



42 CFR 483.25 (F309)

QUALITY OF CARE

Changes to Interpretive Guidance

March 26, 2009

1



Handouts

- Power Point Slides
- BQA Memo 01-042
- CMS S&C Ltr 02-39
- Attachment 01-042a(1)
- CMS S&C Ltr 04-24
Parts 1 and 3
- CMS S&C Ltr 05-014
- CMS S&C Ltr 04-37
- CMS S&C 09-22

2



Training Objectives Part 1

- Clarify F286 – MDS Record Storage
- 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
- Review guidance for ESRD services and Hospice Care, formerly in Appendix P of the SOM

3



MDS Electronic Vs Paper

- S&C Letter 05-014
 - Nursing homes that are capable of implementing electronic signatures for their MDSs DO NOT have to maintain hard copies in the resident's record even if the record is not entirely electronic

4



MDS Electronic VS Paper

- Per CMS 3/11/09
 - MDS information, whether kept electronically or in hard copy, is part of the medical record & therefore needs to be easily accessible by surveyors, CMS and those on the resident's interdisciplinary team

5



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.

6



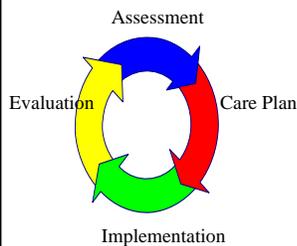
42 CFR 483.25 – Quality of Care F309

- **Note**
- Use the guidance at F309 for review of quality of care issues not specifically covered by 483.25 (a) – (m)
- F309 includes but is not limited to:
 - Bowel Management CHF, CPR
 - Diabetes, Dialysis Failure to assess & treat
 - Non-Pressure Ulcers Pain Management
 - Palliative Care

7



Interpretive Guidelines 483.25 Unavoidable or 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

8



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.

9



General IP - Components

Components include the procedures for:

- Observations;
- Interviews
 - Resident/Representative
 - Nursing Staff on various shifts
- Record Reviews

10



General IP - Components



- Assessment
- Care Planning
- Care Plan Revision
- Interview w/ Health Care Practitioners & Professionals

11



Dialysis Services

- Guidance moved from Appendix P to Appendix PP & inserted at F309
- When dialysis is provided in the facility by an outside entity or the resident leaves the facility to obtain dialysis, the nursing home must have an agreement or arrangement with the entity in accordance with 42CFR 483.75 (h), F500
- CMS S&C Letter 02-39 – Nursing Home That Has No Arrangement to Provide Dialysis Services To Its Residents

12



Dialysis Services

- CMS S&C Letter 04-24 – 3/19/04
 - Attachment B – Survey Protocol for LTC Facilities **for residents receiving home dialysis**
- CMS S&C Letter 04-37 – 7/8/04
 - Follow up Q&A regarding S&C 04-24
 - **Answer 18 - “The LTC surveyors are not expected to survey for appropriate dialysis treatments. ESRD surveyors will conduct the dialysis survey.”**

13



Dialysis Services

- Sampled Resident receiving dialysis care
 - Use F309 General Investigative Protocol AND Dialysis protocol
- Revised the “Note: to refer ESRD concerns as a complaint to the State Agency responsible for survey of dialysis providers

14



Hospice Services

- Guidance moved from Appendix P to Appendix PP and inserted at F309
- Sampled Resident receiving hospice benefit care
 - Use F309 General Investigative Protocol AND Hospice Services protocol
 - May need to use Pain Management Protocol

15



Hospice Services

- Revised the “Note” to refer hospice concerns as a complaint to the State Agency responsible for survey of hospice providers
- BQA Memo 01-042 – Guidelines For Care Coordination For Hospice Patients Who Reside in Nursing Homes

16



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;

17



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:

- Monitored and evaluated the resident’s response to preventive efforts and treatment; and
- Revised the approaches as appropriate

18



Training Objectives Part 2

- 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.

19



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.

20



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

21



IG – 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.

22



IG – Pain Management - Definitions

Definitions:

- Addiction
- Adjuvant Analgesics
- Adverse Consequence
- Complementary and Alternative Medicine (CAM)
- Non-pharmacological Interventions
- Pain
- Physical Dependence
- Standards of Practice
- Tolerance

23



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

24



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

25



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

26



IG – Pain Management - Barriers

Resident, family or staff misconceptions regarding:

- Recognition
- Assessment, and
- Management of Pain

27



IG – Pain Management – Factors Affecting Pain Management:

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

28



Pain Management-Outcomes

Potential outcomes with unresolved persistent pain may involve:

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

29



IG – Pain Management – Care Process

Care processes for pain management:

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

30



IG – Pain Management – Care Process

Assessment/Recognition of Pain:

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

31



IG – Pain Management – Care Process

Assessment/Identification of Pain:

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

32



IG – Pain Management – Care Process

Assessment of Pain:

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

33



IG – Pain Management – Care Process

Assessment of pain characteristics:

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

34



IG – Pain Management – Care Process

Assessment of impact of pain:

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

35



IG –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

36



HFS 132.60(1)(c)

- 5. The nursing home shall provide appropriate assessment and treatment of pain for each resident suspected of or experiencing pain based on accepted standards of practice that includes all of the following:
 - a. An initial assessment of pain intensity that shall include: the resident's self-report of pain, unless the resident is unable to communicate; quality and characteristics of the pain, including the onset, duration and location of pain; what measures increase or decrease the pain; the resident's pain relief goal; and the effect of the pain on the resident's daily life and functioning.

37



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

38



	AKCPR Guidelines for Cancer Pain Components	AKCPR Guidelines for Cancer Pain Distal Pain ROPS	AKCPR Guidelines for Acute Pain	WI Cancer Pain Toolkit	MOH Palliative Care Program	JCAHO Pain Standards	ASPM Standards for Pain Management	AMDA 1999 Guidelines for Pain Management	AGS 2002 Guidelines for the Management of Resident Pain in Older Persons	AGS 2002 Guidelines for the Management of Resident Pain in Older Persons
Intensity	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Impact on ADL's	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Quality	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Location	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Physical Findings	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Constant vs. Intermittent	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Aggravating/Alleviating	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Analgesic History	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Resident Goals	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Resident Attitudes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes

39



IG - Management of Pain

Use of Non-Pharmacological Interventions such as:

- Physical modalities;
- Cognitive interventions; and
- CAM

40



HFS 132.60(1)(c)

- 5. The nursing home shall provide appropriate assessment and treatment of pain for each resident suspected of or experiencing pain based on accepted standards of practice that includes all of the following:
- d. Consideration and implementation, as appropriate, of nonpharmacological interventions to control pain.

41



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)

42



HFS 132.60(1)(c)

5. The nursing home shall provide appropriate assessment and treatment of pain for each resident suspected of or experiencing pain based on accepted standards of practice that includes all of the following:
- b. Regular and periodic reassessment of the pain after the initial assessment, including quarterly reviews, whenever the resident's medical condition changes, and at any time pain is suspected, including prompt reassessment when a change in pain is self-reported, suspected or observed.

43



HFS 132.60(1)(c)

5. The nursing home shall provide appropriate assessment and treatment of pain for each resident suspected of or experiencing pain based on accepted standards of practice that includes all of the following:
- c. The delivery and evaluation of pain treatment interventions to assist the resident to be as free of pain as possible.

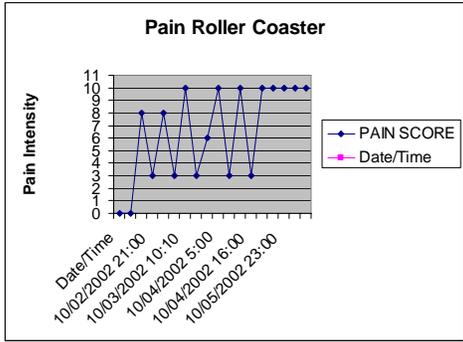
44



IG - EFFECTIVE PAIN MANAGEMENT

- INVOLVES:
- 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
 - 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

45



46



Investigative Protocol (IP) For Pain Management

Quality of care related to the recognition and management of pain

- Objectives
- Use
- Procedures

47



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.

48



IP - Use this protocol for a sampled resident who:

- 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;
- 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

49



IP - Procedures

- Observation
- Interview
- Record Review

50



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.

51



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

52



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.

53



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

54



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

58



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

59



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

60



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

61



Severity Level 4

- Resident experienced continuous, unrelenting, excruciating pain or incapacitating distress because the facility has failed to recognize or address the situation, or failed to develop, implement, monitor, or modify a pain management plan to try to meet the resident's needs; or
- Resident experienced recurring, episodic excruciating pain or incapacitating distress related to specific situations where pain could be anticipated (e.g., because pain has already been identified during dressing changes or therapies) and the facility failed to attempt pain management strategies to try to minimize the pain.

62



Severity Level 3

- The resident experienced pain that compromised his/her function (physical and/or psychosocial) and/or ability to reach his/her highest practicable well-being as a result of the facility's failure to recognize or address the situation, or failure to develop, implement, monitor, or modify a pain management plan to try to meet the resident's needs. For example, the pain was intense enough that the resident experienced recurrent insomnia, anorexia with resultant weight loss, reduced ability to move and perform ADLs, a decline in mood, or reduced social engagement and participation in activities; or
- The resident experienced significant episodic pain (that was not all-consuming or overwhelming but was greater than minimal discomfort to the resident) related to care/treatment, as a result of the facility's failure to develop, implement, monitor, or modify pain management interventions. Some examples include lack of pain management interventions prior to dressing changes, wound care, exercise or physical therapy.

63



Severity Level 2

- The resident experienced daily or less than daily discomfort with no compromise in physical, mental, or psychosocial functioning as a result of the facility's failure to adequately recognize or address the situation, or failure to develop, implement, monitor, or modify a pain management plan to try to meet the resident's needs; or
- The resident experienced minimal episodic pain or discomfort (that was not significant pain) related to care/treatment, as a result of the facility's failure to develop, implement, monitor, or modify a pain management plan.

64



Severity Level 1

Level 1: No actual harm with potential for minimal harm

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

65



Resources

- WI Clinical Resource Center
<https://wcrp.chsra.wisc.edu/>
- CMS Sharing Innovations in Quality (SIQ)
<http://siq.air.org/>

66



Questions

67
