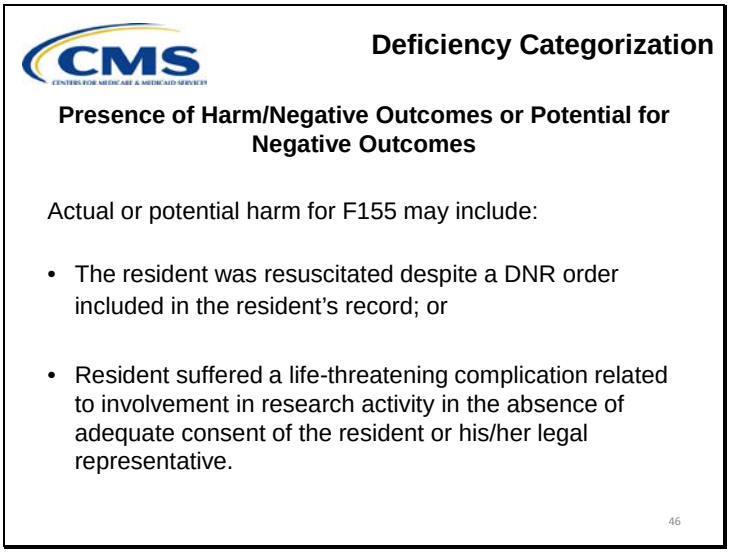
Failure to:

- 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.

Slide 45


Deficiency Categorization
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.
45

Slide 46



Additional examples for discussion:

•The resident was hospitalized contrary to his/her wishes.

•Resident received treatment based on the consent of an individual who was not the resident or his/her legal representative.

Slide 47

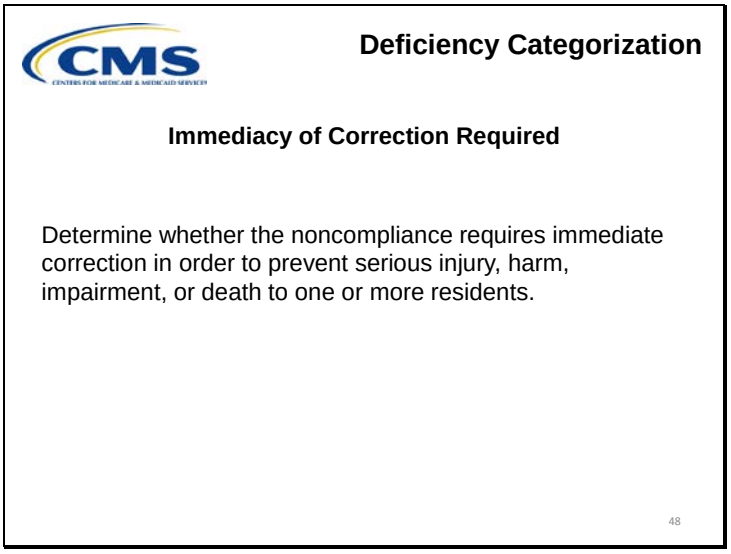
Deficiency Categorization

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

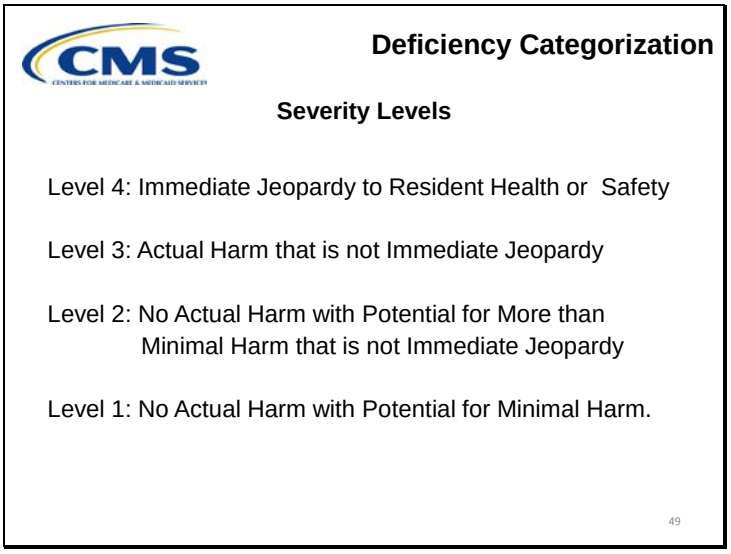
How the facility practices caused, resulted in, allowed, or contributed to actual/potential harm:

- 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.

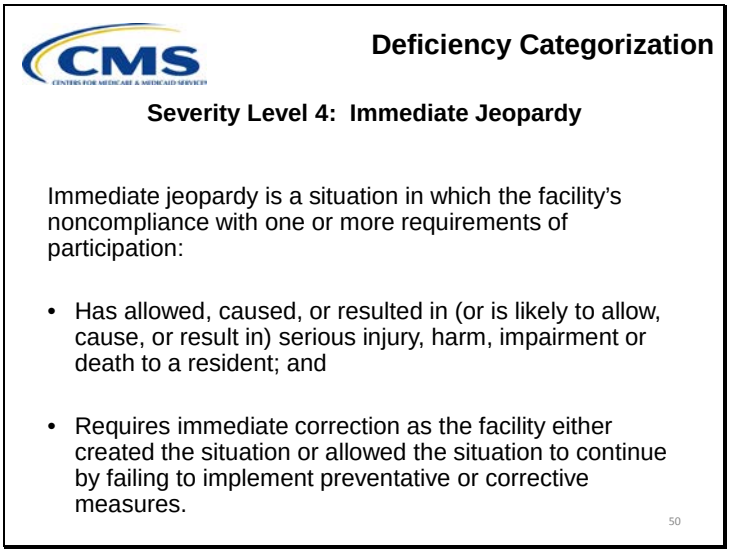
Slide 48


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.
48

Slide 49


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.
49

Slide 50


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.
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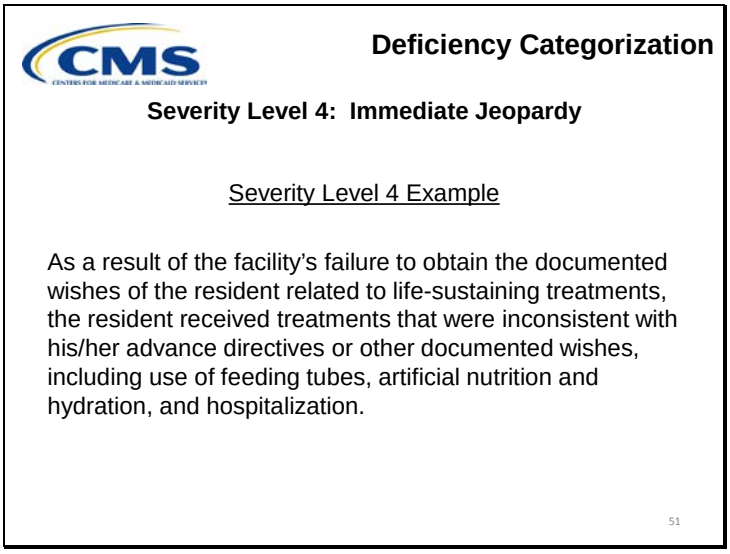

Additional example for discussion:

As a result of the facility's failure to obtain and implement physician orders for two weeks after the resident had documented choices related to life-sustaining treatments, the resident was transferred to the hospital for an acute change of condition, where a feeding tube was placed against the resident's wishes and the resident returned to the facility where the tube feeding was continued for three months despite the facility's knowledge that the intervention was against the resident's wishes.

Ask for additional examples or how this example could be a level 3. Note: There are typically discrepancies in how surveyors choose severity levels.

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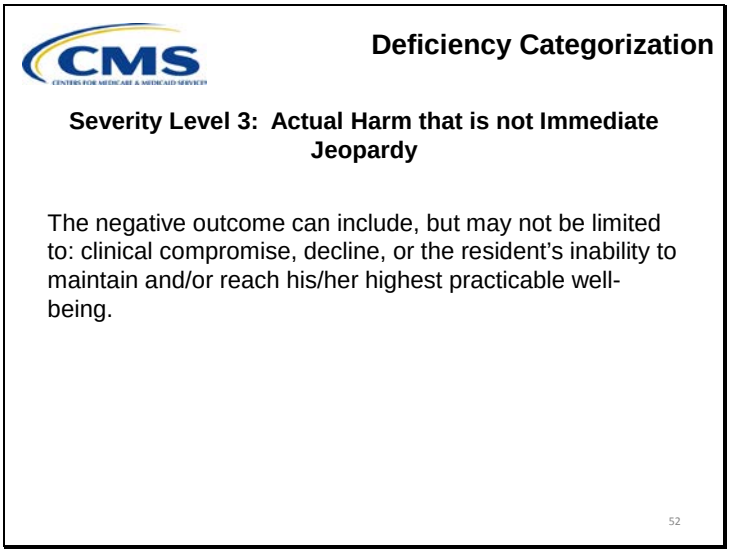
Deficiency Categorization
Severity Level 3: Actual Harm that is not Immediate Jeopardy
The negative outcome can include, but may not be limited to: clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable well-being.
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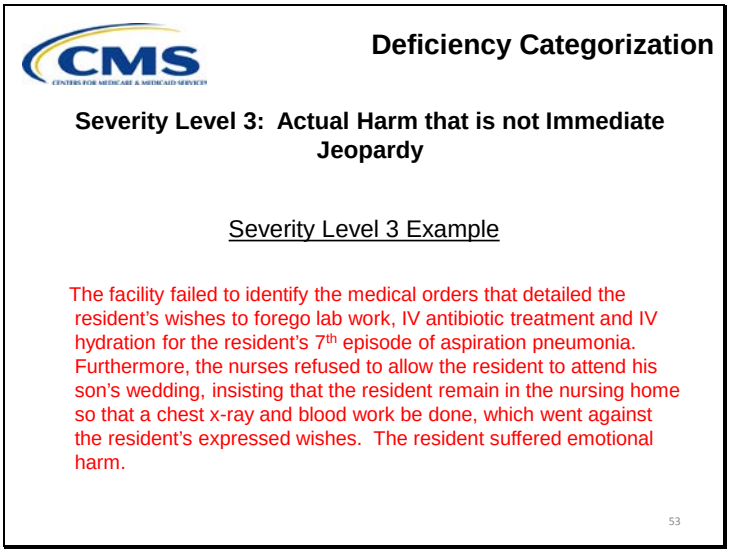

Additional examples for discussion:

As a result of the facility's failure to identify physician orders that were in conflict with the resident's advance directive and plan of care, the facility performed cardiopulmonary resuscitation on the resident and then had the resident transported to the hospital for additional treatment that was also contrary to the resident's documented wishes.

As a result of the failure of the staff and attending physician to monitor and communicate about the resident who was participating in an experimental research activity, the resident experienced clinically significant and enduring decline related to the experimental treatment.

Ask for additional examples or how these examples could be a level 2 or level 4.

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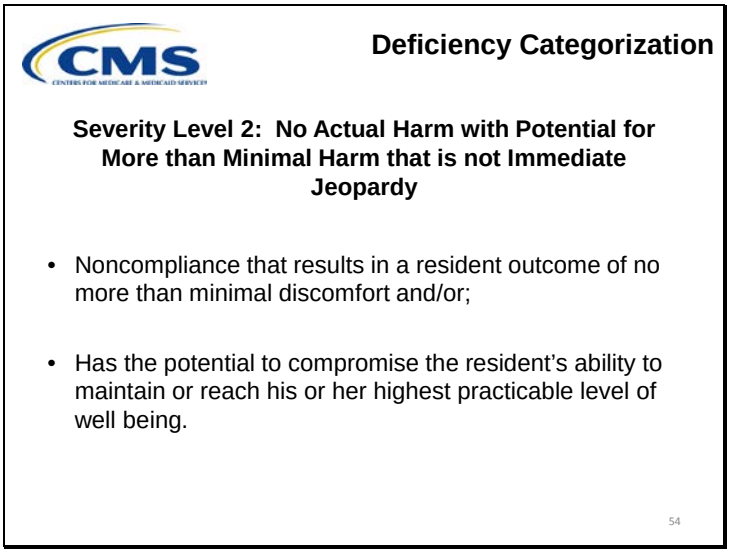
Deficiency Categorization
Severity Level 2: No Actual Harm with Potential for More than Minimal Harm that is not Immediate Jeopardy
• Noncompliance that results in a resident outcome of no more than minimal discomfort and/or;
• Has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well being.
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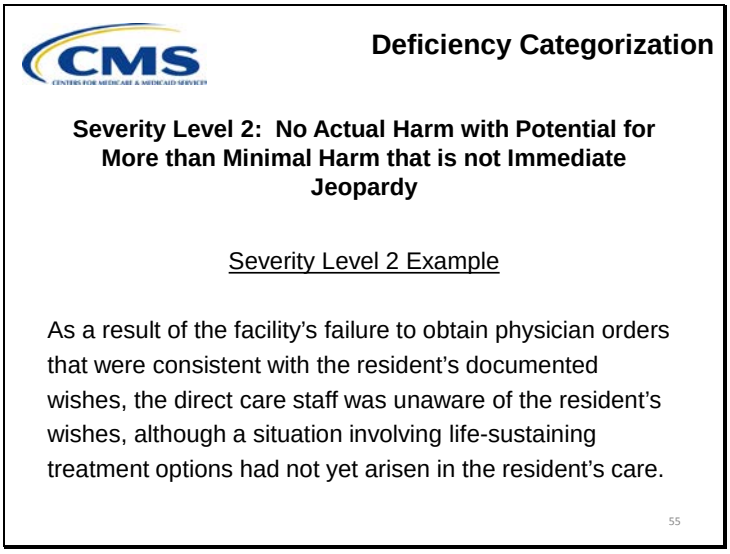

Additional examples for discussion:

As a result of the facility's failure to establish and implement policies and procedures regarding the rights to decline treatment and other related interventions, and to decline to participate in experimental research, the resident and/or the resident's legal representative was unaware of the opportunities to decline medical treatment, although a situation involving the use of life-sustaining treatment options had not yet arisen in the resident's care.

As a result of the facility's failure to take action when the resident requested assistance to develop an advance directive, the resident had not formulated an advance directive, despite the resident's desire to do so.

Ask for additional examples or how these examples could be a level 3.

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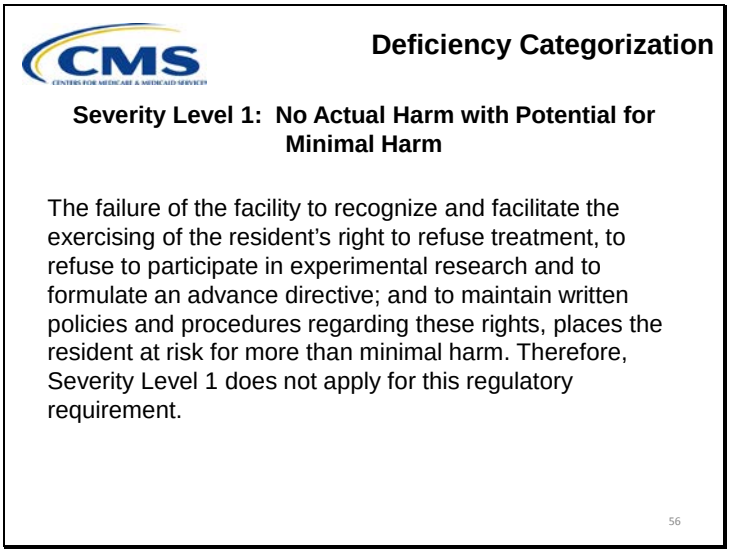
Deficiency Categorization
Severity Level 1: No Actual Harm with Potential for Minimal Harm
The failure of the facility to recognize and facilitate the exercising of the resident's right to refuse treatment, to refuse to participate in experimental research and to formulate an advance directive; and to 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.
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