



§483.25 Naso-Gastric Tubes (F322 Feeding Tubes)

Surveyor Train the Trainer:
Interpretive Guidance
Investigative Protocol



Federal Regulatory Language

483.25(g) Naso Gastric Tubes

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

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



Federal Regulatory Language (cont)

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



Merging Tags F321 and F322

- The revisions to appendix PP – Interpretive Guidelines for Long Term Care Facilities at §483.25(g)(1)(2) combines F321 and F322, and incorporated the guidance into F322.



§483.25(g) Naso-Gastric Tubes*

****For the purpose of the interpretative guidelines at F tag 322 the regulatory title “§483.25(g) Naso-gastric tubes” is considered to include any feeding tube used to provide enteral nutrition to a resident by bypassing oral intake.***



Intent

The intent of this regulation is that:

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



Definitions

“Avoidable/Unavoidable use of a feeding tube”

“Avoidable” -- there is not a clear indication for using a feeding tube, and there is insufficient evidence that it provides a benefit that outweighs associated risks.

“Unavoidable” -- there is a clear indication for using a feeding tube, and there is sufficient evidence that it provides a benefit that outweighs associated risks.



Definitions (cont'd)

“**Bolus feeding**” means the administration of a limited volume of enteral formula over brief periods of time.

“**Continuous feeding**” means the uninterrupted administration of enteral formula over extended periods of time.



Definitions (cont'd)

“Enteral nutrition” (a.k.a. “tube feeding”) means the delivery of nutrients through a feeding tube directly into the stomach, duodenum, or jejunum.

“Feeding tube” means a medical device used to provide enteral nutrition to a resident by bypassing oral intake.



Definitions (cont'd)

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



Definitions

“Jejunostomy tube” (a.k.a. “percutaneous endoscopic jejunostomy” (PEJ) or “J-tube”) means a feeding tube placed directly into the small intestine.

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



Definitions

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

“Tube feeding” (a.k.a. “enteral feeding”) means the delivery of nutrients through a feeding tube directly into the stomach, duodenum, or jejunum.



Overview

The decision to use a feeding tube:

- Has a major impact on a resident and his or her quality of life; and
- Is based on the resident's clinical condition and wishes and federal and state laws.

Use of feeding tubes varies widely among states depending on opinions about non-oral nutrition and varied facility policies and usual practices.



Interpretive Guidance

Considerations Regarding The Use of Feeding Tubes

The resident's clinical condition must demonstrate the use of a feeding tube to be "unavoidable":

- No viable alternative to maintain adequate nutrition and/or hydration; and
- Use is consistent with the clinical need to maintain or improve nutritional /hydration parameters.



Interpretive Guidance

Considerations Regarding The Use of Feeding Tubes (cont'd.)

Other factors that may be associated with use:

- Medical conditions that impair nutrition;
- Need to improve nutritional status or comfort;
- To provide comfort; and
- Desire to prolong life.



Interpretive Guidance

Considerations Regarding The Use of Feeding Tubes (cont'd.)

Clinical rationale supporting the use of a feeding tube includes:

- Assessment of the resident's nutritional and clinical status;
- Relevant functional and psychosocial factors (such as potential ability to maintain activities of daily living ADL); and
- Prior interventions (nutrition therapy and medical intervention tried) and the resident's response.



Interpretive Guidance

Considerations Regarding The Use of Feeding Tubes

Potential benefits of feeding tube use include:

- Addressing malnutrition and dehydration;
- Promoting wound healing;
- Allowing the resident to gain strength (for ADL) including appropriate interventions that may help to restore the residents ability to eat; and
- Improving the resident's ability to make decisions about their care and ability to interact with others.



Interpretive Guidance

Considerations Regarding The Use of Feeding Tubes (cont'd.)

Possible adverse effects of feeding tube use include:

- Diminished socialization;
- Decreased opportunity to experience taste, texture and chewing of foods;
- Complications related to the tube; and
- Restricted movement.



Decisions to Use Feeding tube

Decisions to continue or discontinue the use of a feeding tube:

- Are collaborative and involve the resident (or legal representative), physician and interdisciplinary team; and
- Include the relevance of a feeding tube to the resident's treatment goals and wishes.



Technical and Nutritional Aspects of Feeding Tubes

Facility protocols assure that staff implement and provide care and services related to feeding tubes according to the resident's need and clinical standards of practice.

Protocols regarding some technical aspects include:

- Location – where inserted, when to verify;
- Care – secured externally, cleaning insertion site; and
- Replacement – when, by whom.



Interpretive Guidance

Technical and Nutritional Aspects of Feeding Tubes (cont'd.)

Protocols regarding some nutritional aspects include:

- Enteral nutrition – meeting the resident's nutritional needs;
- Feeding flow – managing and monitoring the rate of flow.

The practitioner's feeding tube order typically include: kind of feeding, caloric value, volume, duration, mechanism of administration, and frequency of flush.



Interpretive Guidance

Significant Complications Related to the Feeding Tube

- Aspiration
- Leakage around the insertion site
- Stomach or Intestinal perforation
- Abdominal wall abscess
- Erosion at the insertion site (including nasal area)



Interpretive Guidance

Esophageal Complications Related to the Feeding Tube

- Peritonitis
- Esophagitis
- Ulcerations
- Strictures
- Tracheoesophageal fistulas
- Clogged tube



Interpretive Guidance

Complications Related to the Administration of the Enteral Nutrition Product

- Nausea;
- Vomiting;
- Diarrhea;
- Abdominal cramping;
- Inadequate nutrition;
- Aspiration;
- Reduced effectiveness of various medications; or
- Metabolic complications.



Aspiration

- Can be dependent on other risk factors;
- Is not necessarily related to gastric residual volumes; and
- Should be assessed individually to implement interventions accordingly (e.g., positioning).



Interpretive Guidance

Enteral Formula May Reduced the Effectiveness of Some Medications

- For example: The effectiveness of phenytoin sodium may be reduced by the drug binding with the enteral feeding's protein component, leading to less free drug availability and possibly inadequate therapeutic levels.



Metabolic Complications

- Metabolic complications related to tube feeding may include inadequate calorie or protein intake, altered hydration, hypo- or hyperglycemia, and altered electrolyte and nutrient levels.



Complications Management

The facility is expected to:

- Identify and address actual or potential complications related to the feeding tube or tube feeding; and
- Notify and involve the practitioner in evaluating and managing care to address these complications and risk factors.



Investigative Protocol

Objectives

To determine if:

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



Investigative Protocol

Procedures

- Observations
- Interviews
- Record Review



Investigative Protocol

Observations

During various shifts, observe staff interactions with the resident and provision of care including:

- Initiation, continuation, and termination of feedings;
- Care of the tube site and equipment; and
- Medication administration via the feeding tube.



Investigative Protocol

Observations (cont'd)

To determine whether staff follow:

- Clinical standards of practice;
- Facility policy;
- Resident care plan; and
- Prescriber's orders.



Investigative Protocol

Observations (cont'd)

Use to determine whether staff try to minimize the risk for complications. For example:

- Providing mouth care, including teeth, gums, and tongue;
- Checking that the tubing remains in the correct location; and
- Properly positioning the resident consistent with the resident's individual needs.



Investigative Protocol

Interviews: Resident/representative

Determine if the facility has involved the resident (or legal representative) in the care plan process to reflect the resident's choices, preferences, and response to tube feeding. For example, determine whether:

- The resident (or legal representative) was informed about benefits and risks of tube feeding and possible alternatives; and/or
- There has been reassessment and discussion with the resident (or legal representative) re: continued appropriateness/necessity of the feeding tube.



Investigative Protocol

Interviews: Facility Staff

Interview the facility staff, who provide direct care, to determine, for example:

- Whether the resident has voiced any complaints or exhibited any physical or psychosocial complications that may be associated with the tube feeding:
 - Nausea and/or vomiting
 - Diarrhea
 - Pain associated with the tube
 - Abdominal discomfort
 - Depression and/or withdrawal



Investigative Protocol

Interviews: Facility Staff (cont'd)

Interview the facility staff, who provide direct care, to determine, for example:

- How these problems have been addressed; and
- To whom a staff member has reported the resident's signs or symptoms.



Investigative Protocol

Interviews: Facility Staff (cont'd)

Interview staff with responsibility for overseeing or training regarding care related to feeding tubes to determine, for example:

- How does staff calculate nutritional needs for the resident and ensure that the resident receives close to the calculated amount of nutrition daily?
- How are staff trained and directed regarding management of feeding tubes and tube feedings in general, and in addressing any specific issues related to this individual resident?



Investigative Protocol

Record review

Review the resident's record for evidence of rationale for feeding tube insertion (including interventions tried), and the potential to restore normal eating skills. For example, did the staff:

- Verify that the feeding tube was properly placed?
- Monitor the resident for possible complications related to a feeding tube and the tube feeding?



Review of Facility Practices

Related concerns may have been identified that would suggest the need for interviews with staff (including facility management) and a review of:

- Facility practices;
- Staffing;
- Staff training; and
- Functional responsibilities.



Interpretive Guidance

Review of Facility Practices (cont'd.)

If there is a pattern of residents who have issues related to the indications, utilization, complications, process or performance issues with feeding tubes, determine whether the facility has incorporated into its quality assurance activities a review of appropriateness and management of tube feedings.



Synopsis of F322 Regulation

The regulation requires that the facility:

- Utilize a feeding tube only after it determines that a resident's clinical condition demonstrates this intervention was unavoidable; and
- Provides the resident who is fed by a tube services to prevent complications and restore normal eating skills to the extent possible.



Determination of Compliance

Criteria for Compliance with F322

The facility is in compliance if staff:

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



Determination of Compliance

Criteria for Compliance with F322 (cont'd.)

The facility is in compliance if staff:

- Manage all aspects of a feeding tube and enteral feeding consistent with current clinical standards of practice in order to meet the resident's nutritional and hydration needs and to prevent complications; and
- Identify and address the potential risks and /or complications associated with feeding tubes, and provide treatment and services to restore, if possible, adequate oral intake.



Determination of Compliance

Noncompliance at F322

Noncompliance with F322 may include, but is not limited to, failure to do one or more of the following:

- Appropriately assess a resident's nutritional status and needs, and identify a clinically pertinent rationale for the use of a feeding tube;
- Identify nutritional requirements for a resident fed by a feeding tube and ensure that a tube feeding meets those needs;



Determination of Compliance

Noncompliance at F322 (cont'd)

Failure to:

- Adequately address the nutritional aspects of enteral feeding and the management of the feeding tube, including prevention of related complications; or
- Use and monitor a feeding tube per facility protocol and pertinent clinical standards of practice, provide services to attempt to restore, if possible, normal eating skills, or identify and manage tube-related or enteral feeding-related complications.



DEFICIENCY CATEGORIZATION (Part IV, Appendix P) Severity Determination Key Components

- Harm/negative outcome(s) or potential for negative outcomes due to a failure of care and services,
- Degree of harm (actual or potential) related to noncompliance, and
- Immediacy of correction required.



Determining Actual or Potential Harm

Actual or potential harm/negative outcome at F322 may include:

- Failure to adequately identify nutritional requirements for a resident fed by a feeding tube and ensure that the tube feeding met those needs (if clinically feasible), resulting in the resident experiencing malnutrition and dehydration; and
- Failure to verify the location of the tube in accordance with current clinical standards, facility protocols, and resident condition; therefore increasing the risk for complications such as aspiration.



Determining Degree of Harm

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

- If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; and
- If harm has not yet occurred, determine how likely the potential is for serious injury, impairment, death, compromise or discomfort to occur to the resident.



Deficiency Categorization

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.



Deficiency Categorization

Severity Levels

Level 4: Immediate Jeopardy to Resident Health or Safety

Level 3: Actual Harm that is Not Immediate Jeopardy

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

Level 1: No Actual Harm with Potential for Minimal Harm



Deficiency Categorization

Severity Level 4 Immediate Jeopardy

- Has allowed/caused/resulted in, or is likely to cause serious injury, harm, impairment, or death to a resident; and



Severity Level 4: Immediate Jeopardy (cont'd)

- Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.



Severity Level 4 Example

Severity Level 4 Example

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



Severity Level 3: Actual Harm that is *not* Immediate Jeopardy

The negative outcome may include but may not be limited to clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable level of well-being.



Severity Level 3 Example

Severity Level 3 Example

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



Severity Determination

Severity Level 2: No Actual Harm with potential for more than minimal harm that is not Immediate Jeopardy

- Noncompliance that results in a resident outcome of no more than minimal discomfort, and/or
- Has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well-being.



Severity Level 2 Example

Severity Level 2 Example

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



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

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