



Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C 12-48-NH

DATE: September 27, 2012
TO: State Survey Agency Directors
FROM: Director
Survey and Certification Group
SUBJECT: F tag 309—Quality of Care- Advance Copy

Memorandum Summary

- **Revisions:** Revisions have been made to Guidance to Surveyors at F tag 309 in Appendix PP of SOM.
- **Power Points:** Power Point training material with speaker notes for Centers for Medicare & Medicaid Services (CMS) Regional Offices (ROs) and State Survey Agencies (SAs) to be used to train surveyors on this revision are provided.

The CMS made changes to surveyor guidance for End of Life in Appendix PP of the SOM to provide clarification to nursing home surveyors when determining compliance with the regulatory requirements for End of Life. The regulatory language remains unchanged.

These revisions should be implemented no later than November 30, 2012 and we are providing an advance copy of the revised guidance with all new language presented in red and italics. Also attached to this memorandum are training materials for the revised tag. This training packet is to be used to assure that all surveyors who survey nursing homes are trained in the revised guidance by the implementation date. These materials will be presented and discussed on a routine teleconference with ROs. We encourage training to be conducted in person with group discussion to optimize learning. However, if this is not feasible to meet the needs of your surveyors, it is acceptable to use other methods. This material may also be used to communicate with provider groups and other stakeholders.

For questions on this memorandum, please contact Susan Joslin at 410-786-3516 or via email at Susan.Joslin@cms.hhs.gov.

Effective Date: No later than November 30, 2012. The State Agency should disseminate this information within 30 days of the date of this memorandum.

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

/s/
Thomas E. Hamilton

Attachments

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- ADVANCE COPY

Date: Month XX ---

SUBJECT: Revisions to Appendix PP – “Interpretive Guidelines for Long-Term Care Facilities F tag 309 Quality of Care”

I. SUMMARY OF CHANGES: This instruction updates the guidance at F tag 309.

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 309

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.**

ADVANCE COPY

F309

42 CFR 483.25 Quality of Care

Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

Rev.

Review of a Resident at or Approaching End of Life

Assessment and Management of Care at End of Life – In order to promote the physical, mental, and psychosocial well-being of a resident who is approaching the end of life, the facility and the practitioner must:

- Identify the resident’s prognosis with supporting documentation; and initiate discussions/considerations with the interdisciplinary team regarding advance care planning and resident choices to clarify resident goals and preferences regarding care as the resident is approaching the end of life. Preferences may include, but are not limited to, controlling pain and other symptoms; maintaining mental, physical, spiritual, and psychosocial functions. Advanced care planning should also address the residents wishes regarding the treatment of acute illness; and hospitalization treating acute illness; and hospitalization.*
- Recognize and advise the resident and/or the resident’s legal representative when the resident is approaching the end of life. If the resident is not already receiving palliative care, advise and educate the resident about palliative care options, including hospice care, if appropriate and when care might include a more palliative focus.*
- Provide and periodically review resident plan of care, addressing services, and support that accommodate and honor the resident’s choices and rights, manage pain and other physical, mental and psychosocial symptoms and strive to meet the resident’s physical, mental, psychosocial, and spiritual needs.*

Definitions Related to Care at End of Life

“Advance care planning” is a process used to identify and update the resident’s preferences regarding care and treatment at a future time including a situation in which the resident subsequently lacks the capacity to do so. For example, when life-sustaining treatments are a potential option for care and the resident is unable to make his or her wishes known.

“Hospice” means a public agency or private organization or subdivision of either of these that-- is primarily engaged in providing hospice care to terminally ill individuals.

“Imminently dying” indicates that death is anticipated within hours to a week or two at most, because there are no treatments or interventions to prolong life; or because the resident has declined to undergo treatment that could potentially prolong life.¹

“Palliative care” means patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, intellectual, emotional, social, and spiritual needs and to facilitate patient autonomy, access to information, and choice.

“Terminally ill” means that the individual has a medical prognosis that his or her life expectancy is 6 months or less if the illness runs its normal course.

Overview Addressing Care at End of Life

As the U.S. population ages, a greater number of older individuals may be admitted to and experience the dying process in nursing homes. It is projected that by 2030 half of the 3 million persons projected to be in a nursing home will die there.²

According to the Centers for Disease Control and Prevention, the most frequent causes of death in America (other than trauma) were diseases common among nursing home residents such as heart disease, stroke, diabetes mellitus, cancer, and Alzheimer’s disease.³ Many factors (such as a resident’s age, overall condition and comorbidities, unexpected acute illness, and treatment choices) in addition to specific diagnoses influence when death may occur. However, certain clinical events, such as major changes in existing conditions or onset of certain new conditions may signal that a resident is approaching the end of life.

Dying is often a process, rather than a single event, with death being the endpoint. Providing appropriate care related to dying involves ongoing recognition, assessment, and response to the resident’s needs and goals. Palliative care may be appropriate regardless of how near he or she may be to the end of life. As a resident becomes unstable, experiences increased symptoms, or identified as nearing the end of life, he or she may be an appropriate candidate for care focusing on palliation rather than cure. Palliative care focuses on symptom relief and comfort, but does not necessarily limit diagnostic, preventive, or curative interventions.

The ABCDE mnemonic is an example of an approach that can be adapted for use to manage symptoms and meet the resident’s physical and emotional needs at the end of life:

- **A:** Ask the resident or his or her legal representative about (and screen for) pain and other symptoms related to the resident’s end of life status on admission and periodically thereafter;
- **A:** Assess regularly and systematically for symptoms (such as dyspnea, fatigue, declining function, anorexia/eating difficulties/weight loss, pain, loneliness, anxiety/apprehension, depression, constipation, and delirium) and their impact on the resident;
- **B:** Believe the resident’s report of pain or other symptoms, what precipitates it or makes it worse, and what relieves it;

- C: Choose symptom control options that are appropriate for the resident;
- D: Deliver interventions in a timely, logical, and coordinated manner;
- E: Empower the resident to participate in defining the goals of treatment and planning the interventions to the extent possible; and
- E: Evaluate the effectiveness of the chosen interventions.⁴

There are various challenges to supporting death with dignity. These include, but are not limited to: resident, staff, and physician discomfort in handling death; family expectations; resident and/or family denial of the resident's condition or lack of knowledge of disease progression and eventual outcome; constraints related to limited staff time; cultural and ethnic diversity; and inadequate communication and/or coordination among various participants and agencies providing aspects of palliative care at the end of life. Since many residents lack a legal representative to speak for them and cannot readily make their needs and goals known, it is important for the interdisciplinary team to identify a substitute decision making method in accordance with state law.^{5 6}

Studies have identified various factors that are considered important for a "good death," including exercising control of decision-making and selection of a decision maker; adequately managing pain and other symptoms; trusting one's physician; avoiding intrusive, unnecessary procedures and a prolonged death; being kept clean; being comfortable with the staff providing the care; knowing what to expect regarding the physical condition; strengthening relationships with loved ones; having someone to listen and to be present; and maintaining one's dignity.^{7, 8}

The facility, including the medical director, develops, implements, and modifies (as needed) policies and procedures to identify, assess, and manage potential palliative care conditions. These policies and procedures include pertinent interventions that are consistent with current standards of practice.

Resources Related to Care at End of Life

Although care for residents approaching the end of life and palliative care are evolving and research is ongoing, many recognized clinical resources address care at the end of life and related issues, including:

- American Academy of Hospice and Palliative Medicine
www.aahpm.org;
- A Guide to End-of-life Care for seniors, (2000), Regional Geriatric Program of Toronto. Accessed November 24, 2010 from: <http://www.rgp.toronto.on.ca/files/File/PDFfiles/eol-english.pdf>;
- Approaching Death: Improving Care at the End of Life, (1997), Institute of Medicine Consensus Report. Accessed November 30, 2010 from: http://www.nap.edu/openbook.php?record_id=5801;

- *California Association of Health Facilities: Compassion and Respect toward the End of Life Recommendations*, (2010). Accessed November 24, 2010 from: http://www.calhospice.org/included/docs/education/8C_Partnering_With_Nursing_Homes_CARE_Recommendations.pdf;
- *Caring Connections: A national consumer and community engagement initiative to improve care at the end of life. It provides free resources and information to help people make decisions about end of life care and services before a crisis.*
www.caringinfo.org;
- *Center to Advance Palliative Care (CAPC): Provides health care professionals with the tools, training and technical assistance necessary to start and sustain successful palliative care programs in hospitals and other health care settings.*
www.capc.org;
- *National Consensus Project for Quality Palliative Care*, (2009), *Clinical Practice Guidelines for Quality Palliative Care, Second Edition*. Accessed on November 30, 2010 from: <http://www.nationalconsensusproject.org>;
- *National Hospice and Palliative Care Organization*
<http://www.nhcopo.org>;
- *Robert Wood Johnson Foundation*
www.rwjf.org;
- *Toolkit of Instruments to Measure End-of-Life Care (TIME)*. Accessed November 30, 2010 from: <http://www.chcr.brown.edu/pcoc/toolkit.htm>; and
- *Massachusetts End of Life Report*. <http://www.mass.gov>

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.*

Assessment of the Resident Approaching End of Life

It is difficult to predict exactly when someone will die. However, it is important to consider the resident's prognosis and assess the resident's decision-making capacity, values, goals, and social support systems at the time of admission. Thereafter, ongoing re-assessment can identify changes that may indicate the resident is approaching the end of life.

Assessment of a resident approaching the end of life should identify remediable symptoms and identifying ways to optimize comfort and relieve suffering. Information obtained during the assessment is used to manage the dying process and the disease process. If the resident lacks health care decision-making capacity, the staff, including nurse aides and others (e.g., family members) who are most familiar with the resident's habits, preferences, and symptoms of pain or discomfort (e.g., anxiety, confusion, agitation, nausea/vomiting) can provide information about

the resident to help identify pertinent interventions. The assessment of the resident who is approaching the end of life includes areas such as:

- *History of present illness, co-morbid medical and psychiatric disorders, and summary of current interventions;*
- *Physical, cognitive, and functional status (e.g., ability to communicate and ADL capacity); symptoms needing management; and whether there are any potentially remediable causes of a resident's current condition that would improve the symptoms and/or prognosis or optimize his/her comfort;*
- *Psychological, emotional, spiritual and environmental issues that may affect the resident's physical and/or psychological comfort (e.g., unresolved interpersonal and family issues; anxiety about dying alone and loss of independence or control; or high noise levels);*
- *Appropriateness and resident's desire for hospice or palliative care services;*
- *Goals for care and treatment;*
- *Resident strengths and available supports; and*
- *Other diagnostic tests and measures, as necessary [e.g., pain scales, blood tests, or the Minimum Data Set (MDS) Cognitive Performance Scale (CPS) Exam].*

Management of Care at End of Life

As age or illness progress, and cure or rehabilitation are no longer realistic expectations, care focuses increasingly on palliation. The goal of palliative care is to relieve suffering and provide the best possible quality of life for the resident and his or her family. Ongoing discussions amongst the resident, family, the attending physician or primary healthcare practitioner, and other members of the interdisciplinary care team help clarify the goals of care.

Care Planning for the Resident Approaching End of Life

A resident's goals and preferences for care, which should be identified upon admission and updated periodically, provide the basis for selecting and implementing care and services at the end of life.

When the resident is nearing the end of life, it is important for the physician/practitioner and interdisciplinary team to review or update the prognosis with the resident and/or the resident's legal representative. It is also important for the team to review and revise the care plan as necessary to address the resident's situation, including expectations and management of specific symptoms and concerns. For a resident receiving hospice care, the nursing facility coordinates care planning with the hospice. The resident's quality of care and life may be enhanced by focusing on comfort, relief of symptoms, and meeting the resident's emotional, spiritual, and social needs (e.g., by adjusting lighting, reducing noise, or allowing the family to spend the night).

Activities of Daily Living (ADLs). *The resident who is approaching the end of life may require more support in performing ADLs. Rather than restoration of a previous level of independence, care planning at this stage emphasizes support for activities of daily living to enhance the resident's comfort and dignity (e.g., assistance with bowel and urinary function for the individual who can no longer toilet him or herself; appropriate adjustments in the frequency of turning, getting out of bed, and dressing).*

Hygiene/Skin Integrity. *Ongoing, consistent oral care helps maintain comfort and prevent complications associated with dry mucous membranes and compromised dentition. Interventions related to skin integrity and personal hygiene strive to minimize pain and anxiety, and consider the resident's underlying illnesses and progressive decline. The resident receiving palliative care at the end of life may require adjustments in the frequency and intensity of measures such as turning and positioning, as well as the use of additional or alternative interventions to enhance comfort (e.g., pressure reducing mattress). The facility addresses the risk of skin breakdown and manages existing wounds unless these prevention and treatment measures are not feasible or cause the resident discomfort that is greater than the benefit from the care.*

Medical Treatment. *Medical treatments with potential benefits are weighed against potential burdens or risks. When the resident approaches the end of life, it is appropriate to reevaluate the benefits and burdens of any medical treatment, and consider discontinuing those treatments where the burdens outweigh the benefits.*

- *Diagnostic tests and monitoring. Although tests may help confirm an individual's prognosis or guide treatment decisions, decisions about diagnostic tests and medical procedures should be related to the resident's prognosis, values, and goals, as well as comfort and dignity. It is often appropriate to discontinue or greatly reduce the frequency of routine tests and monitoring and to use the least intrusive tests possible.*
- *Treatments. Palliative care treatment at the end of life focuses on symptom management (e.g., controlling nausea, vomiting, uncomfortable breathing, agitation, and pain). Simple cause-specific interventions may sometimes provide effective palliation (e.g., resolving abdominal pain by reducing doses of medications with high anticholinergic properties that may lead to constipation or intestinal ileus).*
- *Medications/Drugs. It is important that use of medications be consistent with the goals for comfort, control of symptoms, and for the individual's desired level of alertness. Review the continued need for any routine administration of medication and adjust or discontinue, as appropriate. Routes of administering medications may also need modification. Medication doses may need adjustment to attain desired symptom relief, while still considering whether side effects (such as sedation and nausea) are tolerable and consistent with the resident's wishes or that of his/her legal representative. Anecdotal reports indicate that nursing homes maybe be under treating terminal restlessness because of the fear of being accused of using a chemical restraint. Please note that during advanced care planning, regardless if the patient is receiving hospice care, as a resident approaches the end of life, the palliative use medications to treat terminal restlessness as a symptom is not a chemical restraint.*

Nutrition and Hydration. *Weight loss and fluid imbalance/dehydration at the end of life are common and may be a consequence, rather than a cause, of the dying process. End of life palliative care situations may not be compatible with maintaining normal nutritional parameters. For example, weight loss may be anticipated and this expectation should be documented in the practitioner progress notes and care plan. Routine weight measurements that will not lead to a change in the plan of care should be discontinued. A resident receiving palliative care at the end of life may experience a decline in appetite or have difficulty eating or swallowing. Therefore, it is important to provide desired food and fluids in the form and frequency that best enable the resident to consume them. Previous dietary restrictions may be unnecessary for the resident and may negatively impact quality of life or comfort. Studies suggest that dying individuals may not experience hunger or thirst near the time of death.*⁹

*The determination of whether to use artificial nutrition and hydration, when a terminally ill resident's condition has progressed to the point where he or she may no longer chew or swallow his or her food, is made by the resident, or the resident's legal representative, consistent with applicable state law and regulation. The use of a feeding tube has not been shown to prevent aspiration pneumonia, limit suffering, or promote the quality or extension of life, especially for a resident who is cognitively impaired.*¹⁰ *The interdisciplinary care team provides information to the resident or his/her legal representative to help them make an informed decision.*

Activities. *It is important that activities are consistent with the resident's interest, level of energy, and ethnic and cultural traditions associated with death and dying (e.g., visits from spiritual leaders and other individuals of the same religious/ethnic background; special spiritual ceremonies; reading or sharing information about the resident's culture). As death approaches, activities that provide comfort and symptom relief and those that require less conscious participation, rather than group or interactive activities, may be most appropriate. It is often helpful to involve the family or those with significant relationships with the resident in such activities, if possible.*

Psychosocial Needs. *The care plan may also identify interventions that are pertinent to the psychosocial needs of the dying resident (e.g., treatment for depression, anxiety, loneliness, restlessness or bereavement) and approaches to providing support to the resident (e.g., visits by family and others, expanding visiting hours, and providing desired privacy).*¹¹

The facility provides the needed social services, for example, to give the resident or the resident's legal representative information on available services such as support groups and bereavement services or to assist in settling the resident's affairs (e.g., disposition of the resident's belongings, organ donations, or funeral arrangements).

The care plan may also provide interventions that are consistent with the resident's personal beliefs, cultural practices and spiritual values. A change from a more aggressive treatment plan to a palliative care plan represents a significant change as defined by the MDS, therefore the care plan must be revised to reflect the new plan of care. The facility makes or supports appropriate referrals and contacts (e.g., clergy and religious/spiritual resources, and cultural communities familiar with resident's background and beliefs).^{12,13}

Monitoring the Resident who is Approaching End of Life

Individualized care requires monitoring and reassessment. Close monitoring of a dying individual's symptoms helps assess the effectiveness of the plan of care and also helps identify possible adverse consequences associated with inappropriate, non-palliative approaches to end of life care.

Monitoring can enhance the quality of care at the end of life in other ways; for example, checking the resident's hearing aids to be sure that the individual can hear comforting voices and sounds; or recognizing that a resident's condition has stabilized or improved enough to benefit from having a favorite food or drink. It is important that, as a resident's status changes, the facility and the resident and/or the resident's legal representative revisit the resident's values, goals, and treatment choices, and revise the care plan as necessary.

Election of Hospice Benefit

A Medicare beneficiary with Part A who is certified by a physician as being terminally ill, with a prognosis of six months or less if the illness runs its normal course, may elect the Medicare hospice benefit. If a resident requests hospice care, and a facility does not offer or contract for hospice or with the particular hospice requested, the facility must either (1) arrange with a Medicare certified hospice to provide care to the individual resident, or (2) help the resident and/or the resident's legal representative arrange for a transfer of the resident to a facility that provides the hospice care and/or services the resident desires.

Hospice is an optional state plan benefit in the Medicaid program. Under Medicaid, the individual must elect hospice care and a written physician certification that the individual is terminally ill must have been completed. The Medicaid statute does not define "terminally ill" so a physician is not limited to certifying that the individual is within 6 months of death; at the option of the State Medicaid Agency, a state may exceed the 6-month period. Also, a hospice plan of care must be established before services are provided and the services must be consistent with the plan of care. The Medicaid hospice benefit is unlimited, so if an individual remains eligible for hospice and does not revoke the election, the individual must continue to receive hospice care. If eligible for both Medicare and Medicaid, an individual must elect the hospice benefit simultaneously under both programs (and revoke simultaneously.)

Effective 3/23/10, section 2302 of the Affordable Care Act required that children who elect hospice must continue to receive curative care concurrently with the hospice care. In this regard, Medicaid issued a State Medicaid Director Letter on 9/9/10 and a subsequent Informational Bulletin with a draft preprint on 5/27/11.

Coordinated Plan of Care

When hospice services are involved, the facility and hospice are jointly responsible for developing a coordinated plan of care for the resident that guides both providers and is based upon their assessments and the resident's needs and goals. The coordinated plan of care must identify which provider (hospice or facility) is responsible for various aspects of care. The facility is required to update its plan of care according to CFR § 483.20(k) in accordance with

any Federal, State or local laws and regulations governing the particular facility, just as hospices need to update their plans of care according to 42 CFR § 418.56(d).

The hospice and the facility should have a process by which they can exchange information from their respective plan of care reviews, assessment updates, and patient and family conferences, when updating the plan of care and evaluating outcomes of care. This practice increases assurance that the resident receives the necessary care and services.

Each provider retains responsibility for the quality and appropriateness of the care it provides in accordance with their respective laws and regulations. Both providers must comply with their applicable conditions of participation in Medicare/Medicaid. The facility's services must be consistent with the plan of care developed in coordination with the hospice (i.e., the hospice patient residing in a facility should not experience any lack of services or personal care because of his/her status as a hospice patient); and the facility must offer the same services to its residents who have elected the hospice benefit as it furnishes to its residents who have not elected the hospice benefit. As such, the facility continues responsibility for providing the resident's overall care and comfort. For example, the facility should continue to provide general medical and nursing care, assist with ADLs, administer medications, give personal care, provide activities, if desired, and maintain the cleanliness of the resident's room.

The care plan incorporates the hospice philosophy of care. The care plan includes interventions and orders to manage pain and other uncomfortable symptoms. Procedures exist to assure that the resident receives timely, pertinent non-pharmacologic and pharmacological interventions for optimal palliation. The hospice and facility need to collaborate to train facility staff in managing the resident's symptoms and utilizing any special equipment.

The hospice program is responsible for assessing the patient and identifying the physical, psychosocial, emotional, cultural, and spiritual needs related to the terminal illness and related conditions. These factors are addressed in order to promote the resident's well-being, comfort, and dignity throughout the dying process. When these needs are identified in the hospice interdisciplinary plan of care, hospice team member should, (including the social worker) provide counseling and support. Hospice can use trained volunteers to provide additional practical and emotional support. Note: This paragraph is not intended to represent any SNF/NF requirements independent of the hospice program.

The facility should notify the hospice when the resident experiences a significant change in physical, mental, social, or emotional status, or needs to be transferred from the facility.

In order to ensure that each provider meets its responsibilities, it is essential the facility and hospice have a means to communicate how all needed services, professionals, medical supplies, DME, drugs and biologicals will be made available to the resident 24 hours a day, seven days a week, including who may receive and/or write orders for care, in accordance with State/Federal requirements.

All information related to the resident's plan of care must be shared/made available to practitioners and teams in other settings in the event that the resident is transferred to another setting for care (e.g., emergency department, hospital, home health agency).

Endnotes for Assessment and Management of Care at End of Life

Investigative Protocol for End of Life Care

Quality of Care Related to Assessment and Management of Care at End of Life

Objective

- *To determine if the facility provided appropriate end of life care and services that are or were consistent with the resident's needs, wishes, current standards of practice, and state requirements.*

Use

Use this protocol for a sampled resident:

- *Who is identified by the facility as receiving end of life care, hospice services, palliative care, comfort care, or terminal care; or*
- *Whose diagnoses, assessment, and/or care plan indicate that he/she may be approaching the end of life.*

Procedures

Briefly review the assessment, care plan, orders, and related documentation. Gather information about the resident's mental, physical, functional, and psychosocial status and the interventions identified in the care plan, as the basis for further review. Verify observations by gathering additional information from record review, interviews with the resident or his or her legal representative, relevant staff and practitioners, and/or additional observations.

NOTE: *Determine whether the resident is also receiving care from another entity such as a Medicare-certified hospice.*

1. Observation

Observe the resident during various activities, shifts, and interactions with staff. Use the observations to determine:

- *Whether staff accommodated the resident's needs and goals (such as comfort, independence, and level of functioning during end of life), including, but not limited to:*
 - *Interventions used if the resident exhibited or verbalized pain or other symptoms of distress such as apprehension, restlessness, withdrawal, or lashing out at others;*
 - *Supportive and assistive devices/equipment used such as commodes and/or positioning devices;*

- *Privacy, dignity, calming reassurance used; and*
- *Preferences and choices acknowledged and respected, such as a resident's preferences for bathing, toileting, sleep schedules, activities, food and drink, environment, etc; and*
- *Whether staff consistently implemented the care plan according to the resident's needs and goals.*

2. Resident/Representative Interviews

Interview the resident, family, or responsible party, to the degree possible, to identify:

- *Whether the facility discussed advance directives, the right to make treatment choices (including refusing treatment), available resources and state-required documents related to end of life care or substitute decision making;*
- *Whether the resident is currently having or has been having symptoms (e.g., pain, anxiety, depression, breathing difficulties), and whether the symptoms and extent of relief have been addressed to his/her satisfaction and consistent with his/her preferences and choices;*
- *Whether the resident or his/ her legal representative was involved in the development of the care plan;*
- *Whether the care plan accommodates the resident's needs and goals; and*
- *If interventions were declined, whether information about alternatives and consequences of such refusal were offered and documented.*

3. Staff Interviews

Direct care staff. *Interview direct care staff on various shifts to determine:*

- *Whether staff are aware of the resident's goals for care and treatment at the end of life;*
- *How staff determines when and how to offer each intervention; and*
- *How staff monitors and documents for effectiveness of the intervention.*

Interviews with health care practitioners and professionals. *If the defined interventions or care provided (1) appear to be inconsistent with the resident's preferences or applicable recognized standards of practice; (2) were not implemented as defined; or (3) the resident's symptoms were not adequately controlled, interview one or more health care practitioner(s) and professional(s) as necessary (e.g., physician, hospice nurse, facility charge nurse, certified nursing assistant, social worker, or director of nursing). These individuals, by virtue of training and knowledge of*

the resident, should be able to provide information about the evaluation and management of a resident's physical/psychosocial symptoms and needs related to end of life and palliative care. Depending on the issue, ask about:

- *The basis for a determination that a resident is approaching the end of life;*
- *Whether a discussion occurred with the resident and/or the legal representative regarding a determination that the resident is approaching the end of life and about the resident's options for developing instructions regarding his or her choices for care and treatment (please refer to advance directives guidance at tag F155);*
- *When and how the resident's preferences regarding care at the end of life (including advance directives, if applicable) are communicated to the facility care team as well as emergency department, hospital, or home care teams if the resident is transferred for any reason;*
- *How interventions are monitored for continued appropriateness and adjusted as necessary;*
- *Whether and how the staff communicates with the physician/practitioner regarding the resident's condition and response to interventions; and*
- *For a resident who has been receiving part of his or her care from hospice, how the facility and the hospice have been coordinating the resident's care.*

4. Record review

Assessment. *Review the resident's records for assessments related to end of life care including RAI/MDS, physician orders, hospice orders (as appropriate), available consultants, and progress notes to determine whether such documents or records:*

- *Provided the basis for the determination that the resident is approaching the end of life;*
- *Identified the resident's overall physical, mental, psychosocial and spiritual needs; the underlying factors affecting the resident's comfort, cognition, pain, and functional status; and the resident's values, wishes, choices, and goals (e.g., advance directives or other directions for interventions regarding hospitalization, acute care in the event of an illness or injury, artificial nutrition or hydration approaches, and respiratory and cardiac status);*
- *Indicated that staff implemented interventions, in conjunction with the practitioner, in effort to prevent, minimize or manage symptoms. Whether the interventions addressed the pain and/or potential pain, distress, and/or other symptoms (such as constipation, nausea, and vomiting) consistent with the resident's goals and the facility and practitioner's identification and assessment of factors causing or influencing those symptoms; and*

- *Indicated that the facility monitored the resident's subsequent condition including any changes in status.*

Care Plan. *Review the care plan to determine:*

- *If it is consistent with the resident's specific needs, condition, values, wishes, goals, and progress as identified by periodic assessments;*
- *Whether there is evidence that the care plan has been coordinated with others in providing aspects of care including hospice as appropriate.*

If the resident refuses or resists staff interventions to manage symptoms and the needs identified in the assessment, determine if the record reflects efforts to seek alternatives.

NOTE: *If the resident has elected the Medicare and/or Medicaid hospice benefit and concerns were identified with coordinated plan of care or management of the resident's care, verify that the hospice was advised of the concerns. After verifying the hospice was advised of concerns by the facility and the hospice failed to resolve issues related to the management of a resident's care, coordination of care or implementation of appropriate services, refer the concerns as a complaint to the State Agency responsible for oversight of this hospice program, identifying the specific resident(s) involved and the concerns identified.*

Review of Facility Practices

Any concerns identified by the survey team related to end of life care should trigger a review of the facility's policies and procedures on end of life care and/or related policies (e.g., advance directives). Additional activities may include a review of policies, staffing, staff training and/or functional responsibilities related to care and services provided to a resident approaching the end of life.

DETERMINATION OF COMPLIANCE (Task 6, Appendix P)

Synopsis of Regulation (F309)

A resident approaching the end of life must receive, and the facility must provide, the necessary care and services to attain or maintain his/her highest practicable level of physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

Criteria for Compliance with F309 for a Resident Approaching End of Life

For the resident approaching the end of life, the facility is in compliance with F309 Assessment and Management of Care at End of Life, if staff:

- *Assessed the resident's clinical condition, risk factors, and preferences and identified the resident's prognosis and its basis;*
- *Initiated discussions regarding advance care planning and resident choices to clarify resident's goals and preferences regarding treatment at the end of life;*
- *Recognized and advised the resident and/or the resident's legal representative that the resident was approaching the end of life and, if the resident was not already receiving palliative care, advised that care could potentially be shifted to a palliative focus;*
- *Defined and implemented resident-directed care, treatment interventions, services, and support; consistent with the resident's choices, rights, goals, comprehensive assessment, care plan and the recognized standards of practice. Compliance with this criteria is done in the attempt to manage pain and other physical and psychosocial symptoms and meet the resident's physical, mental, psychosocial, and spiritual needs;*
- *Communicated the resident's goals and preferences to the facility interdisciplinary team, as well as the hospice, emergency department, hospital or home health team in the event of a transfer; and*
- *Monitored and evaluated the impact of the interventions provided to address the resident's end of life condition and revised the approaches as appropriate.*

If not, cite at F309.

NOTE: *Most deficiencies related to end of life care and services can be cited at other regulations (e.g., assessment, care planning, accommodation of needs, and physician supervision). Surveyors should evaluate compliance with these regulations and cite deficiencies at F309 only when other regulations do not address the noncompliance.*

Potential Tags for Additional Investigations

During the investigation of care and services provided at the end of life, the surveyor may identify concerns with related structure, process and/or outcome requirements. 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 noncompliance with the related or associated requirement. Some examples include, but are not limited to, the following:

42 CFR § 483.10(b)(3), (d)(2), F154, Notice of Rights and Services, Free Choice

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

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

42 CFR § 483.10(j), F172, Access and Visitation Rights

42 CFR § 483.12(a)(2), F201, Transfer and Discharge Requirements

42 CFR § 483.15(b), F242, Self-Determination and Participation
42 CFR § 483.15(e), F246, Accommodation of Needs
42 CFR § 483.15(f)(1), F248, Activities
42 CFR § 483.20(b)(1), F272, Comprehensive Assessments
42 CFR § 483.20(k), F279, Comprehensive Care Plans
42 CFR § 483.20(k)(2)(iii), 483.10(d)(3), F280, Comprehensive Care Plan Revision
42 CFR § 483.25(a)(3), F312, Activities of Daily Living
42 CFR § 483.25(k)(6), F328, Special Needs: Respiratory Care
42 CFR § 483.25(l), F329, Unnecessary Drugs
42 CFR § 482.30(a), F353, Sufficient Staff
42 CFR § 483.40(a), F385, Physician Supervision
42 CFR § 483.75(i)(2), F501, Medical Director

V. DEFICIENCY CATEGORIZATION (Part IV, Appendix P)

Once the survey 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. Severity is based on the harm or potential for harm to the resident. The key elements of severity determination for F309 Assessment and Management of Care at End of Life are as follows:

- 1. Presence of harm/negative outcome(s) or potential for negative outcomes from a lack of appropriate treatment and care. Actual or potential harm/negative outcome(s) for F309 Assessment and Management of Care at the End of Life may include, but is not limited to:***
 - Failure to inquire about, document, and implement measures or orders related to a resident's preferences for care and services to be provided during the end of life resulted in a resident receiving unwanted tests or treatment; and*
 - Failure to assess the resident who is approaching the end of life and to address the resident's pertinent symptoms (or to explain why it was not possible to do so) resulted in persistent or recurring physical discomfort or psychological distress.*
- 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 degree of 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 for tag F309 Assessment and Management of Care at End of Life. 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 for a resident at or approaching end of life.

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 include, but are not limited to:

- The facility failed to recognize that the resident was approaching the end of life and continued to implement aggressive medical interventions against the resident's wishes. As a result, the resident experienced severe physical discomfort and/or psychosocial distress; or*
- The resident approaching the end of life experienced prolonged nausea; recurrent vomiting, or daily, prolonged, or repeated moderate to severe pain as a result of the facility's repeated failure to implement interventions in accordance with the doctor's orders and care plan.*

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.*

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

Severity Level 3 indicates noncompliance that resulted in actual harm, and may include, but is not 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:

- *Despite the documented choice to accept partial pain control in order to be more alert, the resident was repeatedly so lethargic or somnolent because of medication used to treat symptoms related to the end of life that he/she was unable to relate to visitors.*

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 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 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.

An example of avoidable outcomes at Severity Level 2 include, but is not limited to:

- *A resident received end of life care from a hospice and there was no evidence in the resident's record of care coordination between the facility and the hospice, but the resident did not experience adverse consequences.*

Severity Level 1: No actual harm with potential for minimal harm

The facility fails to provide appropriate care and services to a resident who is approaching the end of life is more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

¹ Wein, S. (2000). Sedation in the imminently dying patient. *Oncology*, 14(4), 585-592. (<http://www.cancernetwork.com/display/article/10165/67143>)

² *Improving palliative care in nursing homes.* (2008). Center to Advance Palliative Care. Accessed December 6, 2010 from: http://www.capc.org/support-from-capc/capc_publications/nursing_home_report.pdf.

³ Xu, J., Kochanek, K.D., Murphy, S.L., & Tejada-Vera, B. (May 2010). *Deaths: Final Data for 2007.* *National Vital Statistics Reports, Centers for Disease Control, Division of Vital Statistics*, 58 (19). (http://www.cdc.gov/nchs/data/nvsr/nvsr58/nvsr58_19.pdf)

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- ⁴ Agency for Health Care Policy and Research. (1994). *Clinical Practice Guideline No. 9: Management of Cancer Pain*. AHCPR Publication No. 94-0592. Rockville, MD: United States Department of Health and Human Services.
- ⁵ Agency for Healthcare Research and Quality. *Advance Care Planning: Preferences for Care at the End of Life*. *Research in Action, Issue 12*. AHRQ Publication Number 03-0018, March 2003. (<http://www.ahrq.gov/research/endliferia/endria.htm>)
- ⁶ MOLST *Medical Orders for Life Sustaining Treatment* (<http://www.molst-ma.org/>)
- ⁷ Steinhauser K.E., Christakis N.A., Clipp E.D., McNeilly, M., McIntyre, L. & Tulsky, J.A. (2000). *Factors considered important at the end of life by patients, family, physicians, and other care providers*. *Journal of the American Medical Association*, 284(19), 2476-2482.
- ⁸ Singer, P.A., Martin D.K., & Kelner, M. (1999). *Quality end of life care: Patients' perspectives*. *Journal of the American Medical Association*, 281(2), 163-168.
- ⁹ Gillick, M. (2000). *Rethinking the role of tube feeding in patients with advanced dementia*. *New England Journal of Medicine*, 342, 206-210.
- ¹⁰ Finucane, T., Christmas, C., & Travis, K. (1999). *Tube feeding in patients with advanced dementia: A review of the evidence*. *Journal of the American Medical Association*, 282, 1365-1370.
- ¹¹ Steinhauser K.E., et al. (2000).
- ¹² Irish, D., Lundquist, K., & Nelson, V. (eds.). (1993). *Ethnic Variations in Dying, Death, and Grief: Diversity in Universality*. Galen Press, Tucson, AZ. (<http://www.galenpress.com/00312b.html>)
- ¹³ *The George Washington Institute for Spirituality and Health – Spiritual Assessment: FICA Spiritual History Tool*. George Washington University. Accessed December 6, 2010 from: <http://www.gwish.org>.