

Phase 2: Legal & Ethical  
Considerations



**Revised Medicare and Medicaid  
requirements for participation for  
Long Term Care (LTC) Facilities,  
42 CFR part 483, subpart B—  
Legal & Ethical Considerations**

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## Phase 2: Legal & Ethical Considerations

### Overview of Regulation Reform

The regulation reform implements a number of pieces of legislation from the Affordable Care Act (ACA) and the Improving Medicare Post-Acute Care Transformation (IMPACT) Act, including the following:

- Quality Assurance and Performance Improvement (QAPI)
- Reporting suspicion of a crime
- Increased discharge planning requirements
- Staff training section

## Phase 2: Legal & Ethical Considerations

| <b>Implementation Date</b>                     | <b>Type of Change</b>  | <b>Details of Change</b>   |
|--|--|--|
| Phase 1:<br>November 28, 2016<br>(Implemented) | Nursing Home Requirements for Participation                                  | New Regulatory Language was uploaded to the Automated Survey Processing Environment (ASPEN) under current F Tags |
| Phase 2:<br>November 28, 2017                  | F Tag Renumbering Interpretive Guidance (IG)<br>Implement New Survey Process | New F Tags<br>Updated IG<br>Begin Surveying with the new survey process  |
| Phase 3:<br>November 28, 2019                  | Requirements that need more time to implement                                | Requirements that need more time to implement  |

## Phase 2: Legal & Ethical Considerations

### Phase 2 Implementations

#### Resident Rights – 483.10

F574 – Required Notices and Contact Information; 483.10(g)(4)(ii) – (v)

- The resident has the right to receive notices orally (meaning spoken) and in writing (including Braille) in a format and a language he or she understands, including;
  - Information and contact information for State and local advocacy organizations, including but not limited to the State Survey Agency, the State Long-Term Care Ombudsman program, and the protection and advocacy system;
  - Information regarding Medicare and Medicaid eligibility and coverage;
  - Contact information for the Aging and Disability Resource Center; or other No Wrong Door Program; and
  - Contact information for the Medicaid Fraud Control unit.

## Phase 2: Legal & Ethical Considerations

### Potential Legal & Ethical Issues

#### *Resident Rights – 483.10*

F574 – Required Notices and Contact Information; 483.10(g)(4)(ii) – (v)

- Not having written translations in the resident's dominant language, including Braille;
- For hearing impaired and non-verbal residents whose primary language is American Sign Language (ASL), the facility is expected to provide an interpreter.
- Large print texts of the facility's statement of rights and responsibilities should also be available.
- Don't make the mistake of assuming that a hearing impaired resident who is able to write in English can understand what is presented simply because it is written in English.
- Failure to provide an ASL interpreter can lead to either a lawsuit or a civil rights action by the State on the resident's behalf.

## Phase 2: Legal & Ethical Considerations

### Phase 2 Implementations

#### *Freedom from Abuse, Neglect, and Exploitation – 483.12*

##### F608– Reporting of Reasonable Suspicion of a Crime; 483.12(b)(5)

- Ensure reporting of crimes occurring in federally-funded long-term care facilities in accordance with section 1150B of the Act.
  - Annually notifying covered individuals, as defined at Section 1150B(a)(3) of the Act, of that individual's obligation to comply with the following reporting requirements;
    - Each covered individual shall report to the State Agency and one or more law enforcement entities any reasonable suspicion of a crime against any individual who is a resident of, or is receiving care from, the facility;
    - Each covered individual shall report immediately, but not later than 2 hours after forming the suspicion, if the events that cause the suspicion result in serious bodily injury, or not later than 24 hours if the events that cause the suspicion do not result in serious bodily injury;
  - Posting a conspicuous notice of employee rights, as defined at Section 1150B(d)(3) of the Act; and
  - Prohibiting and preventing retaliation, as defined as Section 1150B(d)(1) and (2) of the Act.

## Phase 2: Legal & Ethical Considerations

### Potential Legal & Ethical Issues

#### *Freedom from Abuse, Neglect, and Exploitation – 483.12*

F608– Reporting of Reasonable Suspicion of a Crime; 483.12(b)(5)

- Once an individual suspects that a crime has been committed, facility staff must exercise caution when handling materials.
- There have been reports that investigations have been impeded by washing clothing or linens, destroying documentation, bathing or cleaning the resident before an examination can be performed, or failure to transfer a resident to the ER for examination, including obtaining a rape kit, if appropriate.
- If a sexual abuse lawsuit is filed and that evidence is unavailable, it can lead to a spoliation charge.
  - This allows the Plaintiff to establish that the evidence was unfavorable to the nursing home, and grants them an adverse inference against the facility at the time of trial.
- Difference between “no serious bodily injury” (24-hour reporting time) vs. “serious bodily injury”
- Failure to report by a covered individual can result in a civil money penalty of up to \$200,000. If the failure to report exacerbates the harm to the victim of the crime or results in harm to another person, it can result in a civil penalty up to \$300,000.
- Facilities should develop and implement policies that prohibit retaliation against employees who report suspicion of a crime, such as discharging, demoting, suspending, threatening, harassing or denying a promotion or other employment related benefit to an employee, or discriminating against them in any other manner because of lawful acts.

## Phase 2: Legal & Ethical Considerations

### Phase 2 Implementations

#### Admission, Transfer and Discharge— 483.15

#### F622 – Transfer and Discharge Requirements; 483.15(c)(2)

- When the facility transfers or discharges a resident under any of the circumstances specified in paragraphs (c)(1)(i)(A) through (F) of this section, the facility must ensure that the transfer or discharge is documented in the resident's medical record and appropriate information is communicated to the receiving health care institution or provider.
  - Documentation in the resident's medical record must include
    - The basis for the transfer per paragraph (c)(1)(i) of this section;
    - In the case of paragraph (c)(1)(i)(A) of this section, the specific resident needs that cannot be met, facility attempts to meet the resident's needs, and the service available at the receiving facility to meet the needs;
  - The documentation required by paragraph (c)(2)(i) of this section must be made by—
    - The resident's physician when transfer or discharge is necessary under paragraph (c)(1)(i)(C) or (D);
  - Information provided to the receiving provider must include a minimum of the following:
    - Contact information of the practitioner responsible for the care of the resident, resident representative information including contact information, advance directive information, all special instructions or precautions for ongoing care, as appropriate, comprehensive care goals, and all other necessary information, including a copy of the resident's discharge summary, consistent with § 483.21(c)(2), as applicable, and any other documentation, as applicable, to ensure a safe and effective transition of care.



## Phase 2: Legal & Ethical Considerations

### Potential Legal & Ethical Issues

#### Admission, Transfer and Discharge– 483.15

#### F622 – Transfer and Discharge Requirements; 483.15(c)(2)

- The goal here is to protect the resident against involuntary discharges
- Facilities are required to determine their capacity and capability to care for the residents they admit, and should not admit residents whose needs they cannot meet based on the Facility Assessment.
- Facilities can initiate transfers or discharges in the following limited circumstances:
  - It is necessary for the resident's welfare and the facility cannot meet the resident's needs;
  - The resident's health has improved such that they no longer need the facility's care and services;
  - The resident's clinical or behavioral status endangers the safety of individuals in the facility;
  - The resident's clinical or behavioral status otherwise endangers the health of individuals in the facility;
  - The resident has failed, after reasonable and appropriate notice to pay, or have paid under Medicare or Medicaid, for his or her stay at the facility; or
  - The facility ceases to operate.
- For circumstances 1, 3 and 4, surveyors will look to see that the facility has fully evaluated the resident, and does not base the discharge on the resident's status at the time of transfer to the acute care facility.

## Phase 2: Legal & Ethical Considerations

### Potential Legal & Ethical Issues

#### Admission, Transfer and Discharge– 483.15

#### F622 – Transfer and Discharge Requirements; 483.15(c)(2)

- Transfers that turn into discharges
  - When a situation begins as a transfer, and then turns into a discharge, surveyors will review both transfer and discharge requirements.
  - If the transfer is due to a significant change in condition, but not an emergency requiring an immediate transfer, the facility must conduct and document the appropriate assessment to determine if revisions to the care plan would allow the facility to meet the resident's needs.
- Refusal of Treatment
  - A resident's refusal of treatment does not constitute grounds for discharge, unless the facility is unable to meet the needs of the resident or protect the health and safety of others.
  - The facility must be able to demonstrate that the resident or, if applicable their representative, received information regarding the risks of refusal, and that staff conducted the appropriate assessment to determine if care plan revisions would allow the facility to meet the resident's needs or protect the health and safety of others.
- Non-Payment: In situations where a resident representative has failed to pay, the facility may discharge for non-payment. However, if there is evidence of exploitation or misappropriation of funds by the representative, the facility must first notify the appropriate authorities before discharging the resident.

## Phase 2: Legal & Ethical Considerations

### Phase 2 Implementations

#### *Comprehensive Resident Centered Care Plans; 483.21*

#### **F655 – Baseline Care Plan; 483.21(a)(1) – (3)**

- The facility must develop and implement a baseline care plan for each resident that includes the instructions needed to provide effective and person-centered care of the resident that meet professional standards of quality care.
  - Must be developed within 48 hours of admission;
  - Must include the minimum healthcare information necessary to properly care for a resident including, but not limited to: initial goals based on admission orders, physician orders, dietary orders, therapy services, social services, and PASAPR recommendation, if applicable.
- The facility may develop a comprehensive care plan in place of the baseline care plan if the comprehensive care plan—
  - Is developed within 48 hours of the resident's admission, and meets the requirements set forth in paragraph (b) of this section (excepting paragraph (b)(2)(i) of this section).
- The facility must provide the resident and their representative with a summary of the baseline care plan that includes, but is not limited to:
  - The initial goals of the resident, a summary of the resident's medications and dietary instructions, any services and treatments to be administered by the facility and personnel acting on behalf of the facility, and any updated information based on the details of the comprehensive care plan, as necessary.

## Phase 2: Legal & Ethical Considerations

### Potential Legal & Ethical Issues

#### *Comprehensive Resident Centered Care Plans; 483.21*

##### F655 – Baseline Care Plan; 483.21(a)(1) – (3)

- The baseline care plan should strike a balance between conditions and risks affecting the resident's health and safety, and what is important to the resident.
- However, facilities can complete a comprehensive care plan instead of the baseline care plan. If the facility chooses to complete a comprehensive care plan in lieu of the baseline care plan, a written summary of the comprehensive care plan must be provided to the resident or representative, and in a language they can understand.
  - The format and location of the summary is at the facility's discretion. However, the medical record must contain evidence that the summary was given to the resident or representative.
  - The facility can provide the baseline care plan itself as the summary, provided it meets all the requirements.
- If the comprehensive assessment and comprehensive care plan identify a change in the resident's goals, or physical, mental, or psychosocial functioning, which was otherwise not identified in the baseline care plan, those changes must be incorporated into an updated summary provided to the resident or representative.

## Phase 2: Legal & Ethical Considerations

### Phase 2 Implementations

#### Nursing Services; 483.25

#### F725, F726– Sufficient Nursing Staff, Competent Nursing Staff; 483.25(a)(1) – (4)

- The facility must have sufficient nursing staff with the appropriate competencies and skill sets to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental, and psychosocial wellbeing of each resident, as determined by resident assessments and individual plans of care and considering the number, acuity and diagnoses of the facility's resident population in accordance with the facility assessment required at § 483.70(e).
  - The facility must provide services by sufficient numbers of licensed nurses, and other nursing personnel, including but not limited to nurse aides, except when waived under paragraph (e) of this section;
  - The facility must also designate a licensed nurse to serve as a charge nurse on each tour of duty, except when waived under paragraph (c) of this section;
  - The facility must ensure that licensed nurses have the specific competencies and skill sets necessary to care for residents' needs, as identified through resident assessments, and described in the plan of care.
  - Providing care includes but is not limited to assessing, evaluating, planning and implementing resident care plans and responding to resident's needs.

## Phase 2: Legal & Ethical Considerations

### Potential Legal & Ethical Issues

#### *Nursing Services; 483.25*

F725, F726– Sufficient Nursing Staff, Competent Nursing Staff;  
483.25(a)(1) – (4)

- Federal Regulations do not define minimum nursing staff ratios; however New Jersey does (2.5 hours ppd plus acuities).
- If the facility does not meet State regulations for staffing, surveyors are instructed not to cite that as a deficiency.
- However, they can always cite to F836, §483.70(b), which requires the facility comply with all applicable Federal, State and local laws.
- “Concerns such as falls, weight loss, dehydration, pressure ulcers, as well as the incidence of elopement and resident altercations can also offer insight into the sufficiency of the numbers of staff. Surveyors must investigate if these adverse outcomes are related to sufficient staffing.”

## Phase 2: Legal & Ethical Considerations

### Phase 2 Implementations

#### Behavioral Health Services; 483.40

#### F740 – Behavioral Health Services; 483.40(b)(3); (c)(1) – (2)

- Each resident must receive and the facility must provide the necessary behavioral health care and services to attain or maintain the highest practicable physical, mental, and psychosocial wellbeing, in accordance with the comprehensive assessment and plan of care. Behavioral health encompasses a resident's whole emotional and mental well-being, which includes, but is not limited to, the prevention and treatment of mental and substance use disorders.
  - The facility must ensure that a resident who displays or is diagnosed with dementia, receives the appropriate treatment and services to attain or maintain his or her highest practicable physical, mental, and psychosocial wellbeing.
  - If rehabilitative services such as but not limited to physical therapy, speech-language pathology, occupational therapy, and rehabilitative services for mental disorders and intellectual disability, are required in the resident's comprehensive plan of care, the facility must–
    - Provide the required services, including specialized rehabilitation services as required in §483.65; or obtain the required services from an outside source (in accordance with §483.70(g) of this part) from a Medicare and/or Medicaid provider of specialized rehabilitative services.



## Phase 2: Legal & Ethical Considerations

### Potential Legal & Ethical Issues

#### Behavioral Health Services; 483.40

F740 – Behavioral Health Services; 483.40(b)(3); (c)(1) – (2)

- The facility must provide necessary behavioral health care and services which include:
  - Ensuring that the necessary care and services are person-centered and reflect the resident's goals for care, while maximizing the resident's dignity, autonomy, privacy, socialization, independence, choice, and safety;
  - Ensuring that staff interact and communicate in a manner that promotes mental and psychosocial well-being.
  - Providing meaningful activities which promote engagement, and positive meaningful relationships between residents and staff, families, other residents, and the community. Meaningful activities are those that address the resident's customary routines, interests, preferences, etc., and enhance the resident's well-being.
  - Ensuring that pharmacological interventions are only used when non-pharmacological interventions are ineffective or when clinically indicated.



## Phase 2: Legal & Ethical Considerations

### Phase 2 Implementations

#### Pharmacy Services; 483.45

F756, F758 – Drug Regimen Review, Report Irregular, Act on; Free from Unnecessary Psychotropic Drugs/PRN Use; 483.45(c)(2), (e)

- The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.
- The facility must ensure that—
  - Residents who have not used psychotropic drugs are not given these drugs unless the medication is necessary to treat a specific condition as diagnosed and documented in the clinical record;
  - Residents who use psychotropic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs;
  - Residents do not receive psychotropic drugs pursuant to a PRN order unless that medication is necessary to treat a diagnosed specific condition that is documented in the clinical record; and
  - PRN orders for anti-psychotic drugs are limited to 14 days and cannot be renewed unless the attending physician or prescribing practitioner evaluates the resident for the appropriateness of that medication.

## Phase 2: Legal & Ethical Considerations

### Potential Legal & Ethical Issues

#### Pharmacy Services; 483.45

F756, F758 – Drug Regimen Review, Report Irregular, Act on; Free from Unnecessary Psychotropic Drugs/PRN Use; 483.45(c)(2), (e)

- Medication Regimen Review (MRR): It may be necessary for the pharmacist to conduct MRR more frequently, for example weekly, depending on the resident's condition and the risk for adverse consequences related to medications. Regulations prohibit the pharmacist from delegating MRR to other staff.
- MRR policies and procedures need to address residents who are anticipated to stay less than 30 days, and residents who experience an acute change in condition and for whom an immediate MRR is requested after appropriate staff have notified the resident's physician, medical director, and director of nursing.
- The pharmacist is to document any identified irregularities. Those irregularities must then be reviewed by the attending physician. The facility should have a procedure in place for when the attending physician disagrees with, or does not take any action on the identified irregularities.

## Phase 2: Legal & Ethical Considerations

### Potential Legal & Ethical Issues

#### Pharmacy Services; 483.45

F756, F758 – Drug Regimen Review, Report Irregular, Act on; Free from Unnecessary Psychotropic Drugs/PRN Use; 483.45(c)(2), (e)

- Stronger push for less medication:
  - Old language – “It is important for the interdisciplinary team to consider non-pharmacological approaches.”
  - New language – “It is important for the IDT to implement non-pharmacological approaches designed to meet the needs of each resident.”
- While there may be isolated situations where a pharmacological intervention is required first, these situations do not negate the obligation of the facility to develop and implement non-pharmacological interventions.
- Permission given by or a request made by the resident and/or representative does not serve as a sole justification for the medication itself.

## Phase 2: Legal & Ethical Considerations

| Type of PRN Order   | Time Limitation | Exception   | Required Actions  |
|---|-----------------|---|---|
| PRN Orders for psychotropic medications, excluding antipsychotics | 14 Days         | Order may be extended beyond 14 days if the attending physician or prescribing practitioner believes it is appropriate to extend the order. | Attending physician or prescribing practitioner should document the rationale for the extended time period in the medical record and indicate a specific duration.  |
| PRN Orders for antipsychotic medications only                     | 14 Days         | None  | If the attending physician or prescribing physician wishes to write a new order for the PRN antipsychotic, the attending physician or prescribing practitioner must first evaluate the resident to determine if the new order for the PRN antipsychotic is appropriate. |

## Phase 2: Legal & Ethical Considerations

### Phase 2 Implementations

#### *Dental Services; 483.55*

F790, F791 – Routine/Emergency Dental Services in SNF's;  
483.55(a)(3), (a)(5); (b)(3) and (b)4)

- A facility must have a policy identifying those circumstances when the loss or damage of dentures is the facility's responsibility and may not charge a resident for the loss or damage of dentures determined in accordance with facility policy to be the facility's responsibility.
- The facility must promptly, within 3 days, refer residents with lost or damaged dentures for dental services. If the referral does not occur within 3 days, the facility must provide documentation of what they did to ensure the resident could still eat and drink adequately while awaiting dental services and the extenuating circumstances that led to the delay.

## Phase 2: Legal & Ethical Considerations

### Potential Legal & Ethical Issues

#### Dental Services; 483.55

F790, F791 – Routine/Emergency Dental Services in SNF's;  
483.55(a)(3), (a)(5); (b)(3) and (b)4)

- The facility must have a policy identifying those instances when the loss or damage of partial or full dentures is the facility's responsibility, such as when the facility discards dentures placed on a meal tray.
- A blanket policy of facility non-responsibility for the loss or damage of dentures or a policy stating the facility is only responsible when the dentures are in actual physical possession of facility staff would not meet the requirement.
- In addition, the facility is prohibited from requesting or requiring residents or potential residents to waive any potential facility liability for losses of personal property.

## Phase 2: Legal & Ethical Considerations

### Phase 2 Implementations

#### Food and Nutrition Services; 483.60

F800 – F802 Provided Diet meets needs of each Resident; Qualified Dietary Staff, Sufficient Dietary Support Personnel; 483.60(a); (a)(1)(iv); (a)(2)(i)

- The facility must employ sufficient staff with the appropriate competencies and skill sets to carry out the functions of the food and nutrition service, taking into consideration resident assessments, individual plans of care, and the number, acuity and diagnoses of the facility's resident population in accordance with the facility assessment required at §483.70(e).
  - For dietitians hired or contracted with prior to November 28, 2016, they must meet these requirements no later than 5 years after that date, or as required by state law;
  - If a qualified dietitian or other clinically qualified nutrition professional is not employed full-time, the facility must designate a person to serve as the director of food and nutrition services who is a certified dietary manager; or a certified food service manager; or has similar national certification for food service management and safety from a national certifying body; or has an associate's or higher degree in food service management or in hospitality, if the course study includes food service or restaurant management, from an accredited institution of higher learning.

## Phase 2: Legal & Ethical Considerations

### Phase 2 Implementations

#### *Infection Control; 483.80*

#### F880, F881– Infection Prevention and Control; Antibiotic Stewardship Program; 483.80(a), (a)(3)

- The facility must establish an infection prevention and control program (IPCP) that must include, at a minimum the following elements:
  - A system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, volunteers, visitors, and other individuals providing services under a contractual agreement based upon the facility assessment conducted according to §483.70(e) and following accepted national standards; and
  - An antibiotic stewardship program that includes antibiotic use protocols and a system to monitor antibiotic use.



## Phase 2: Legal & Ethical Considerations

### Potential Legal & Ethical Issues

#### *Infection Control; 483.80*

#### F880, F881– Infection Prevention and Control; Antibiotic Stewardship Program; 483.80(a), (a)(3)

- The goal of the antibiotic stewardship program is to reduce antibiotic resistance
- The antibiotic is to be prescribed for the correct indication, dose, and duration to appropriately treat the resident, while at the same time also attempting to reduce the development of antibiotic-resistant organisms.
- Potential adverse outcomes associated with antibiotic use include: increased adverse drug events and interactions (e.g. allergic rash, anaphylaxis or death); serious diarrheal infections from *C. diff.*; disruption of normal flora (e.g. overgrowth of *Candida* such as oral thrush); and/or colonization and/or infection with antibiotic-resistant organisms such as MRSA, VRE, and multi-drug resistant GNB.

## Phase 2: Legal & Ethical Considerations

### Phase 2 Implementations

#### *Physical Environment; 483.90*

#### F926 – Smoking Policies; 483.90(i)(5)

- The facility must provide a safe, functional, sanitary, and comfortable environment for the residents, staff and the public. The facility must—
  - Establish policies, in accordance with applicable Federal, State, and local laws and regulations, regarding smoking, smoking areas, and smoking safety that also take into account non-smoking residents.