Department of Health & Human Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 13-15-NH

DATE: **March 8, 2013**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Physician Delegation of Tasks in Skilled Nursing Facilities (SNFs) and Nursing Facilities (NFs)

This memorandum replaces Survey and Certification memorandum S&C-04-08 dated November 13, 2003, which discusses physician delegation of tasks in SNFs and NFs.

Memorandum Summary

- **Guidance revision:** This memo provides clarification of Federal guidance related to physician delegation of certain tasks in SNFs and NFs to non-physician practitioners (NPPs; formerly "physician extenders") such as nurse practitioners, physician assistants, or clinical nurse specialists
- **Implements Section 3108 of the Affordable Care Act (ACA):** Implements section 3108 of the Affordable Care Act, which adds physician assistants to the list of practitioners that can perform Skilled Nursing Facility (SNF) level of care certifications and re-certifications.
- **Co-signing of orders:** Clarifies policy on co-signing orders in SNFs and NFs.

A. Background

The Centers for Medicare & Medicaid Services (CMS) is clarifying for State survey agencies and providers the regulatory differences concerning physician delegation of tasks in SNFs and NFs. The distinction in policies between these two settings (SNFs and NFs) is based in statute and regulation. Improper application of these regulations may affect a facility's compliance and may also affect payment to providers. The key to accurate application is to identify:

(1) in which setting, SNF or NF, the physician services are being provided;
(2) whether the task must be performed personally by the physician; and
(3) whether or not the non-physician practitioner (NPP) is employed by the facility.

The "setting" is determined by whether the visit to a patient in a certified bed is to a resident whose care is paid for by Medicare Part A in a SNF or under Medicaid in a NF. This memorandum addresses the authority of NPPs (i.e., nurse practitioners, physician assistants, or

clinical nurse specialists) to perform certain tasks such as conducting physician visits and writing orders, and to sign certifications and re-certifications.

B. Physician Delegation of Tasks in Skilled Nursing Facilities (SNFs)

Under the requirements for long-term care facilities, 42 C.F.R. §483.40(e)(2) provides that, "A physician may not delegate a task when the regulations specify that the physician must perform it personally, or when the delegation is prohibited under State law or by the facility's own policies."

Physician Required and other Medically Necessary Visits in SNFs: Under 42 C.F.R. §483.40(c)(3), all required physician visits must be made by the physician personally and cannot be delegated. A required physician visit includes the initial comprehensive visit in a SNF and every alternate required visit thereafter, as required in 42 C.F.R. §483.40(c)(4). The initial comprehensive visit in a SNF is the initial visit during which the physician completes a thorough assessment, develops a plan of care and writes or verifies admitting orders for the resident. Under 42 C.F.R. §483.40(c)(1), the initial comprehensive visit must occur no later than 30 days after a resident's admission into the SNF. Further, under 42 C.F.R. §483.40(c)(4) and (e), the physician may not delegate the initial comprehensive visit in a SNF. Non-physician practitioners may perform other medically necessary visits prior to and after the physician's initial comprehensive visit.

Once the physician has completed the initial comprehensive visit in the SNF, the physician may then delegate alternate visits to a Physician Assistant (PA), Nurse Practitioner (NP), or Clinical Nurse Specialist (CNS) who is licensed as such by the State and performing within the scope of practice in that State, as permitted under 42 C.F.R. §483.40(c)(4). These alternate visits, as well as medically necessary visits, may be performed and signed by the NPP (physician co-signature is not required).

Certifications/Re-certifications in SNFs: Under 42 C.F.R. §424.20, certifications and re-certifications are required to verify that a resident requires daily skilled nursing care or rehabilitation services. Section 424.20(e)(2) (which reflects the requirements of section 1814 (a)(2) of the Social Security Act (Act)) states that NPs and CNSs who are not employed by the facility and who are working in collaboration with a physician may sign the required initial certification and re-certifications when permitted under the scope of practice for the State. Effective with services furnished on or after January 1, 2011, Section 1814(a)(2) of the Act, which was amended by section 3108 of the Affordable Care Act, authorizes physician assistants who are not employed by the facility to perform the required initial certification and periodic re-certifications of a beneficiary's need for a SNF level of care.

C. Performance of Physician Tasks in Nursing Facilities (NFs)

Physician Required and Other Medically Necessary Visits in NFs: Similar to a SNF, the initial comprehensive visit in a NF is the initial visit during which the physician completes a thorough assessment, develops a plan of care and writes or verifies admitting orders for the resident, which must take place no later than 30 days after admission. Section 483.40(f) provides that "At the

option of the State, any required physician task in a NF (including tasks which the regulations specify must be performed personally by the physician) may also be satisfied when performed by a nurse practitioner, clinical nurse specialist, or physician assistant who is not an employee of the facility but who is working in collaboration with a physician." In other words, NPPs that have a direct relationship with a physician and who are not employed by the facility may perform the initial comprehensive visit, any other required physician visit, and other medically necessary visits for a resident of a NF as the State allows. NPPs may also perform other medically necessary visits prior to and after the physician initial comprehensive visit.

At the option of the State, NPs, PAs, and CNSs who are employees of the facility, while not permitted to perform visits required under the schedule prescribed at 42 C.F.R. §483.40(c)(1), are permitted to perform other medically necessary visits and write orders based on these visits. For example, if a resident complains of a headache, the NP, CNS, or PA employed by the NF may assess the resident and write orders to address the condition. The physician is not required, other than by State law as applicable, to verify and sign orders written by NPPs who are employed by the facility for other medically necessary visits. These medically necessary visits performed by NPs, CNSs, and PAs employed by the facility may not take the place of the physician required visits, nor may the visit count towards meeting the required physician visit schedule prescribed at 42 C.F.R. §483.40(c)(1).

In contrast to the initial SNF visit, NPPs may provide initial NF visits and other required visits under 42 C.F.R. §§483.40(c)(3) and (f) if the State permits it. Under these regulations, required physician tasks, such as verifying and signing orders in an NF, may be delegated to a PA, NP, or CNS who is **not** an employee of the facility but who is working in collaboration with a physician. Orders written by an NPP who is employed by the NF and are written during visits that are not required visits, and are therefore "other medically necessary visits," do not require physician co-signature except as mandated by State law.

We are issuing this clarification because, where a NPP is permitted to perform a medically necessary visit, the NPP is likewise permitted to write applicable orders during that visit. The Federal requirements restricting NPPs who are employed by the NF from performing a *required visit*, do not apply to *other medically necessary visits*. Thus, this guidance clarifies when an NPP employed by a NF may write orders without a countersignature unless State law requires it.

NOTE: Regulatory language is included for reference purposes:

> **§483.40(f) Performance of Physician Tasks in NFs**
> **At the option of the State, any required physician task in a NF (including tasks which the regulations specify must be performed personally by the physician) may also be satisfied when performed by a nurse practitioner, clinical nurse specialist, or physician assistant who is not an employee of the facility but who is working in collaboration with a physician.**

D. Dually-Certified Facilities (SNF/NFs)

While the regulations do not address dually-certified SNF/NFs directly, the law is clear about who can perform tasks in a SNF and in a NF. In a facility where beds are dually–certified under

Medicare and Medicaid, the facility must determine how the particular resident stay is being paid. For residents in a Part A Medicare stay, the NPP must follow the guidelines for services in a SNF. For residents in a Medicaid stay, the NPP must follow the provisions outlined for care in NFs. As such, in a dually-certified nursing home, any required physician task for a Medicaid beneficiary in a Medicaid stay certified bed, at the option of the State, may be performed by a NPP who is not an employee of the facility but who is working in collaboration with a physician. In addition, in a dually-certified nursing home and at the option of a physician, required physician visits for a Medicare beneficiary in a Part A Medicare stay certified bed may be alternated between personal visits by the physician and visits by a NPP after the physician makes the initial first visit.

Table 1 below summarizes the requirements for non-physician practitioners to perform visits, sign orders, and sign certifications and re-certifications, when this function is permitted under the scope of practice for the State.

Table 1: Authority for Non-physician Practitioners to Perform Visits, Sign Orders and Sign Certifications/Re-certifications When Permitted by the State*

	Initial Comprehensive Visit /Orders	**Other Required Visits^**	**Other Medically Necessary Visits & Orders+**	**Certification/ Recertification**
SNFs				
PA, NP & CNS employed by the facility	May not perform/ May not sign	May perform alternate visits	May perform and sign	May not sign
PA, NP & CNS not a facility employee	May not perform/ May not sign	May perform alternate visits	May perform and sign	May sign subject to State Requirements
NFs				
PA, NP, & CNS employed by the facility	May not perform/ May not sign	May not perform	May perform and sign	Not applicable ±
PA, NP, & CNS not a facility employee	May perform/ May sign	May perform	May perform and sign	Not applicable ±

*This reflects clinical practice guidelines
^Other required visits are the required monthly visits.
+Medically necessary visits may be performed prior to the initial comprehensive visit.
± This requirement relates specifically to coverage of a Part A Medicare stay, which can take place only in a Medicare-certified SNF.

For questions on this memorandum, please contact Alice Bonner at alice.bonner@cms.hhs.gov.

Effective Date: This policy is in effect immediately.

Training: This policy should be shared with all appropriate survey and certification staff, their managers, and the state/regional office training coordinator.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
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

DEPARTMENT OF HEALTH & HUMAN SERVICES
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Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 13-17-NH

DATE: **March 8, 2013**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: F tag 322—Naso-Gastric Tubes - Revised Advance Copy

This memorandum replaces a previous version of S&C: 12-46-NH dated September 27, 2012.

Memorandum Summary

- **Revisions:** Additional revisions have been made to Surveyor Guidance at F tag 322 in Appendix PP of the State Operations Manual (SOM) and the associated training slides since the release of S&C 12-46 on September 27, 2012. The revisions include:
  - Revision of the Regulatory Language format.
  - Additional clarification regarding the Centers for Medicare and Medicaid Services (CMS) expanded definition of "Naso-Gastric tubes."
  - 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 12-46-NH, the CMS conducted a further review of the interpretive guidelines for F tag 322 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 when determining compliance with §483.25(g).

Revisions

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

- Revision of the regulatory language to now resemble the formatting of §483.25(g) in the Code of Federal Regulations (CFR).

- Additional clarification related to the expanded definition of "Naso-Gastric tubes."

- Updated Power Point Training slides to correlate with revisions made to the Surveyor Guidance at F tag 322. Revisions made to the training slides have a red font color.

Please note that the manual changes to Surveyor Guidance for F tag 322 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 322 (Feeding Tube)"

I. SUMMARY OF CHANGES: This instruction revises F321 by incorporating the regulatory language into F322.

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 tag 321
R	Appendix PP/F 322// §483.25(g)(1)(2)

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.**

F322

(Rev.)

483.25(g) Naso-Gastric Tubes

Based on the comprehensive assessment of a resident, the facility must ensure that --

(1) A resident who has been able to eat enough alone or with assistance is not fed by naso-gastric tube unless the resident's clinical condition demonstrates that use of a naso-gastric tube was unavoidable; and

(2) A resident who is fed by a naso-gastric or gastrostomy tube receives the appropriate treatment and services to prevent aspiration pneumonia, diarrhea, vomiting, dehydration, metabolic abnormalities, and nasal-pharyngeal ulcers and to restore, if possible, normal eating skills.

INTENT: (F322) §483.25(g)(1) and (2)

The intent of this regulation is that:

- *The feeding tube is utilized only after adequate assessment determines that the resident's clinical condition makes this intervention medically necessary;*
- *A feeding tube is utilized in accordance with current clinical standards of practice and services are provided to prevent complications to the extent possible; and*
- *Services are provided to restore normal eating skills to the extent possible.*

NOTE: For the purpose of the interpretative guidelines at F tag 322 the regulatory title "§483.25(g) Naso-gastric tubes" is considered to include any feeding tube used to provide enteral nutrition to a resident by bypassing oral intake. Since the regulation was promulgated, use of naso-gastric tubes has become extremely rare, and use of other types of enteral feeding tubes (such as those listed in the definitions section) has become prominent.

DEFINITIONS

"Avoidable/Unavoidable use of a feeding tube"

- *"Avoidable" means there is not a clear indication for using a feeding tube or there is insufficient evidence that it provides a benefit that outweighs associated risks.*
- *"Unavoidable" means there is a clear indication for using a feeding tube or there is sufficient evidence that it provides a benefit that outweighs associated risks.*

"Bolus feeding" *is the administration of a limited volume of enteral formula over brief periods of time.*

"Continuous feeding" *is the uninterrupted administration of enteral formula over extended periods of time.*

"Enteral nutrition" *(a.k.a. "tube feeding") is the delivery of nutrients through a feeding tube directly into the stomach, duodenum, or jejunum.*

"Feeding tube" *refers to a medical device used to provide enteral nutrition to a resident by bypassing oral intake.*

"Gastrostomy tube" *("G-tube") is a tube that is placed directly into the stomach through an abdominal wall incision for administration of food, fluids, and medications. The most common type is a percutaneous endoscopic gastrostomy (PEG) tube.*

"Jejunostomy tube" *(a.k.a. "percutaneous endoscopic jejunostomy" (PEJ) or "J-tube") is a feeding tube placed directly into the small intestine.*

"Nasogastric feeding tube" *("NG tube") is a tube that is passed through the nose and down through the nasopharynx and esophagus into the stomach.*

"Transgastric jejunal feeding tube" *("G-J tube") is a feeding tube that is placed through the stomach into the jejunum and that has dual ports to access both the stomach and the small intestine.*

"Tube feeding" *(a.k.a. "enteral feeding") is the delivery of nutrients through a feeding tube directly into the stomach, duodenum, or jejunum.*

OVERVIEW

A decision to use a feeding tube has a major impact on a resident and his or her quality of life. It is important that any decision regarding the use of a feeding tube be based on the resident's clinical condition and wishes as well as applicable federal and state laws and regulations for decision making about life-sustaining treatments.

The use of feeding tubes varies widely within and among states. Reasons for this variability are unclear, but they may include diverse opinions about the benefits and risks of non-oral nutrition, and variable facility policies and usual practices. [1,2,3,4,5]

NOTE*: Refer to §483.10(b)(4) and (b)(8), Notice of Rights and Services, Right to Refuse Treatment and Experimental Research and to Formulate Advance Directives; and §483.15(b), Self-Determination and Participation, in order to determine if the use of a feeding tube is consistent with the wishes and instructions of the resident, if known (e.g., verbal or handwritten instructions, advance directive or living will) or the instructions*

of the resident's legal representative, if the resident is unable to make his or her wishes known.

RESOURCES

- ***The American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.)*** *is dedicated to improving patient care by advancing the science and practice of nutrition support therapy. A.S.P.E.N. maintains a Guidelines and Standards Library. The Guidelines and Standards make specific practice recommendations.*
  http://www.nutritioncare.org/Library.aspx

- ***The Alzheimer's Association*** *offers a fact sheet regarding care and patient rights: Ethical Issues in Alzheimer's Disease, Assisted Oral Feeding and Tube Feeding.*
  http://www.alz.org/alzwa/documents/alzwa_Resource_EOL_FS_Oral_Feeding.pdf

NOTE*: References to non-CMS sources or sites on the Internet are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services. CMS is not responsible for the content of pages found at these sites. URL addresses were current as of the date of this publication.*

CONSIDERATIONS REGARDING THE USE OF FEEDING TUBES

The regulations at §483.25(g) require that the resident's clinical condition demonstrates the use of a feeding tube to be unavoidable. A feeding tube may be considered unavoidable only if no other viable alternative to maintain adequate nutrition and/or hydration is possible and the use of the feeding tube is consistent with the clinical objective of trying to maintain or improve nutritional and hydration parameters.[6]

Several factors may be involved in the decision to use a feeding tube including medical conditions that impair the resident's ability to maintain appropriate nutritional parameters (e.g., cerebrovascular accident, esophageal cancer, delirium, reconstructive facial or oral surgery), the need to improve the resident's nutritional status or level of comfort, or the desire to prolong the resident's life. The duration of use of a feeding tube may vary, depending on the clinical situation.

The interdisciplinary team, with support and guidance from the physician, is responsible for assuring the ongoing review, evaluation and decision-making regarding the continuation or discontinuation of all treatments, devices or approaches implemented to care for the resident. Involving the resident, family, and/or the resident's legal representative in discussions about the indications, use, potential benefits and risks of tube feeding, types of approaches, and alternatives helps support the resident's right to make an informed decision to use or not use artificial nutrition and hydration.

A clinically pertinent rationale for using a feeding tube includes, but is not limited to:

- *An assessment of the resident's nutritional status, which may include usual food and fluid intake, pertinent laboratory values, appetite, and usual weight and weight changes;*

- *An assessment of the resident's clinical status, which may include the ability to chew, swallow, and digest food and fluid; underlying conditions affecting those abilities (e.g., coma, stroke, esophageal stricture, potentially correctable malnutrition that cannot be improved sufficiently by oral intake alone); factors affecting appetite and intake (e.g., medications known to affect appetite, taste, or nutrition utilization); and prognosis;*

- *Relevant functional and psychosocial factors (e.g., inability to sufficiently feed self, stroke or neurological injury that results in loss of appetite, psychosis that prevents eating); and*

- *Interventions prior to the decision to use a feeding tube and the resident's response to them. (Refer to F325 for discussion and examples of interventions to improve and restore normal nutritional parameters.)*

***NOTE**: Refer to §483.20 Resident Assessment and the Assessment Section of the General Investigative Protocol at Quality of Care (F309) for discussion of the comprehensive evaluation that comprises an assessment.*

The use of a feeding tube may potentially benefit or may adversely affect a resident's clinical condition and/or psychosocial well-being. Examples of some possible benefits of using a feeding tube may include:

- *Addressing malnutrition and dehydration;*

- *Promoting wound healing; and*

- *Allowing the resident to gain strength, receive appropriate interventions that may help restore the resident's ability to eat and, perhaps, return to oral feeding.*

Examples of some possible adverse effects of using a feeding tube may include:

- *Diminishing socialization, including, but not limited to, the close human contact associated with being assisted to eat or being with others at mealtimes;*

- *Not having the opportunity to experience the taste, texture, and chewing of foods;*

- *Causing tube-associated complications; and*

- *Reducing the freedom of movement related to efforts to prevent the resident from pulling on the tube or other requirements related to the tube or the tube feeding.*

In order to assure that the resident being fed by a feeding tube maintains the highest degree of quality of life possible, it is important to minimize possible social isolation or negative

psychosocial impact to the degree possible (e.g., continuing to engage in appropriate activities, socializing in the dining room). Because of the possible side-effects and discomfort associated with the use of nasogastric tubes, there should be clinically pertinent documentation for extended use of nasogastric tubes (e.g., greater than 30 days).

Nutrition and feeding issues and their underlying causes in the resident with advanced dementia or other chronic neurological disorders such as Parkinson's disease present a particular set of issues and considerations that are discussed in F325. The extended use of enteral feeding tubes in individuals with advanced dementia remains controversial. The literature regarding enteral feeding of these individuals suggests that there is little evidence that enteral feeding improves clinical outcomes (e.g., prevents aspiration or reduces mortality). [7,8,9,10,11,12]

Resident Rights

The regulations at 483.10(d)(2) state that the resident has the right to be fully informed in advance about care and treatment and of any changes in the care or treatment that may affect the resident's well-being. In addition, the regulations at 483.10(b)(4) state that the resident has the right to refuse treatment and to formulate an advance directive.

If a resident has had a feeding tube placed prior to admission or in another setting while residing in the facility, the physician and interdisciplinary care team review the basis (e.g., precipitating illness or condition change) for the initial placement of the feeding tube and the resident's current condition to determine if there is a continued rationale for its use and to ensure that its continued use is consistent with the resident's treatment goals and wishes. Decisions to continue or discontinue the use of a feeding tube are made through collaboration between the resident (or a legal representative for a resident who lacks capacity to make and communicate such decisions), the physician, and the interdisciplinary care team. This includes a discussion of the relevance of a feeding tube to attaining a resident's goals (e.g., whether the nutritional intervention is likely to have a significant impact on the individual's underlying condition or overall status).

TECHNICAL AND NUTRITIONAL ASPECTS OF FEEDING TUBES

It is important that staff providing care and services to the resident who has a feeding tube are aware of, competent in, and utilize facility protocols regarding feeding tube nutrition and care. These protocols are required to be developed with the medical director in order to assure staff implement and provide care and services according to resident needs and clinical standards of practice.

Technical Aspects of Feeding Tubes

Facility procedures regarding the technical aspects of feeding tubes include, but are not limited to, the following:

Location of the feeding tube. *Direction to staff regarding how to monitor and check that the feeding tube is in the right location (e.g., stomach or small intestine, depending on the tube) or verify that placement was checked, such as:*

- *Techniques to verify that tube placement is appropriate before beginning a feeding and before administering medications; and*

- *The frequency with which staff should monitor for proper location of the feeding tube to assure that the enteral retention device is properly approximated to the abdominal wall and the surrounding skin is intact.*

Care of the feeding tube. *Direction to staff on how to provide care such as:*

- *Securing a feeding tube externally;*

- *Providing needed personal, skin, oral, and nasal care to the resident;*[13]

- *Examining and cleaning the insertion site in order to identify, lessen or resolve possible skin irritation and local infection;*

- *Using infection control precautions and related techniques to minimize the risk of contamination; for example, in connecting the tube and the tube feeding; and*

- *Defining the frequency of and volume used for flushing, including flushing for medication administration, and when a prescriber's order does not specify.*

Feeding tube replacement. *Direction for staff regarding the conditions and circumstances under which a tube is to be changed, such as:*

- *When to replace and/or change a feeding tube (generally replaced either as planned/scheduled or as needed such as when a long-term feeding tube comes out unexpectedly or a tube is worn or clogged);*

- *How and when to examine a feeding tube and the infusion plug to identify splits or cracks that could produce leakage;*

- *Instances when a tube can be replaced within the facility and by whom;*

- *Instances when a tube must be replaced in another setting (e.g., hospital, ambulatory surgery center); and*

- *Notification of the practitioner when the need for a tube change arises unexpectedly.*

Nutritional Aspects of Feeding Tubes

When a resident is receiving nutrition via a feeding tube, the practitioner and the interdisciplinary team identify the resident's nutritional needs and facility procedures that direct staff in providing care and services to the resident. The practitioner's orders related to tube feeding typically include the following components: kind of feeding and its caloric value; volume, duration, and mechanism of administration (e.g., gravity or pump); and frequency of flush.

Facility procedures regarding the nutritional aspects of feeding tubes include, but are not limited to:

Enteral nutrition. *Direction to staff regarding the nutritional product and meeting the resident's nutritional needs such as:*

- *Types of enteral nutrition formulas available for use;*
- *How to determine whether the tube feedings meet the resident's nutritional needs and when to adjust them accordingly;*
- *How to balance essential nutritional support with efforts to minimize complications related to the feeding tube;*
- *Ensuring that the selection and use of enteral nutrition is consistent with manufacturer's recommendations;*
- *Ensuring that the administration of enteral nutrition is consistent with and follows the practitioner's orders; and*
- *Ensuring that the product has not exceeded the expiration date.*[14] [15]

Flow of feeding. *Direction for staff regarding how to manage and monitor the rate of flow, such as:*

- *Use of gravity flow;*
- *Use of a pump;*
- *Periodic evaluation of the amount of feeding being administered for consistency with practitioner's orders;*
- *Calibration of enteral feeding pumps to ensure that pump settings accurately provide the rate and volume consistent with the resident's care plan; and*
- *Periodic maintenance of feeding pumps consistent with manufacturer's instructions to ensure proper mechanical functioning.*

Complications Related to the Feeding Tube

An enteral feeding tube may be associated with significant complications, including aspiration, leaking around the insertion site, abdominal wall abscess, or erosion at the insertion site including the nasal areas. Feeding tubes can perforate the stomach or small intestine, with resultant peritonitis. Esophageal complications of feeding tubes may also occur including esophagitis, ulcerations, strictures, and tracheoesophageal fistulas. The use of tubes not designed or intended for enteral feeding may increase the risk of complications.[16,17]

Tubes may clog for various reasons, including plugging by formula, pill fragments, or the precipitation of medications incompatible with the formula.[18] *Flushing feeding tubes regularly and in association with medication administration, as indicated by current clinical standards of practice and provided in the resident care policies, can help reduce the risk of clogging.*

Complications Related to the Administration of the Enteral Nutrition Product

The administration of an enteral nutrition product may be associated with other complications including, but not limited to, nausea, vomiting, diarrhea, abdominal cramping, inadequate nutrition and aspiration. Additionally, interactions between the formula and various medications can affect the absorption and/or effectiveness of the medication. For example, the effectiveness of phenytoin sodium may be reduced by the drug binding with the enteral feeding's protein component, leading to less free drug availability and possibly inadequate therapeutic levels.

Metabolic complications related to tube feeding may include inadequate calorie or protein intake, altered hydration, hypo- or hyperglycemia, and altered electrolyte and nutrient levels. These risks may be reduced by calculating the nutritional needs of the resident, taking into account comorbid conditions and medications that affect these balances, monitoring for adequate nutritional status and complications, and adjusting the tube feeding accordingly.

While a feeding tube may be initiated with the intent to address certain medical conditions, the use of a feeding tube does not necessarily decrease the risk of aspiration for individuals with other risk factors, such as moderate or less severe swallowing abnormalities. Aspiration risk may potentially be affected by factors such as diminished level of consciousness, improper positioning of the resident during administration of the feeding, and failure to assure the feeding tube is correctly positioned within the stomach or intestine. The evidence is inconsistent and conflicting regarding any connection between gastric residual volume and the risk or occurrence of aspiration.[19]

Risk of aspiration should be assessed individually and appropriate interventions (e.g., proper positioning, rate of flow) implemented accordingly. There may be situations where other coexisting factors influence decisions about elevating the head of the bed; for example, a resident being fed by a tube who may be at risk for shearing by sliding down the sheets when the head of the bed is elevated to a recommended angle.

Complications Management

The facility is expected to identify and address actual or potential complications related to the feeding tube or tube feeding and to notify and involve the practitioner in evaluating and managing care to address these complications and risk factors.[20]

ENDNOTES

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INVESTIGATIVE PROTOCOL FOR FEEDING TUBES

Objectives

- *To determine if a feeding tube is utilized only after adequate assessment determines that the resident's clinical condition makes this intervention medically necessary;*
- *To determine if a feeding tube is utilized in accordance with current clinical standards of practice and if services are provided to prevent complications to the extent possible; and*
- *To determine if services are provided to restore normal eating skills to the extent possible.*

Use

Use this protocol for a resident who has a feeding tube.

Procedures

The surveyor(s) should conduct the following observations, interviews and record reviews. If there are concerns regarding the facility's use and care of feeding tubes, review facility policies and practices with regard to the use and care of feeding tubes.

Observations

During various shifts, observe staff interactions with the resident and provision of care including: initiation, continuation, and termination of feedings; care of the tube site and equipment; and medication administration via the feeding tube, if possible. Use the observations to determine whether staff follow clinical standards of practice, facility policy, the resident care plan, and prescriber's orders and if they try to minimize the risk for complications including but not limited to:

- *Implementing interventions to minimize the negative psychosocial impact that may occur as a result of tube feeding;*
- *Providing mouth care, including teeth, gums, and tongue;*
- *Checking that the tubing remains in the correct location;*
- *Properly positioning the resident consistent with the resident's individual needs;*
- *Using universal precautions and clean technique and following the manufacturer's recommendations when stopping, starting, flushing, and giving medications through the feeding tube;*

- *Ensuring the cleanliness of the feeding tube, insertion site, dressing (if present) and nutritional product; and*

- *Providing the type, rate, volume and duration of the feeding as ordered by the practitioner and consistent with the manufacturer's recommendations.*

Note staff response if there is evidence of possible complications, such as diarrhea, nausea, vomiting, abdominal discomfort, nasal discomfort (if a nasogastric tube is being used); evidence of leakage and/or skin irritation at the tube insertion site; or risk of inadvertent removal of the tube.

Interviews

Resident/Representative

Interview the resident and/or resident's legal representative (as appropriate) regarding involvement in development of the care plan including goals and approaches; whether the interventions reflect the resident's choices and preferences; and the resident's response to the tube feeding, including the following:

- *Whether staff provided assistance to the resident to increase the food intake, prior to inserting a feeding tube (e.g., identifying underlying causes of anorexia; hand feeding; changing food consistency, texture, form; offering alternate food choices; and/or providing assistive devices);*

- *Whether the resident and/or the resident's legal representative (as appropriate) was informed about the relevant benefits and risks of tube feeding, and involved in discussing alternatives and making the decision about using a feeding tube;*

- *Whether the resident has had any significant new or worsening physical, functional or psychosocial changes; whether the resident informed the staff; and how the problems were addressed;*

- *Whether there has been a reassessment and discussion with the resident or the resident's legal representative regarding the continued appropriateness/necessity of the feeding tube.*

***NOTE**: Prior to inserting a feeding tube, the prescriber reviews the resident's choices/instructions and goals, including all relevant information that may be identified in advance directives (See F155, F156 and F242).*

Facility staff

Interview staff that provide direct care on various shifts to determine:

- *How staff and practitioner determined the cause(s) of decreased oral intake/weight loss or impaired nutrition and attempted to maintain oral intake prior to the insertion of a feeding tube, such as did staff collaborate with the physician to identify medical causes of decreased appetite or try to help the resident eat enough food (e.g., cueing or hand feeding; changing food consistency, texture, form; seeking and addressing causes of anorexia; providing assistive devices);*

- *What the specific care needs for the resident are (e.g., special positioning, personal care, insertion site care, amount of feeding taken in);*

- *How the staff determined the resident's nutritional status was being met such as periodically weighing the resident and how they decide whether the tube feeding is adequate to maintain acceptable nutrition parameters;*

- *Whether the resident has voiced any complaints or exhibited any physical or psychosocial complications that may be associated with the tube feeding (e.g., nausea or vomiting, diarrhea, pain associated with the tube, abdominal discomfort, depression, withdrawal); and how these problems have been addressed;*

- *To whom a staff member has reported the resident's signs or symptoms; and*

- *Whether there has been a periodic reassessment and discussion with the resident or his/her legal representative regarding the continued appropriateness/necessity of the feeding tube; and whether the care plan has been revised and implemented as necessary.*

Health care practitioners and professionals

The assigned surveyor should review, as indicated, the facility's policies, procedures, records of incidents and corrective actions related to feeding tubes; documentation of staff knowledge and skills related to the aspects of administering tube feeding; and should, as necessary, interview facility staff with responsibility for overseeing or training in this aspect of care to determine:

- *How the facility identified the resident at risk for impaired nutrition, identified and addressed causes of impaired nutrition, and determined that use of a feeding tube was unavoidable;*

- *How staff calculated nutritional needs for the resident and how they ensure that the resident receives close to the calculated amount of nutrition daily;*

- *How staff monitor the resident for the benefits and risks related to a feeding tube, and address adverse consequences of the feeding tube use (e.g., altered mood, nausea and vomiting, pain, or restraint use to try to prevent the resident from removing the feeding tube);*

- *How staff are trained and directed regarding management of feeding tubes and tube feedings in general, and in addressing any specific issues related to this individual resident;*

- *Whether the physician and staff attempted to identify the circumstances that led to the placement of the feeding tube (e.g., when the tube was placed in another facility); and*

- *Whether the resident was periodically reassessed for the continued appropriateness/necessity of the feeding tube; and whether the care plan was revised and implemented, as necessary, with input from the resident or his/her legal representative, to the extent possible.*

***NOTE**: During the course of the review, if the surveyor needs to contact the attending physician 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 for his/her review prior to responding to the surveyor's inquiries. If the attending physician is unavailable, interview the medical director, as appropriate.*

Record Review

Review information such as physician orders, tube feeding records, multidisciplinary progress notes, RAI/MDS and any available assessment regarding the rationale for feeding tube insertion and the potential to restore normal eating skills, including the interventions tried (to avoid using the feeding tube before its insertion, restore oral intake after tube insertion, and prevent potential complications). In order to identify concerns or to further investigate identified concerns about tube feedings, review to determine:

- *How the staff verify that the feeding tube is properly placed;*

- *That staff are assigned responsibilities for various aspects of enteral feedings consistent with their position and training (e.g., administering the feeding, determining and verifying correct formula; calculating the amount of formula, feeding intervals, flow rate);*

- *How staff have monitored a resident for possible complications (e.g., depression, nutritional deficits, withdrawal, aspiration, aspiration pneumonia, dehydration, metabolic abnormalities, diarrhea, nausea, vomiting, abdominal discomfort, nasal discomfort, nasal-pharyngeal ulcer, etc.) related to a feeding tube and the tube feeding, and have identified and addressed such complications; and*

- *That the resident was periodically reassessed and the care plan was revised and implemented, as necessary with input from the resident or his/her legal representative, to the extent possible.*

Review of Facility Practices

Related concerns may have been identified that would suggest the need for a review of facility practices. Examples of such activities may include a review of policies, staffing, and staff training, functional responsibilities, and interviews with staff (including facility management). If there is a pattern of residents who have issues related to the indications, utilization, complications, process or performance issues with feeding tubes, determine whether the facility has incorporated into its quality assurance activities a review of appropriateness and management of tube feedings.

DETERMINATION OF COMPLIANCE

Synopsis of Regulation (F322)

The feeding tube requirement has two aspects. The first aspect requires that the facility utilizes a feeding tube only after it determines that a resident's clinical condition demonstrates this intervention was unavoidable. The second aspect requires that the facility provides to the resident who is fed by a tube, services to prevent complications, to the extent possible, and services to restore normal eating skills, if possible.

Criteria for Compliance

The facility is in compliance with 42 CFR §483.25(g), if staff:

- *Use a feeding tube to provide nutrition and hydration only when the resident's clinical condition makes this intervention necessary based on adequate assessment and after other efforts to maintain or improve the resident's nutritional status have failed;*

- *Manage all aspects of a feeding tube and enteral feeding consistent with current clinical standards of practice in order to meet the resident's nutritional and hydration needs and to prevent complications; and*

- *Identify and address the potential risks and /or complications associated with feeding tubes, and provide treatment and services to restore, if possible, adequate oral intake.*

If not, cite at F322.

Noncompliance for F322

After completing the Investigative Protocol, analyze the data in order to determine whether noncompliance with the regulation exists. Noncompliance for F322 may include, but is not limited to, failure to do one or more of the following:

- *Appropriately assess a resident's nutritional status and needs, and identify a clinically pertinent rationale for the use of a feeding tube;*

- *Identify nutritional requirements for a resident fed by a feeding tube and ensure that a tube feeding meets those needs;*

- *Adequately address the nutritional aspects of enteral feeding and the management of the feeding tube, including prevention of related complications; or*

- *Use and monitor a feeding tube per facility protocol and pertinent clinical standards of practice, provide services to attempt to restore, if possible, normal eating skills, or identify and manage tube-related or enteral feeding-related complications.*

Potential Tags for Additional Investigations

If an additional concern has been identified, the surveyor must investigate the identified concern. Do not cite any related or associated requirements before first conducting an investigation to determine compliance or non-compliance with the related or associated requirements. Some examples include, but are not limited to, the following:

- *42CFR §483.10(b)(3);(d)(2), F154, Right to Be Fully Informed*

    - *Determine if the facility has fully informed the resident of his or her total health status and has provided the resident with information about the use of a feeding tube (including risks, benefits and alternatives) so that an informed decision can be made.*

- *42 CFR §483.10(b)(4)(8),F155, Notice of Rights and Services, Right to Refuse Treatment and Experimental Research and to Formulate Advance Directives, Maintenance and Provision of Written Policies of These Rights*

    - *Determine if the facility has given the resident or legal representative the opportunity to participate in the decision about tube feeding and informed the resident of the right to make advance directives and to decline life-sustaining treatments including artificial nutrition and hydration;*

    - *Determine if the facility maintains written policies and procedures regarding advance directives; and*

    - *Determine if the facility informs and provides written information to all adult residents concerning the right to accept or refuse medical treatment and formulate advance directives.*

- *42 CFR §483.10(b)(11), F157, Notification of Changes*

    - *Determine if staff notified:*

- *The physician when they suspected or identified inability to maintain adequate oral intake or complications related to use of the feeding tube; and*

- *The resident and the resident's legal representative (if known) of significant changes in the resident's condition in relation to the feeding tube or inability to take nutrition orally;*

- *42 CFR §483.15(a), F241, Dignity*

  - *Determine whether the staff provided respectful care for the resident being tube fed to maintain and enhance the resident's dignity;*

- *42 CFR §483.15(b), F242, Self-determination and Participation*

  - *Determine whether staff provided the resident with relevant information and choices regarding feeding tubes;*

- *42 CFR §483.20(b), F272, Comprehensive Assessments*

  - *Determine if the resident's comprehensive assessment reflects the resident's nutritional status, including factors that may have contributed to inadequate oral intake, and evaluates the resident's response to the implementation of tube feeding, including nutritional and psychosocial aspects;*

- *42 CFR §483.20(g), F278, Accuracy of Assessments*

  - *Determine whether the assessment accurately reflects the resident's status;*

- *42 CFR §483.20(k), F279, Comprehensive Care Plans*

  - *Determine if the resident's comprehensive care plan includes measurable objectives, time frames, and specific interventions consistent with the resident's specific nutritional status, risks, needs, and current clinical standards of practice. This includes interventions prior to the insertion of the feeding tube to attempt to avoid tube feeding and after the insertion of the tube to prevent tube-related and tube-feeding related complications and restore, if possible, adequate oral intake;*

- *42 CFR §483.20(k)(2)(iii), F280, Comprehensive Care Plan Revision*

  - *Determine if the care plan was periodically reviewed and revised by appropriate staff, in conjunction with the practitioner and with input from the resident or his/her legal representative, to try to meet the resident's*

nutritional and hydration needs; reduce, prevent, or address potential complications; and attempt to restore normal eating skills, if possible;

- *42 CFR §483.20(k)(3)(i), F281, Services Provided Meet Professional Standards of Quality*

    - *Determine if staff provided care in accordance with accepted professional standards of quality to maintain or restore adequate oral intake, if possible, and to manage the feeding tube to maintain or improve nutrition and prevent complications, to the extent possible;*

- *42 CFR §483.20(k)(3)(ii), F282, Care Provided by Qualified Persons in Accordance with the Plan of Care*

    - *Determine whether care of the resident with a feeding tube is being provided by qualified staff and/or whether the care plan is adequately and/or correctly implemented;*

- *42 CFR §483.25(i), F325, Nutrition*

    - *Determine if the facility has managed the resident's nutritional interventions to meet the resident's nutritional needs, while using a feeding tube;*

- *42 CFR §483.25(l), F329, Unnecessary Drugs*

    - *Determine if the facility has reviewed the resident's medication regimen for medications that may have caused or contributed to a decline in oral intake, or ability to chew and/or swallow, that may have contributed to the decision to place a feeding tube or affected the efforts to restore normal eating;*

- *42 CFR §483.30, F353, Nursing Services*

    - *Determine if the facility has sufficient nursing staff that is qualified to provide necessary care and services to the resident being fed by a feeding tube;*

- *42 CFR §483.40(a), F385, Physician Supervision*

    - *Determine if a physician is supervising the medical aspects of the tube feedings including assessment of causes of impaired nutritional status, development of a treatment regimen consistent with current clinical standards of practice, monitoring, and response to notification of change in the resident's medical status;*

- *42 CFR §483.60, F425, Pharmacy Services*
    - *Determine if the policies were developed and implemented for the safe administration of medications for a resident with a feeding tube;*
- *42 CFR §483.65, F441, Infection Control*
    - *Determine if the facility established and maintained an infection control policies for safe and sanitary care and services for a resident being fed by a tube;*
- *42 CFR §483.75(i), F501, Medical Director*
    - *Determine whether the medical director helped the facility develop and implement policies addressing the assessment and management of individuals with impaired or at-risk nutrition and hydration status and recognizing, addressing, and preventing complications related to tube feedings;*
- *42 CFR §483.75(l), F514, Clinical Records*
    - *Determine whether the clinical record:*
        - *Accurately, completely and, in accordance with current clinical standards, documents: the resident's status (including changes in condition), care and services provided to the resident with a feeding tube, response to treatment and the resident's goals; and*
        - *Provides the basis for determining the continued need for tube feeding and whether changes in treatment are necessary.*

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 F322 are as follows:

1. ***Presence of harm/negative outcome(s) or potential for negative outcomes because of lack of appropriate care and services.*** *Actual or potential harm/negative outcomes for F322 may include but are not limited to:*
    - *Failure to adequately assess a resident's nutritional status and the care and services needed to maintain or improve the resident's nutritional status and/or to identify why the use of a feeding tube was medically unavoidable;*

- *Failure to adequately identify nutritional requirements for a resident fed by a feeding tube and ensure that the tube feeding met those needs (if clinically feasible), resulting in the resident experiencing malnutrition and dehydration;*

- *Failure to verify the location of the tube in accordance with current clinical standards, facility protocols, and resident condition; therefore increasing the risk for complications such as aspiration; and*

- *Failure to use and monitor a feeding tube per facility protocol and current clinical standards of practice or to identify and manage feeding tube-related or tube-feeding related complications, thereby allowing the complication to continue without appropriate intervention.*

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:

- *The facility failed to train staff about how to ensure proper placement of a feeding tube, and/or to ensure that staff were checking for tube placement consistently and correctly. As a result of staff failure to verify tube placement, a resident got peritonitis (infection of the lining of the abdominal cavity) and died following the administration of tube feeding; or*

- *As a result of the facility routinely keeping a resident lying almost flat in bed while administering the resident's tube feeding, the resident aspirated some of the tube feeding and acquired aspiration pneumonia.*

***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, actual resident outcomes that demonstrate severity at Level 3 may include, but are not limited to:

- *The facility failed to monitor for complications related to a resident's feeding tube and tube feeding. As a result, the resident experienced significant but not life-threatening tube feeding-related complications; or*

- *As a result of facility failure to assess the resident's nutritional needs and to continue to administer, monitor, and adjust tube feeding accordingly, a resident experienced significant weight loss that cannot be otherwise attributed to a medically unavoidable cause.*

***NOTE:** If Severity Level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate 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 staff failure to anchor a feeding tube properly, the resident had leakage and irritation around the tube insertion site that required topical treatment and resolved without complications;*

- *As a result of staff failure to manage a tube feeding pump properly, the resident did not receive the calculated amount of tube feeding, without resulting in significant weight loss or other GI complications; or*

- *As a result of staff failure to consistently flush a resident's feeding tube as ordered, the tube clogged and had to be replaced, but there were no other complications.*

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

The failure of the facility to provide appropriate care and services for feeding tubes, places the resident at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.