


42 CFR 483.25 (F309)

QUALITY OF CARE

Changes to Interpretive Guidance


1



Training Objectives

- Review guidance for hospice and/or ESRD services, formerly in the SOM in Appendix P;
- Describe when to use F309 for Quality of Care issues;
- Identify when and how to use the investigative protocols:
 - The General Investigative Protocol; and
 - The Investigative Protocol for pain or the management of pain
- Identify compliance related to the provision of care;
- Describe the care process and examples of non-compliance and severity determinations related to pain management
- Review clinical interventions for addressing pain management


2



***Overview of changes**

- **Revised** the general quality of care guidance
- **Added** a new general investigative protocol for quality of care
- **Added** a new guidance and an investigative protocol for pain management
- **Moved** the survey protocol language regarding review of residents receiving hospice care and dialysis services into F309
- **Deleted** the investigative protocol for unintended weight loss at F309 (Now at F325 Nutrition)
- **Deleted** sentence at F286 requiring storage of paper copy for homes using electronic records

3



Other Changes

- At the same time F309 changes are issued, we are issuing the following other changes:
 - Appendix P: deletion of Unintended Weight Loss Investigative Protocol (use protocol at F325)
 - Appendix P: deletion of Task 5C, parts K (Review of a Resident Receiving Hospice Care) and L (Review of a Resident Receiving Dialysis Services). These were moved to F309

4



Other Changes

- Appendix P: deletion of part VII (demand billing procedure) and insertion of new procedure into Task 5C Resident Review, new part L: Liability Notices and Beneficiary Appeal Rights
 - This new procedure went into effect via a recent Survey and Certification letter
 - These changes were necessary due to a change in demand billing requirements
 - See this letter for additional information

5



Other Changes

- Appendix PP
 - Deletion of sentence at F286 (MDS Use) requiring storage of paper copy of MDS for homes using all electronic records. This is no longer required for these homes.

6



42 CFR 483.25 Quality of Care (F309)

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.

7



*Definition of “Highest Practicable”

- “Highest practicable *physical, mental, and psychosocial well-being*” is defined as the highest *possible* level of functioning and well-being, limited by the individual’s *recognized pathology and normal aging process*. Highest practicable is determined through the comprehensive resident assessment *and* by *recognizing and* competently and thoroughly addressing the physical, mental or psychosocial needs of the individual.
- (Revised guidance at F309, S&C 09-22)

8



42 CFR 483.25 Quality of Care (F309)

Note:

Use guidance at F309 for review of quality of care not specifically covered by 483.25 (a) – (m). F309 includes but is not limited to care such as end-of-life, diabetes, renal disease, fractures, congestive heart failure, non-pressure-related skin ulcers, pain, or fecal impaction.


9



Hospice Services

- Guidance formerly in Appendix P of the SOM, inserted at F309
- Revised the note to refer hospice concerns as a complaint to the State Agency responsible for oversight of hospice survey activities identifying the specific resident(s) involved and the concerns identified.


10



SNF/NF - Hospice Coordination of Care

Note: Refer hospice concerns as a complaint to the State Agency responsible for oversight of hospice survey activities identifying the specific resident(s) involved and the concerns identified.


11



Hospice

- When a facility resident has also elected the Medicare hospice benefit, the hospice and the nursing home must communicate, establish, and agree upon a plan of care that is coordinated for both providers which reflects the hospice philosophy, and is based on an assessment of the individual's needs and unique living situation in the facility.
- (Revised guidance at F309, S&C 09-22)

12



Hospice

- The NH and the hospice are responsible for performing each of their respective functions that have been agreed upon and included in the plan of care.

13



Hospice

- The hospice retains overall professional management responsibility for directing the implementation of the plan of care related to the terminal illness and related conditions.

14



Hospice

- The plan of care reflects the participation of the hospice, the facility, and the resident or representative to the extent possible.
- **The hospice and the facility are aware of the other's responsibilities in implementing the plan of care.**

15



Hospice

NURSING HOME RESPONSIBILITIES

- Assess resident
- Maintain MDS/RAI
- Provide personal care
- Coordinate plan with hospice
- Provide activities
- Meet all NH regulations
- Give medications
- Orient hospice staff
- Clean room
- Activities of daily living
- Notify hospice of any change in condition

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16

Hospice

HOSPICE RESPONSIBILITIES

- Assess resident
- Coordinate PoC with NH
- Provide hospice care and services
- Financial responsibility
- Professional management
- Monitor care- review and update
- Determine level of care
- QAPI
- Orient and Train NH staff
- Interdisciplinary Group
- Meet all hospice CoPs

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17

MDH WEB LINK

Compliance Monitoring Division Clinical Web Window at:

<http://www.health.state.mn.us/divs/fpc/cww/cwwindex.html>

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18

ESRD Services

Guidance formerly in Appendix P inserted at F309

- Revised bulleted item on medication administration.
- Revised the note to refer ESRD concerns as a complaint to the State Agency responsible for survey of dialysis providers, identifying the specific resident(s) involved and the concerns identified.

19



ESRD

- For the resident who requires dialysis, the nursing home must have an arrangement with the entity that identifies how the resident's care is to be managed.

20



ESRD

The arrangement would assure medications are administered before and after dialysis as ordered by the physician for the optimal timing to maximize effectiveness and avoid adverse effects of the medications;

21



ESRD

- The arrangement would identify how to manage emergencies and complications.

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22

ESRD

- The arrangement would identify the care of shunts/fistulas, infection control, waste handling, nature and management of end stage renal disease.

Revised guidance at F309, S&C F309, 09-22

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23

Non Pressure Ulcer/Wound

- The assessment and diagnosis of a skin ulcer/wound, should include documentation of the clinical basis of the ulcer/wound, especially if the ulcer has characteristics consistent with a pressure ulcer, but is determined not to be one.
- (Revised guidance at F309, S&C 09-22)

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24

Non Pressure Ulcer/Wound

- Documentation should include the underlying condition contributing to the ulceration, ulcer edges and wound bed, location, shape, and condition of surrounding tissues.

25



General Investigative Protocol

Use the General Investigative Protocol (IP):

- To investigate any Quality of Care concern not otherwise covered in the remaining tags of §483.25, Quality of Care;

Note: For investigating concerns related to pain or the management of pain, use the pain management investigative protocol.

26



General IP - Components

Components include the procedures for:


- Observations;
- Resident/Representative Interview;
- Nursing Staff Interview;

27




General IP - Components

- Assessment;
- Care Planning
- Care Plan Revision
- Interview with Health Care Practitioners and Professionals

28 


*Unavoidable – Avoidable

- **In any instance in which there has been a lack of improvement or a decline, the survey team must determine if the occurrence was unavoidable or avoidable. A determination of unavoidable decline or failure to reach highest practicable well-being may be made only if all of the following are present:**
- An accurate and complete assessment
- A care plan that is implemented consistently and based on information from the assessment: and
- Evaluation of the results of the interventions and revising the interventions as necessary
- (Revised guidance at F309, S&C 09-22)

29 

Concerns with Independent but Associated Structure, Process, and/or Outcome Requirements

<ul style="list-style-type: none"> • 42 CFR 483.10(b)(11), F157, Notification of Changes • 42 CFR 483.20(b), F272, Comprehensive Assessments • 42 CFR 483.20(k), F279, Comprehensive Care planning 	<ul style="list-style-type: none"> • 42 CFR 483.20(k)(2)(iii), 483.10(d)(3), F280, Care Plan Revision • 42 CFR 483.20(k)(3)(i), F281, Services Provided Meets Professional Standards of Quality
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30 

Concerns with Independent but Associated Structure, Process, and/or Outcome Requirements

- 42 CFR 483.20(k)(3)(ii), F282, Care Provided by Qualified Persons in Accordance with Plan of Care
- 42 CFR 483.30(a)(1)&(2), F353, Sufficient Staff
- 42 CFR 483.40(a)(1)&(2), F385, Physician Supervision
- 42 CFR 483.75(f), F498, Proficiency of Nurse Aides
- 42 CFR 483.75(i)(2), F501, Medical Director
- 42 CFR 483.75(l), F514, Clinical Records



Determination Of Compliance - F309

Criteria for Compliance with F309, Quality of Care, that is not related to pain/pain management. The facility is in compliance with this requirement, if staff have:

- Recognized and assessed factors placing the resident at risk for specific conditions, causes and/or problems;
- Defined and implemented interventions in accordance with resident needs, goals, and recognized standards of practice;
- Monitored and evaluated the resident's response to preventive efforts and treatment; and
- Revised the approaches as appropriate.



DEFICIENCY CATEGORIZATION


Follow Part IV, Appendix P: The key elements for severity determination for F309 Quality of Care requirements:

1. Presence of harm/negative outcome (s) or potential for negative outcomes because of lack of appropriate treatment and care;
2. Degree of harm (actual or potential) related to the non-compliance.
3. The immediacy of correction required.

Follow the general guidance in Appendix P regarding Guidance on Severity and Scope Levels and Psychosocial Outcome Severity Guide.



PAIN



34



Interpretive Guidance – Related to Pain

Review of a Resident who:

- Has pain symptoms;
- Is being treated for pain; or
- Who has the potential for pain symptoms related to conditions or treatments.


35



Training Objectives

- Describe the relationship between the regulation and the pain guidance;
- Describe the care process related to pain management;
- Identify when and how to use the Investigative Protocol; and
- Evaluate compliance with F309 as it relates to pain, including severity determinations.


36



Interpretive Guidance (IG) Related to Pain

Regarding Pain Recognition and Management:


- Introduction
- Definitions
- Overview
- Care Process for Pain Management
- Investigative Protocol
- Compliance Determination
- Deficiency Categorization

37 

IG – Pain/Pain Management Introduction


Introduction: To help a resident attain or maintain his/her highest practicable level of well-being and to prevent or manage pain, to the extent possible, the facility:

- Recognizes when the resident is experiencing pain and identifies circumstances when pain can be anticipated;
- Evaluates the existing pain and the cause(s); and
- Manages or prevents pain, consistent with the resident’s goals, the comprehensive assessment and plan of care, and current clinical standards of practice.

38 

IG – Pain/Pain Management - Definitions

<p>Definitions:</p> <ul style="list-style-type: none"> • Addiction • Adjuvant Analgesics • Adverse Consequence • Complementary and Alternative Medicine (CAM) 	<ul style="list-style-type: none"> • Non-pharmacological Interventions • Pain • Physical Dependence • Standards of Practice • Tolerance
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39 

IG – Pain/Pain Management - Definitions

Pain:

An unpleasant sensory and emotional experience that can be acute, recurrent or persistent

40



CHRONIC PAIN



41





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IG – Pain/Pain Management - Definitions

Acute Pain:

Generally pain of abrupt onset and limited duration, often associated with an adverse chemical, thermal or mechanical stimulus, such as surgery, trauma and acute illness.

Persistent/Chronic Pain:

Pain that continues for a prolonged period of time or recurs more than intermittently for months or years.

43



IG – Pain/Pain Management - Definitions

Adjuvant analgesics:

Medication with a primary indication other than pain management but with analgesic properties in some painful conditions.

44



IG – Pain/Pain Management - Definitions

Addiction:

A primary, chronic, neurobiological disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations—characterized by an overwhelming craving for medication or behaviors including impaired control over drug use, compulsive use, continued use despite harm, and/or craving

45



IG – Pain/Pain Management - Definitions

Physical Dependence:

Physiological state of neuro-adaptation that is characterized by a withdrawal syndrome if medication is stopped or decreased abruptly, or if an antagonist is administered

46



IG – Pain/Pain Management - Definitions

Tolerance:

Physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect or a reduced effect is observed with a constant dose

47



IG – Pain/Pain Management - Overview

Resident, family or staff misconceptions regarding:

- Recognition
- Assessment, and
- Management of Pain

48



IG – Pain/Pain Management - Overview

Potential outcomes with unresolved persistent pain may involve:

- Function and/or mobility
- Mood
- Sleep
- Participation in usual activities

49



IG – Pain/Pain Management - Overview

Acute Pain – The onset potentially signals

- New injury or illness
- Possible life-threatening condition

50



IG – Pain/Pain Management - Overview

Factors affecting pain management:

- Language and cultural barriers
- Non-specific symptoms
- Co-morbidities
- Staff and practitioner knowledge, skill, training
- Misunderstanding about analgesics, including opioids

51



IG – Pain/Pain Management – Care Process

Care processes for pain management:

- Assessment
- Address/treat underlying cause(s)
- Develop and implement approaches
- Monitor
- Modify approaches

52



IG – Pain/Pain Management – Care Process

Pain Recognition/Identification:

- Admission
- Ongoing observation
- Evaluation

53



IG – Pain/Pain Management – Care Process

Assessment/Recognition of Pain:

- Change in condition/function
- Diagnoses, care, treatments associated with pain
- Verbal expressions

54



IG – Pain/Pain Management – Care Process

Assessment/Identification of Pain:

- Symptoms associated with pain
 - Non-verbal indicators
 - Cognitive Impairment
- Resident/representative or staff reports

55



IG – Pain/Pain Management – Care Process

Assessment of Pain:

- History of pain
- Prior treatment
- Effectiveness of prior treatment

56



IG – Pain/Pain Management – Care Process

Assessment of pain characteristics:

- Intensity
- Descriptors
- Pattern
- Location and radiation
- Frequency, timing and duration

57



IG – Pain/Pain Management – Care Process

Assessment of impact of pain:

- Factors that may precipitate/aggravate pain
- Factors that may lessen pain

58



IG – Pain/Pain Management – Care Process

Assessment of present condition:

- Current medical condition and medications
- Resident’s goal for pain management
- Satisfaction with current level of pain control

59



IG – Management of Pain

Care Plan:

- Care plan
- Clinical Standards of Practice
- Responsibility

Interventions

- Resident’s needs/goals
- Source, type and severity of pain;
- Available treatment options

Approaches

- Address underlying cause, when possible
- Target strategies to source, intensity, nature of symptoms
- Prevent/minimize anticipated pain

60



IG – Management of Pain

Certified hospice and pain management:

- SNF/NF – primary care giver
- Hospice – professional management
- Coordination of care

61 

IG - Management of Pain

True or False:


Non-Pharmacological Approaches are rarely effective, unless they are used with one or more pain medications.

62 

IG - Management of Pain

Use of Non-Pharmacological Interventions such as:


- Physical modalities;
- Cognitive interventions; and
- CAM

63 

IG - Management of Pain


Judicious use of pharmacological interventions

- Factors influencing selection of medications and doses include, but are not limited to:
 - Resident condition
 - Source/nature/location of pain
 - Risk/benefit/resident choice considerations
 - Use of Analgesics/Adjuvants
 - PRN (on-demand) vs Scheduled (by the clock)

64 

IG - Monitoring and Re-assessment


- Why
- What
- How
- When
- By whom

65 

IG - EFFECTIVE PAIN MANAGEMENT

INVOLVES:

<ul style="list-style-type: none"> • Facility - wide commitment to resident comfort • Addressing misconceptions and/or barriers to pain management • Identifying residents with pain or at risk for pain • Assessing the pain 	<ul style="list-style-type: none"> • Understanding resident's goals • Identifying and treating underlying causes, to the extent possible • Developing/Implementing approaches to manage or prevent pain • Monitoring the effectiveness of interventions • Revising interventions as necessary
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66 

Investigative Protocol (IP) For Pain Management

IP: Quality of care related to the recognition and management of pain


- Objectives
- Use
- Procedures

67 

IP - Objectives

To determine whether:


- The facility provided and the resident received care and services to address and manage the resident's pain, and
- The resident's highest practicable level of physical, mental, and psychosocial well-being were supported, in accordance with the comprehensive assessment and plan of care.

68 

IP - Use


Use this protocol for a sampled resident who:

<ul style="list-style-type: none"> • States he/she has pain or discomfort; • Displays possible indicators of pain that cannot be readily attributed to another cause; • Has a disease or condition or who receives treatments that cause or can reasonably be anticipated to cause pain; 	<ul style="list-style-type: none"> • Has an assessment indicating that he/she experiences pain; • Receives or has orders for treatment for pain; and/or • Has elected a hospice benefit for pain management
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69 

IP - Procedures


- Observation
- Interview
- Record Review

70 

IP - Observation

Observe the resident during various activities and over various shifts to determine:


- If the plan of care for the management of pain (if any) is implemented as written;
- Whether the resident has pain and the impact of the pain; and
- If staff recognized potential or actual pain and their response.

71 

IP - Resident Interview

Interview the resident or responsible party to determine:


- If the resident has or has had pain and its characteristics;
- Care-planning participation and goals; and
- Implementation and results/effectiveness of approaches

72 

IP - Nurse Aide Interview

Interview direct care staff on various shifts to determine:


- Whether they are aware of resident's pain; and
- How they respond to the resident's pain.

73 

IP - Record Review


Assessment:

- Review information sources, e.g., orders, MAR, progress notes, assessments including RAI/MDS
- Determine if information accurately, and comprehensively reflects resident's condition

74 

ASSESSMENT


- “Although Federal requirements dictate the completion of RAI assessments according to certain time frames, standards of good clinical practice dictate that the assessment process is more fluid and should be ongoing.” (Federal Register Vol.62, No.246, 12/23/97, page 67193)

75 

IP: Care Plan

Review


- Pain management goals
- Interventions
- Monitoring
- Facility specific pain management protocol, if being used
- Revised as necessary

76 

IP - Nurse Interview

Interview a nurse who is knowledgeable about the resident's pain management to determine how staff:


- Identify, assess, develop interventions, monitor the response, communicate with the prescriber and revise the plan as appropriate; and
- For a resident receiving the hospice benefit, coordinate approaches, communicate and monitor the outcomes (both effectiveness and adverse consequences) with the hospice.

77 

IP - Interview

Interview other knowledgeable health care professionals about the evaluation and management of the resident's pain/symptoms if:

- Interventions or care appear inconsistent with current standards of practice; and/or
- Resident's pain appears to persist or recur.

78 

Determination of Compliance-Synopsis of Regulation (F309)

The resident 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.

Determination of Compliance-Criteria for Compliance

The facility is in compliance with 42 CFR §483.25 (F309), Quality of Care regarding care for the resident with pain, if the facility:

- Recognized and evaluated the resident who experienced pain
- Developed and implemented interventions to prevent or manage the resident's pain
- Recognized and provided measures to minimize or prevent pain for situations where pain could be anticipated
- Monitored the response to the interventions
- Communicated with the health care practitioner when the resident's pain was not adequately managed or the resident had a suspected or confirmed adverse consequence related to the treatment and
- Modified the approaches as indicated

Noncompliance with Quality of Care for Resident with Pain-F309

Examples of noncompliance for F309 with regard to pain management, may include failure to:

- Recognize and evaluate the resident who is experiencing pain in enough detail to permit pertinent individualized pain management;
- Develop interventions for a resident who is experiencing pain;
- Provide pain management interventions in situations where pain can be anticipated;
- Implement interventions to address pain to the greatest extent possible consistent with the resident's goals and current standards of practice and failed to provide a clinically pertinent rationale why this was not done;
- Monitor the effectiveness of intervention to manage pain; or
- Coordinate pain management with an involved hospice as needed

Concerns with Independent but Associated Structure, Process, and/or Outcome Requirements

- 42 CFR 483.10(b)(4) F155, The Right to Refuse Treatment
- 42 CFR 483.10(b)(11), F157, Notification of Changes
- 42 CFR 483.15(b), F242, Self-determination and Participation.
- 42 CFR 483.15(e)(1), F246, Accommodation of Needs

82



Concerns with Independent but Associated Structure, Process, and/or Outcome Requirements

- 42 CFR 483.20, F272, Comprehensive Assessments
- 42 CFR 483.20(g) F278, Accuracy of 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 483.20(k)(3)(i), F281, Services provided meet professional standards of quality
- 42 CFR 483.20(k)(3)(ii), F282, Care provided

83



Concerns with Independent but Associated Structure, Process, and/or Outcome Requirements

- 42 CFR 483.25(l), F329, Unnecessary Drugs
- 42 CFR 483.40(a), F385, Physician Supervision
- 42 CFR 483.60, F425, Pharmacy Services
- 42 CFR 483.75(i)(2), F501, Medical Director
- 42 CFR 483.75(l) F514, Clinical Records


84



Deficiency Categorization
Pain Recognition and Management

Severity Determination Considerations Levels 4 through 1. The key elements for severity determination are:


- Presence of harm or potential for negative outcomes
- Degree of harm or potential harm related to noncompliance
- Immediacy of correction required

85 

Severity Level 4

Level 4: Immediate Jeopardy to resident health or safety. Noncompliance with one or more requirements of participation:


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

86 

Severity Level 3

Level 3: Actual Harm, not Immediate Jeopardy

- Noncompliance resulted in harm
- May include clinical compromise, decline, inability to maintain/reach highest practicable well-being

87 

Severity Level 2

Level 2: No actual harm with potential for more than minimal harm that is not immediate jeopardy.

Noncompliance resulted in:

- No more than minimal discomfort,
- The potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well-being, and/or
- The potential for greater harm if interventions are not provided

88



Severity Level 1

Level 1: No actual harm with potential for minimal harm

- Noncompliance with F309 with regard to quality of care for a resident with pain places the resident at risk for more than minimal harm
- Severity Level 1 does not apply for F309 Quality of Care related to Recognition and Management of Pain

89



Complimentary and Alternative Medicine Links:

- National institutes of Health at <http://nccam.nih.gov/health/whatiscom>
- Wellness Providers at <http://www.becomingwell.org/>

90



KEY CONCEPTS

- Have an understanding of F309 and how it relates to quality of care.
- Knowledgeable of the care processes and investigative protocols for Hospice, ESRD, Pain, and other care concerns.
- Able to identify examples of non compliance and understand severity determinations.

91