Medicare CoP Final Rule for Skilled Nursing Facilities Phase 2 Implementation

October 2017

The Hospital + Healthsystem Association of Pennsylvania

Leading for Better Health

MEDICARE CONDITIONS OF PARTICIPATION (CoP)
Skilled Nursing Facilities
CMS Final Rule—Phase 2 Implementation Required by November 28, 2017

Overview

The Centers for Medicare & Medicaid Services (CMS) issued a final rule to improve the care and safety of residents in long-term care facilities that participate in the Medicare and Medicaid programs.

The policies in the final rule are targeted at reducing unnecessary hospital readmissions and infections, improving the quality of care, and strengthening safety measures for residents.

The rule implements a number of safeguards that have been identified by resident advocates and other stakeholders, and includes additional protections required by the Affordable Care Act (ACA). According to CMS, changes finalized in this rule include:

- Strengthening the rights of long-term care facility residents, including prohibiting the use of pre-dispute binding arbitration agreements
- Ensuring that long-term care facility staff members are properly trained in caring for residents with dementia and in preventing elder abuse
- Ensuring that long-term care facilities take into consideration the health of residents when making decisions about the kinds and levels of staffing a facility needs to properly take care of its residents
- Ensuring that staff members have the right skill sets and competencies to provide person-centered care to residents. The care plans developed for residents will take into consideration their goals of care and preferences
- Improving care planning, including discharge planning for all residents with involvement of the facility's interdisciplinary team and consideration of the caregiver's capacity, giving residents information they need for follow-up after discharge, and ensuring that instructions are transmitted to any receiving facilities or service providers
- Allowing dietitians and therapy providers the authority to write orders in their areas of expertise when a physician delegates the responsibility and state licensing laws allow
- Updating the long-term care facility's infection prevention and control program, including requiring an infection prevention and control officer and an antibiotic stewardship program that includes antibiotic use protocols and a system to monitor antibiotic use

These regulations are effective through the following implementation phases:

- Phase 1: November 28, 2016
- Phase 2: November 28, 2017
- Phase 3: November 28, 2019

This resource tool provides guidance for the implementation of Phase 2.

PHASE 2 IMPLEMENTATION
November 28, 2017

Regulatory Requirement	State Operations Manual

§483.10 Resident Rights

(g)*Information and communication.*

(4) 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;

(ii) 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 (established under section 712 of the Older Americans Act of 1965, as amended 2016 (42 U.S.C. 3001 et seq.) and the protection and advocacy system (as designated by the state, and as established under the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (42 U.S.C. 15001 et seq.);

(iii) Information regarding Medicare and Medicaid eligibility and coverage;

(iv) Contact information for the Aging and Disability Resource Center (established under Section 202(a)(20)(B)(iii) of the Older Americans Act); or other No Wrong Door Program

(v) Contact information for the Medicaid Fraud Control Unit.

(Page 625 of final rule)

Intent: This requirement is intended to assure that each resident know his or her rights and responsibilities and that the facility communicates this information prior to or upon admission, as appropriate during the resident's stay, and when the facility's rules change.

Interpretive Guidelines—Communication of Information: "In a language that the resident understands" is defined as communication of information concerning rights and responsibilities that is clear and understandable to each resident, to the extent possible considering impediments which may be created by the resident's health and mental status. If the resident's knowledge of English or the predominant language of the facility is inadequate for comprehension, a means to communicate the information concerning rights and responsibilities in a language familiar to the resident must be available and implemented. For foreign languages commonly encountered in the facility locale, the facility should have written translations of its statements of rights and responsibilities, and should make the services of an interpreter available. In the case of less commonly encountered foreign languages, however, a representative of the resident may sign that he or she has explained the statement of rights to the resident prior to his/her acknowledgement of receipt. For hearing impaired residents who communicate by signing, the facility is expected to provide an interpreter. Large print texts of the facility's statement of resident rights and responsibilities should also be available.

"Both orally and in writing" means if a resident can read and understand written materials without assistance, an oral summary, along with the written document, is acceptable.

Any time State or Federal laws relating to resident rights or facility rules change during the resident's stay in the facility, he/she must promptly be informed of these changes.

"All rules and regulations" relates to facility policies governing resident conduct. A facility cannot reasonably expect a resident to abide by rules he or she has never been told about. Whatever rules the facility has formalized, and by which it expects residents to abide, should be included in the statement of rights and responsibilities.

Residents should be told in advance when changes will occur in their bills. Providers must fully inform the resident of services and related changes.

"Periodically" means that whenever changes are being introduced that will affect the residents' liability and whenever there are changes in services.

A Medicare beneficiary who requires services upon admission that are not covered under Medicare may be required to submit a deposit provided the notice provisions, if applicable, are met.

Protection and Advocacy Network: "The protection and advocacy network" refers to the system established to protect and advocate the rights of individuals with developmental disabilities specified in the Developmental Disabilities Assistance and Bill of Rights Act, and the protection and advocacy system established under the Protection and Advocacy for Mentally Ill Individuals Act.

Procedures: At the Entrance Conference, request a copy of the written information that is provided to residents regarding their rights and review it to determine if it addresses the specified requirements.

§483.10 Resident Rights

Suggested Checklist for Implementation

- Develop and implement a document or brochure that defines the resident's rights and responsibilities while they are in your care
- Have the document/brochure available in the preferred languages for your patient population
- Have provisions in place for the use of translators

Promising Practices Shared by Members of HAP's Council for Long-Term Care Providers

(Responses received from July 28, 2017 query)

"Our NHA group is currently working on implementing a statement in the admission packet that will state where and how this information is disseminated."

"We are collaborating with our Disability Division to secure documents in Braille and alternative languages."

"I will be using Language Services Associates to translate the document as it is needed."

Regulatory Requirement

§483.12 Freedom from abuse, neglect, and exploitation

(b) The facility must develop and implement written policies and procedures that:

(5) Ensure reporting of crimes occurring in federally-funded long-term care facilities in accordance with section 1150B of the Act. The policies and procedures must include but are not limited to the following elements.

(i) 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.

(A) Each covered individual shall report to the State Agency and one or more law enforcement entities for the political subdivision in which the facility is located any reasonable suspicion of a crime against any individual who is a resident of, or is receiving care from, the facility.

(B) 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.

(ii) Posting a conspicuous notice of employee rights, as defined at section 1150B(d)(3) of the Act.

(iii) Prohibiting and preventing retaliation, as defined at section 1150B(d)(1) and (2) of the Act.

(Page 639 of final rule)

State Operations Manual

Intent: The intent is for the facility to develop and implement policies and procedures that:

- Ensure reporting of crimes against a resident or individual receiving care from the facility occurring in nursing homes within prescribed timeframes to the appropriate entities, consistent with Section 1150B of the Act;
- Ensure that all covered individuals, such as the owner, operator, employee, manager, agent or contractor report reasonable suspicion of crimes, as required by Section 1150B of the Act;
- Provide annual notification for covered individuals of these reporting requirements;
- Post a conspicuous notice of employee rights, including the right to file a complaint; and
- Assure that any covered individual who makes a report to be made, or is in the process of making a report, is not retaliated against.

Guidance Note: Once an individual suspects that a crime has been committed, facility staff must exercise caution when handling materials that may be used for evidence or for a criminal investigation. It has been reported that some investigations were impeded due to washing linens or clothing, destroying documentation, bathing or cleaning the resident before the resident has been examined, or failure to transfer a resident to the emergency room for examination including obtaining a rape kit, if appropriate.

Please refer to the facility's obligations under "Reporting Reasonable Suspicion of a Crime in a Long-Term Care Facility: Section 1150B of the Social Security Act," (See S&C Memo: 11-30-NH, revised January 20, 2012, http://www.cms.gov/Medicare/ProviderEnrollment-and-Certification/SurveyCertificationGenInfo/downloads/scletter11_30.pdf).

See Addendum A: *Required Policies and Procedures for Reporting Suspicions of a Crime*

Procedures: Obtain and review the facility's policies and procedures to determine whether the facility is in compliance with the requirements at 1150B for:

- Ensuring the reporting reasonable suspicion of crimes,
- Notifying covered individuals of their reporting responsibilities,
- Prohibiting and preventing retaliation, and
- Posting notification of employee rights.

Observe whether the facility has posted notification of employee rights and whether the notification includes all of the required components. Note the location of the notification, in relation to whether it is likely to be noticed by all employees.

If the surveyor discovers an incident that has criminal implications and has not been reported by the facility, the facility should be encouraged to make the report to the appropriate agencies. If the facility refuses, the surveyor should consult with his/her supervisor immediately, since the State Agency may need to assume this responsibility.

For those covered individuals who did not report the reasonable suspicion of a crime, discuss with the State Survey Agency and next steps for referral for follow-up and possible sanctions.

§483.12 Freedom from abuse, neglect, and exploitation

Suggested Checklist for Implementation

- Develop and implement policies and procedures that
  - Outline the reporting process for crimes committed against a resident or individual receiving care from the facility
  - Outline the annual notification process for employees
  - Provide for the posting of signage regarding employees' rights related to prohibition of retaliation for reporting crimes

NOTE: The State Operations Manual outlines the following key elements of noncompliance:

"To cite deficient practice, the surveyor's investigation will generally show that the facility failed to develop and implement policies and procedures for any one or more of the following:

- Ensure the reporting of suspected crimes, within mandated timeframes (i.e., immediately but not later than two hours if the suspected crime resulted in serious bodily injury, within 24 hours for all other cases);

- Notify covered individuals annually of their reporting obligations;

- Post signage of employee rights related to retaliation against the employee for reporting a suspected crime; or

- Prohibit and prevent retaliation. "

Regulatory Requirement

§483.15 Admission, transfer, and discharge rights

*(c)**Transfer and discharge –***

(2)*Documentation.* 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.

(i) Documentation in the resident's medical record must include:

(A) The basis for the transfer per paragraph (c)(1)(i) of this section.

(B) In the case of paragraph (c)(1)(i)(A) of this section, the specific resident need(s) that cannot be met, facility attempts to meet the resident needs, and the service available at the receiving facility to meet the need(s).

(ii) The documentation required by paragraph (c)(2)(i) of this section must be made by –

(A) The resident's physician when transfer or discharge is necessary under paragraph (c)(1)(A) or (B) of this section; and

(B) A physician when transfer or discharge is necessary under paragraph (b)(1)(i)(C) or (D) of this section.

(iii) Information provided to the receiving provider must include a minimum of the following:

(A) Contact information of the practitioner responsible for the care of the resident

(B) Resident representative information including contact information.

(C) Advance Directive information.

(D) All special instructions or precautions for ongoing care, as appropriate.

(E) Comprehensive care plan goals,

(F) All other necessary information, including a copy of the residents 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.

(Page 644 of final rule)

State Operations Manual

Intent: To specify the limited conditions under which a skilled nursing facility or nursing facility may initiate transfer or discharge of a resident, the documentation that must be included in the medical record, and who is responsible for making the documentation. Additionally, these requirements specify the information that must be conveyed to the receiving provider for residents being transferred or discharged to another healthcare setting.

Guidance Note: The provisions at §§483.15(c)(1)and (2)(i)-(ii), only apply to transfers or discharges that are initiated by the facility, not by the resident. Section 483.15(c)(2)(iii) applies to both facility and resident initiated transfers (for information required at discharge, refer to F661, Discharge Summary).

These regulations limit the circumstances under which a facility can initiate a transfer or discharge, thus protecting nursing home residents from involuntary discharge.

In the following limited circumstances, facilities may initiate transfers or discharges**:**

1. The discharge or transfer is necessary for the resident's welfare and the facility cannot meet the resident's needs.
2. The resident's health has improved sufficiently so that the resident no longer needs the care and/or services of the facility.
3. The resident's clinical or behavioral status (or condition) endangers the safety of individuals in the facility.
4. The resident's clinical or behavioral status (or condition) otherwise endangers the health of individuals in the facility.
5. 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.
6. The facility ceases to operate.

Procedure: Briefly review the most recent comprehensive assessment, comprehensive care plan, progress notes, and orders to identify the basis for the transfer or discharge; during this review, identify the extent to which the facility has developed and implemented interventions to avoid transferring or discharging the resident, in accordance with the resident's needs, goals for care and professional standards of practice. This information will guide observations and interviews to be made in order to corroborate concerns identified.

§483.15 Admission, transfer, and discharge rights

Suggested Checklist for Implementation

- Develop and implement policies and procedures that the facility is to follow when initiating the transfer or discharge of a resident. These policies and procedures should include, but not be limited to:
    - Steps to be taken to ensure the resident's safe return to the facility following hospitalization or therapeutic leave
    - Steps to be taken to ensure the appropriate information is included in the medical record regarding the resident's discharge

NOTE: The State Operations Manual outlines the following key elements of noncompliance:

"To cite deficient practice, the surveyor's investigation will generally show that the facility failed to:

- Establish and/or implement a policy that is in accordance with the State Medicaid plan, and addresses returning to the facility following hospitalization or therapeutic leave; or

- Ensure that residents whose hospitalization or therapeutic leave exceeds the State's bed-hold period are returned to their previous room and/or the first available bed in a semiprivate room; or

- Ensure (for a resident not permitted to return) the medical record and notification contain a valid basis for discharge; or

- Permit a resident to return to the same composite distinct part in which they previously resided. "

Regulatory Requirement

§483.21 Comprehensive person-centered care planning

(a)***Baseline care plans.***

(1) 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. The baseline care plan must –

(i) Be developed within 48 hours of a resident's admission.
(ii) Include the minimum healthcare information necessary to properly care for a resident including, but not limited to:

(A) Initial goals based on admission orders.
(B) Physician orders.
(C) Dietary orders.
(D) Therapy services.
(E) Social services.
(F) PASARR recommendation, if applicable.

(2) The facility may develop a comprehensive care plan in place of the baseline care plan if the comprehensive care plan –

(i) Is developed within 48 hours of the resident's admission.
(ii) Meets the requirements set forth in paragraph (b) of this section (excepting paragraph (b)(2)(i) of this section).

(3) The facility must provide the resident and their representative with a summary of the baseline care plan that includes but is not limited to:

(i) The initial goals of the resident.
(ii) A summary of the resident's medications and dietary instructions.
(iii) Any services and treatments to be administered by the facility and personnel acting on behalf of the facility.
(iv) Any updated information based on the details of the comprehensive care plan, as necessary.

(Page 652 of final rule)

State Operations Manual

Intent: Completion and implementation of the baseline care plan within 48 hours of a resident's admission is intended to promote continuity of care and communication among nursing home staff, increase resident safety, and safeguard against adverse events that are most likely to occur right after admission; and to ensure the resident and representative, if applicable, are informed of the initial plan for delivery of care and services by receiving a written summary of the baseline care plan.

Guidance: Nursing homes are required to develop a baseline care plan within the first 48 hours of admission which provides instructions for the provision of effective and person-centered care to each resident.

The facility must provide the resident and the representative, if applicable, with a written summary of the baseline care plan by completion of the comprehensive care plan. The summary must be in a language and conveyed in a manner the resident and/or representative can understand. This summary must include:

- Initial goals for the resident;
- A list of current medications and dietary instructions, and
- Services and treatments to be administered by the facility and personnel acting on behalf of the facility.

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 and resident representative, if applicable. The facility may choose to provide a copy of the baseline care plan itself as the summary, as long as it meets all of the requirements of the summary.

Procedures: Use the Critical Element (CE) Pathway associated with the issue under investigation, or if there is no specific CE Pathway, use the probes below to assist in your investigation:

Was the baseline care plan developed and implemented within 48 hours of admission to the facility?

Does the resident's baseline care plan include:

- The resident's initial goals for care;
- The instructions needed to provide effective and person-centered care that meets professional standards of quality care;
- The resident's immediate health and safety needs;
- Physician and dietary orders;
- PASARR recommendations, if applicable; and
- Therapy and social services.

Was the baseline care plan revised and updated as needed to meet the resident's needs until the comprehensive care plan was developed?

If the resident experienced an injury or adverse event prior to the development of the comprehensive care plan, should the baseline care plan have identified the risk for the injury/event (i.e., if risk factors were known or obvious)?

Did the facility provide the resident and his or her representative, if applicable, with a written summary of the baseline care plan that contained at least, without limitation:

- Initial goals of the resident;
- A summary of current medications and dietary instructions;
- Services and treatments to be provided or arranged by the facility and personnel acting on behalf of the facility; and
- Any updated information based on details of the admission comprehensive assessment.

§483.21 Comprehensive person-centered care planning

Suggested Checklist for Implementation

- Develop and implement policies and procedures to ensure that the resident's baseline care plan is available within the first 48 hours of admission

Regulatory Requirement

§483.35 Nursing Services

The facility must have sufficient nursing staff with the appropriate competencies and skills sets to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental, and psychosocial well-being 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) (*referenced below*).

(Page 666 of final rule)

Reference to § 483.70(e) ***Facility assessment.***

The facility must conduct and document a facility-wide assessment to determine what resources are necessary to care for its residents competently during both day-to-day operations and emergencies. The facility must review and update that assessment, as necessary, and at least annually. The facility must also review and update this assessment whenever there is, or the facility plans for, any change that would require a substantial modification to any part of this assessment. The facility assessment must address or include:

(1) The facility's resident population, including, but not limited to,

(i) Both the number of residents and the facility's resident capacity;

(ii) The care required by the resident population considering the types of diseases, conditions, physical and cognitive disabilities, overall acuity, and other pertinent facts that are present within that population;

(iii) The staff competencies that are necessary to provide the level and types of care needed for the resident population;

(iv) The physical environment, equipment, services, and other physical plant considerations that are necessary to care for this population; and

(v) Any ethnic, cultural, or religious factors that may potentially affect the care provided by the facility, including, but not limited to, activities and food and nutrition services.

(2) The facility's resources, including but not limited to,

(i) All buildings and/or other physical structures and vehicles;

(ii) Equipment (medical and non-medical);

(iii) Services provided, such as physical therapy, pharmacy, and specific rehabilitation therapies;

(iv) All personnel, including managers, staff (both employees and those who provide services under contract), and volunteers, as well as their education and/or training and any competencies related to resident care;

(v) Contracts, memorandums of understanding, or other agreements with third parties to provide services or equipment to the facility during both normal operations and emergencies; and

(vi) Health information technology resources, such as systems for electronically managing patient records and electronically sharing information with other organizations.

(3) A facility-based and community-based risk assessment, utilizing an all-hazards approach.

State Operations Manual

Intent: To assure that all nursing staff possess the competencies and skill sets necessary to provide nursing and related services to meet the residents' needs safely and in a manner that promotes each resident's rights, physical, mental and psychosocial well-being.

"Competency" is a measurable pattern of knowledge, skills, abilities, behaviors, and other characteristics that an individual needs to perform work roles or occupational functions successfully.

Guidance: Many factors must be considered when determining whether or not facility staff have the specific competencies and skill sets necessary to care for residents' needs, as identified through the facility assessment, resident-specific assessments, and described in their plan of care. A staff competency deficiency under this requirement may or may not be directly related to an adverse outcome to a resident's care or services. It may also include the potential for physical and psychosocial harm.

The facility's assessment must address/include an evaluation of staff competencies that are necessary to provide the level and types of care needed for the resident population.

Procedures: Surveyors must determine through information obtained by observations, interviews and verified by record reviews, whether the facility employs competent nursing staff to provide care and services in assisting residents to attain or maintain their highest practicable level of physical, mental, functional and psychosocial well-being.

§483.35 Nursing Services

Suggested Checklist for Implementation (*Content from State Operations Manual*)

"Surveyors will be determining compliance through information obtained by observations, interviews and verified by record reviews. They will attempt to find answers for the following:

- How are staff competencies and skill sets evaluated upon their initial hire and routinely thereafter and when new technologies/equipment are put into use?
- Does the facility assessment describe the type of competencies required to meet each resident's needs as required under §483.70(e). Do the competencies of the staff reflect the expectations described in the facility assessment?
- Is there evidence that staff are able to identify and address resident changes in condition? What are the practices or tools used that demonstrate this ability? Is there evidence of a lack of competency, such as:
    - Adverse events that could have been prevented;
    - Conditions that occurred that could have been identified and addressed earlier to prevent them from worsening; or
    - Hospital transfers that could have been potentially avoided if the reason for the transfer had been identified and addressed earlier.
- How are staff evaluated to determine that they demonstrate knowledge of individual residents and how to support resident preferences?
- When observing the provision of care, does the nursing staff demonstrate:
    - Necessary competencies and skill sets in accordance with current standards of practice? For example, if the resident requires a manual lift for transferring, do staff demonstrate knowledge and skill in the proper use of the lift and perform the activity in a safe manner?
    - The use of techniques and skills that maintain or improve the resident's physical, mental or psychosocial functioning as identified through required assessments and the care plan such as, but not limited to, the following:
        - Providing mobility assistance, such as assistance with walking and transferring.
        - Assisting with Activities of Daily Living: eating, bathroom needs, bed mobility, bathing, oral care, incontinence care, dressing, etc.
        - Providing care to residents with communication needs and ensuring that devices are utilized per the care plan.
        - Demonstrating knowledge about residents' condition and behavior and when to report changes to the licensed or registered nurse.
- Determine how agency/contract staff have been evaluated to ensure their competencies and skills to care for the facility's resident population.

"Examples for evaluating competencies may include but are not limited to:

- Lecture with return demonstration for physical activities;
- A pre-and post-test for documentation issues;
- Demonstrated ability to use tools, devices, or equipment that were the subject of training and used to care for residents;
- Reviewing adverse events that occurred as an indication of gaps in competency; or
- Demonstrated ability to perform activities that is in the scope of practice an individual is licensed or certified to perform. "

§483.35 Nursing Services

Suggested Checklist for Implementation, *continued*

"Nursing leadership with input from the Medical Director should delineate the competencies required for all nursing staff to deliver, individualize, and provide safe care for the facility's residents. There should also be a process to evaluate staff skill levels, and to develop individualized competency-based training, that ensure resident safety and quality of care and service being delivered. A competency-based program might include the following elements:

- Evaluates current staff training programming to ensure nursing competencies (e.g. skills fairs, training topics, return demonstration).
- Identifies gaps in education that is contributing to poor outcomes (e.g. potentially preventable re-hospitalization) and recommends educational programing to address these gaps.
- Outlines what education is needed based on the resident population (e.g. geriatric assessment, mental health needs) with delineation of licensed nursing staff verses non-licensed nursing and other staff member of the facility.
- Delineates what specific training is needed based on the facility assessment (e.g. ventilator, IV's, trachs).
- Details the tracking system or mechanism in place to ensure that the competency-based staffing model is assessing, planning, implementing, and evaluating effectiveness of training.
- Ensures that competency-based training is not limited to online computer based but should also test for critical thinking skills as well as the ability to manage care in complex environments with multiple interruptions."

NOTE: The State Operations Manual outlines the following key elements of noncompliance:

> "To cite deficient practice, the surveyor's investigation will generally show that the facility failed to ensure the licensed nurses and other nursing personnel have the knowledge, competencies and skill sets to provide care and respond to each resident's individualized needs as identified in his/her assessment and care plan."

Regulatory Requirement

§483.40 Behavioral Health Services

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 well-being, 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.

(a) The facility must have sufficient staff who provide direct services to residents with the appropriate competencies and skills sets to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental and psychosocial well-being 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 §483.70(e). These competencies and skills sets include, but are not limited to, knowledge of and appropriate training and supervision for:

(1) *To be implemented in Phase 3*

(2) Implementing non-pharmacological interventions.

(Page 669 of final rule)

State Operations Manual

Intent (§483.40(a), (a)(1) & (a)(2)):
The intent of this requirement is to ensure that the facility has sufficient staff members who possess the basic competencies and skills sets to meet the behavioral health needs of residents for whom the facility has assessed and developed care plans. The facility must consider the acuity of the population and its assessment in accordance with §483.70(e). This includes residents with mental disorders, psychosocial disorders, or substance use disorders. Facility staff members must implement person-centered, care approaches designed to meet the individual needs of each resident. Additionally, for residents with behavioral health needs, non-pharmacological interventions must be developed and implemented.

Guidance (§483.40(a), (a)(1) & (a)(2)): Sufficient Staff to Provide Behavioral Health Care and Services
The facility must address in its facility assessment under §483.70(e) (F838), the behavioral health needs that can be met and the numbers and types of staff needed to meet these needs. If a resident qualifies for specialized Level II services under PASARR, please refer to §483.20(k) (F645). If the resident does not qualify for specialized services under PASARR, but requires more intensive behavioral health services (e.g., individual counseling), the facility must demonstrate reasonable attempts to provide for and/or arrange for such services. This would include ensuring that the types of service(s) needed is clearly identified based on the individual assessment, care plan and strategies to arrange such services. Facilities must have sufficient direct care staff (nurse aides and licensed nurses) with knowledge of behavioral health care and services in accordance with the care plans for all residents, including those with mental or psychosocial disorders.

Facilities may be concerned about accessing sufficient professional behavioral health resources (e.g., psychiatrists) to meet these requirements due to shortages in behavioral and mental health providers in their area. A facility will not be cited for non-compliance, if there are demonstrated attempts to access such services.

Facilities are not expected to provide services that are not covered by Medicare or Medicaid. They are expected to take reasonable steps to seek alternative sources (state, county or local programs) but if they are not successful, it is not the basis for a deficient practice.

Non-pharmacological Interventions
This guidance is not intended to exclude the use of pharmacological interventions when they are clinically necessary and appropriate. While there may be situations where a pharmacological intervention is indicated first, these situations do not negate the obligation of the facility to also develop and implement appropriate non-pharmacological interventions.

Procedures: Skill and Competency of Staff
The facility must identify the skills and competencies needed by staff to work effectively with residents (both with and without mental disorders and psychosocial disorders). Staff need to be knowledgeable about implementing non-pharmacological interventions. The skills and competencies needed to care for residents should be identified through an evidence-based process that could include the following: an analysis of Minimum Data Set (MDS) data, review of quality improvement data, resident-specific and population needs, review of literature, applicable regulations, etc.

§483.40(a) and (a)(2) Behavioral Health Services, Sufficient Staff

Suggested Checklist for Implementation (*Content from State Operations Manual*)

"Determination of Sufficient Staffing
One factor used to determine sufficiency of staff (including both quantity and competency of staff) is the facility's ability to provide needed care for residents as determined by resident assessments and individual care plans. A staffing deficiency must be supported by examples of care deficits caused by insufficient quantity or competency of staff. The surveyor's investigation will include whether inadequate quantity or competency of staff prevented residents from reaching the highest practicable level of well-being.
A deficiency of insufficient staffing is determined through observations, interviews, and/or record reviews. Information gathered through these sources will help the surveyor in determining non-compliance. Concerns such as expressions or indications of distress by residents or family members, residents living with mental, psychosocial, and/or substance use disorders who lack care plan interventions to address their individual needs, lack of resident engagement, and the incidence of elopement and resident altercations, can also offer insight into the sufficiency and competency of staff and the adequacy of training provided to them to care for residents with behavioral health needs.

"Determination of Staff Competencies
As required under §483.70(e) (F838), the facility's assessment must include an evaluation of staff competencies that are necessary to provide the level and types of care needed for the resident population. The facility must have a process for evaluating these competencies.
If sufficient and/or competent staffing concerns are present during the surveyor's investigation or while completing the Sufficient and Competent Staffing Facility Task refer to the Behavioral and Emotional Status (CMS-20067) Critical Element Pathway.

"Non-pharmacological Interventions
Examples of individualized, non-pharmacological interventions to help meet behavioral health needs may include, but are not limited to:

- Ensuring adequate hydration and nutrition (e.g., enhancing taste and presentation of food, addressing food preferences to improve appetite and reduce the need for medications intended to stimulate appetite); exercise; and pain relief;

- Individualizing sleep and dining routines, as well as schedules to use the bathroom, to reduce the occurrence of incontinence, taking into consideration the potential need for increased dietary fiber to prevent or reduce constipation, and avoiding, where clinically inappropriate, the use of medications that may have significant adverse consequences (e.g., laxatives and stool softeners);

- Adjusting the environment to be more individually preferred and homelike (e.g., using soft lighting to avoid glare, providing areas that stimulate interest or allow safe, unobstructed walking, eliminating loud noises thereby reducing unnecessary auditory environment stimulation);

- Assigning staff to optimize familiarity and consistency with the resident and their needs (e.g., consistent caregiver assignment);"

§483.40(a)(2) Behavioral Health Services

Examples of Non-pharmacological Interventions, *continued*

- "Supporting the resident through meaningful activities that match his/her individual abilities (e.g., simplifying or segmenting tasks for a resident who has trouble following complex directions), interests, and needs, based upon the comprehensive assessment, and that may be reminiscent of lifelong work or activity patterns (e.g., providing an early morning activity for a farmer used to waking up early);

- Utilizing techniques such as music, art, massage, aromatherapy, reminiscing; and

- Assisting residents with substance use disorders to access counseling programs (e.g., substance use disorder services) to the fullest degree possible."

NOTE: The State Operations Manual outlines the following key elements of noncompliance:

"To cite deficient practice, the surveyor's investigation will generally show that the facility failed to:

- Rule out underlying causes for the resident's behavioral health care needs through assessment, diagnosis, and treatment by qualified professionals, such as physicians, including psychiatrists or neurologists;

- Identify competencies and skills sets needed in the facility to work effectively with residents with mental disorders and other behavioral health needs;

- Provide sufficient staff who have the knowledge, training, competencies, and skills sets to address behavioral health care needs;

- Demonstrate reasonable attempts to secure professional behavioral health services, when needed;

- Utilize and implement non-pharmacological approaches to care, based upon the comprehensive assessment, and in accordance with the resident's abilities, customary daily routine, life-long patterns, interests, preferences, and choices;

- Monitor and provide ongoing assessment of the resident's behavioral health needs, as to whether the interventions are improving or stabilizing the resident's status or causing adverse consequences;

- Attempt alternate approaches to care for the resident's assessed behavioral health needs, if necessary; or

- Accurately document all relevant actions in the resident's medical record."

Regulatory Requirement

§483.40 Behavioral Health Services

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 well-being, 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.

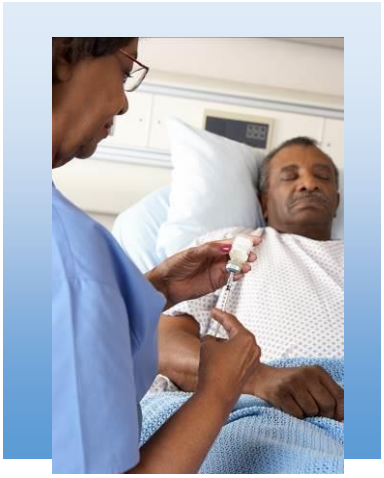
(b) Based on the comprehensive assessment of a resident, the facility must ensure that –

(1) *Implemented in Phase 1*

(2) *Implemented in Phase 1*

(3) 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 well-being.

(Page 669 of final rule)



State Operations Manual

Intent (§483.40(b)(3): Providing care for residents living with dementia is an integral part of the person-centered environment, which is necessary to support a high quality of life with meaningful relationships and engagement. Fundamental principles of care for persons living with dementia involve an interdisciplinary approach that focuses holistically on the needs of the resident living with dementia, as well as the needs of the other residents in the nursing home. Additionally, it includes qualified staff that demonstrate the competencies and skills to support residents through the implementation of individualized approaches to care (including direct care and activities) that are directed toward understanding, preventing, relieving, and/or accommodating a resident's distress or loss of abilities.

Guidance (§483.40(b)(3): It is expected that a facility's approach to care for a resident living with dementia follows a systematic care process. In order to ensure that residents' individualized dementia care needs are met, the facility is expected to assess, develop, and implement care plans through an interdisciplinary team (IDT) approach that includes the resident, their family, and/or resident representative, to the extent possible.

The facility must provide dementia treatment and services which may include, but are not limited to the following:

- Ensuring adequate medical care, diagnosis, and supports based on diagnosis;
- Ensuring that the necessary care and services are person-centered and reflect the resident's goals, while maximizing the resident's dignity, autonomy, privacy, socialization, independence, choice, and safety; and
- Utilizing individualized, non-pharmacological approaches to care (e.g., purposeful and meaningful activities). Meaningful activities are those that address the resident's customary routines, interests, preferences, and choices to enhance the resident's wellbeing.

Procedures: Review, as needed, all appropriate resident assessments, associated care planning and care plan revisions, along with physician's orders to identify initial concerns and guide the investigation. Review the Minimum Data Set (MDS) and other supporting documentation to help determine if the facility is in compliance. Observe for evidence that dementia care needs are met and related services are provided. Staff are expected to assess and provide appropriate care for residents with dementia.

§483.40(b)(3) Behavioral Health Services, Dementia

Suggested Checklist for Implementation

- Develop and implement policies and procedures to assess, develop, and implement care plans through an interdisciplinary team (IDT) approach that includes the resident, their family, and/or resident representative

NOTE: The State Operations Manual outlines the following key elements of noncompliance:

"To cite deficient practice, the surveyor's investigation will generally show that the facility failed to:

- Assess resident treatment and service needs through the Resident Assessment Instrument (RAI) process;
- Identify, address, and/or obtain necessary services for the dementia care needs of residents;
- Develop and implement person-centered care plans that include and support the dementia care needs, identified in the comprehensive assessment;
- Develop individualized interventions related to the resident's symptomology and rate of progression (e.g., providing verbal, behavioral, or environmental prompts to assist a resident with dementia in the completion of specific tasks);
- Review and revise care plans that have not been effective and/or when the resident has a change in condition;
- Modify the environment to accommodate resident care needs; or
- Achieve expected improvements or maintain the expected stable rate of decline "

Regulatory Requirement

§483.40 Behavioral Health Services

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 well-being, 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.

(c) 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 –

(1) Provide the required services, including specialized rehabilitation services as required in § 483.65; or

(2) Obtain the required services from an outside resource (in accordance with § 483.70(g) of this part) from a Medicare and/or Medicaid provider of specialized rehabilitative services.

(Page 669 of final rule)

State Operations Manual

Intent (§483.40(c)): The intent of this regulation is to ensure that every resident receives specialized rehabilitative services as determined by their comprehensive plan of care to assist them to attain, maintain or restore their highest practicable level of physical, mental, functional and psycho-social wellbeing.

The intent is also to ensure that residents with a Mental Disorder (MD), Intellectual Disability (ID) or a related condition receive services as determined by their Preadmission Screening and Resident Review (PASARR).

Guidance (§483.40(c)) "Specialized Rehabilitative Services" includes but is not limited to physical therapy, speech-language pathology, occupational therapy, or respiratory therapy and are provided or arranged for by the nursing home. They are "specialized" in that they are provided based on each resident's individual assessed rehabilitative needs based on their comprehensive plan of care and can only be performed by or under the supervision of qualified personnel.

These services must be provided by the facility or an outside resource and delivered by qualified personnel as defined below in the guidance under tag F826 and who are acting within the State's scope of practice laws and regulations.

The facility must provide or arrange for the provision of specialized rehabilitative services to all residents that require these services for the appropriate length of time as assessed in their comprehensive plan of care. These services are considered a facility service provided to all residents who need them based on their comprehensive plan of care and are included within the scope of facility services.

Procedures: For each of the required services, surveyors should determine through information obtained by observations, interviews and record reviews, that the facility not only delivered these services, but that the services and interventions:

(1) Were monitored for their effectiveness; and
(2) Assisted residents to attain or maintain their highest practicable level of physical, mental, functional and psycho-social well-being or to prevent or slow a decline in condition.

NOTE: Concerns related to the provision of rehabilitative services are assessed and any related deficiencies are cited under §483.65, Specialized Rehabilitation Services. Concerns related to the obtainment of outside resources are assessed and any related deficiencies are cited under §483.70, Administration.

§483.40(c) Behavioral Health Services, Rehabilitation Services

Suggested Checklist for Implementation

- Develop and implement policies and procedures that outline how the provision of specialized rehabilitative services is provided to all residents that require these services for the appropriate length of time as assessed in their comprehensive plan of care

NOTE: The State Operations Manual outlines the following key elements of noncompliance:

"To cite deficient practice, the surveyor's investigation will generally show that the facility failed to:

- Provide specialized rehabilitative services based on a resident's comprehensive plan of care;

  Or

- Obtain specialized rehabilitative services from an outside resource that is a provider of specialized rehabilitation services that is NOT excluded from participating in any federal or state health care programs pursuant to section 1128 and 1156 of the Social Security Act."

Regulatory Requirement

§483.45 Pharmacy Services

The facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in § 483.70(g). The facility may permit unlicensed personnel to administer drugs if State law permits, but only under the general supervision of a licensed nurse.

(c)*Drug regimen review.*

(1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.

(2) This review must include a review of the resident's medical chart.

(Page 672 of final rule)

State Operations Manual

Intent: The intent of this requirement is that the facility maintains the resident's highest practicable level of physical, mental and psychosocial well-being and prevents or minimizes adverse consequences related to medication therapy to the extent possible, by providing oversight by a licensed pharmacist, attending physician, medical director, and the director of nursing (DON).

Guidance: The pharmacist must review each resident's medication regimen at least once a month in order to identify irregularities and to identify clinically significant risks and/or actual or potential adverse consequences which may result from or be associated with medications. It may be necessary for the pharmacist to conduct the medication regiment review (MRR) more frequently, for example weekly, depending on the resident's condition and the risks for adverse consequences related to current medications. Regulations prohibit the pharmacist from delegating the medication regimen reviews to other staff. The requirement for the medication regiment review applies to all residents (whether short or long-stay) without exceptions.

The pharmacist performing the monthly medication regiment review must also review the resident's medical record to appropriately monitor the medication regimen and ensure that the medications each resident receives are clinically indicated.

Facilities must develop policies and procedures to address the medication regiment review. The policies and procedures must specifically address:

- The appropriate time frames for the different steps in the medication regiment review process; and
- The steps a pharmacist must follow when he or she identifies an irregularity that requires immediate action to protect the resident and prevent the occurrence of an adverse drug event.

Medication regiment review policies and procedures should also address, but not be limited to:

- Medication regiment reviews for residents who are anticipated to stay less than 30 days;
- Medication regiment reviews for residents who experience an acute change of condition and for whom an immediate medication regiment review is requested after appropriate staff have notified the resident's physician, the medical director, and the director of nursing about the acute change.

Procedures: Surveyors will use the Unnecessary Medications, Psychotropic Medications, and Medication Regimen Review Critical Element Pathway, as appropriate, along with the interpretive guidelines when determining if the facility meets the requirements for, or investigating concerns related to Medication Regimen Review.

§483.45(c) Pharmacy Services, Drug Regimen Review

Suggested Checklist for Implementation

- Develop and implement policies and procedures that specifically outlines the medication regiment review process to ensure that residents—no matter their length of stay—receives the highest quality of care for the resident's medication therapy

NOTE: The State Operations Manual outlines the following key elements of noncompliance:

"To cite deficient practice, the surveyor's investigation will generally show that:

- The medication regiment review was not conducted by a licensed pharmacist; or
- The pharmacist failed to conduct a complete medication regiment review, at least monthly (or more frequently, as indicated by the resident's condition) for every resident of the facility; or
- The pharmacist's findings in the medication regiment review did not show evidence that the pharmacist also reviewed the resident's chart, for example, the pharmacist did not reference the resident response to a particular medication that was cited as an irregularity.; or
- The pharmacist failed to identify or report the absence of or inadequate indications for use of a medication, or a medication or medication combination with significant potential for adverse consequences or medication interactions; or
- The pharmacist failed to identify and/or report medications prescribed or administered in excessive dose (including but not limited to duplicate therapy); or
- The pharmacist failed to identify and/or report medications prescribed or administered for excessive duration; or
- The pharmacist failed to identify and/or report medications prescribed or administered without adequate monitoring; or
- The pharmacist failed to identify or report medications in a resident's regimen that could (as of the review date) be causing or associated with new, worsening, or progressive signs and symptoms; or
- The pharmacist failed to identify and report the absence of any explanation as to why or how the benefit of a medication(s) with potential for clinically significant adverse consequences outweighs the risk; or
- The attending physician failed to document that he or she reviewed the pharmacist's identified irregularities and/or failed to document the action taken or not taken to address the irregularities; or
- The facility failed to develop, maintain, and implement policies and procedures which address the time frames for the steps in the medication regiment review process; or
- The facility failed to develop and implement policies and procedures which address steps the pharmacist must take when he or she identifies an irregularity that requires urgent action to protect the resident."

Regulatory Requirement

§483.45 Pharmacy Services

The facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in § 483.70(g). The facility may permit unlicensed personnel to administer drugs if State law permits, but only under the general supervision of a licensed nurse.

(e)*Psychotropic drugs.*

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

(1) 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;

(2) Residents who use psychotropic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs;

(3) 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

(4) PRN orders for psychotropic drugs are limited to 14 days. Except as provided in§ 483.45(e)(5), if the attending physician or prescribing practitioner believes that it is appropriate for the PRN order to be extended beyond 14 days, he or she should document their rationale in the resident's medical record and indicate the duration for the PRN order.

(5) 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.

(Page 672 of final rule)

State Operations Manual

Intent: The intent of this requirement is that:

- Each resident's entire drug/medication regimen is managed and monitored to promote or maintain the resident's highest practicable mental, physical, and psychosocial wellbeing;
- The facility implements gradual dose reductions(GDR) and non-pharmacological interventions, unless contraindicated, prior to initiating or instead of continuing psychotropic medication; and
- PRN orders for psychotropic medications are only used when the medication is necessary and PRN use is limited.

Guidance: As clarified in the section on Indication for Use, residents must not receive any medications which are not clinically indicated to treat a specific condition. The medical record must show documentation of the diagnosed condition for which a medication is prescribed. This requirement is especially important when prescribing psychotropic medications which, as defined in this guidance, include, but are not limited to, the categories of anti-psychotic, anti-depressant, anti-anxiety, and hypnotic medications. All medications included in the psychotropic medication definition may affect brain activities associated with mental processes and behavior. Use of psychotropic medications, other than antipsychotics, should not increase when efforts to decrease antipsychotic medications are being implemented, unless the other types of psychotropic medications are clinically indicated. Other medications which may affect brain activity such as central nervous system agents, mood stabilizers, anticonvulsants, muscle relaxants, anticholinergic medications, antihistamines, NMDA receptor modulators, and over the counter natural or herbal products must also only be given with a documented clinical indication consistent with accepted clinical standards of practice. Residents who take these medications must be monitored for any adverse consequences, specifically increased confusion or over-sedation. The regulations and guidance concerning psychotropic medications are not intended to supplant the judgment of a physician or prescribing practitioner in consultation with facility staff, the resident and his/her representatives and in accordance with appropriate standards of practice. Rather, the regulations and guidance are intended to ensure psychotropic medications are used only when the medication(s) is appropriate to treat a resident's specific, diagnosed, and documented condition and the medication(s) is beneficial to the resident, as demonstrated by monitoring and documentation of the resident's response to the medication(s).

Procedures: Surveyors are expected to review factors related to the implementation, use, monitoring, and documentation of medications.

§483.45(e) Pharmacy Services, Psychotropic Drugs

Suggested Checklist for Implementation

- Develop and implement policies and procedures that ensure the attending physician or prescribing practitioner documents the diagnosed specific condition and indication for the PRN medication in the medical record

The required evaluation of a resident before writing a new PRN order for an antipsychotic entails the attending physician or prescribing practitioner directly examining the resident and assessing the resident's current condition and progress to determine if the PRN antipsychotic medication is still needed. As part of the evaluation, the attending physician or prescribing practitioner should, at a minimum, determine and document the following in the resident's medical record:

- Is the antipsychotic medication still needed on a PRN basis?
- What is the benefit of the medication to the resident?
- Have the resident's expressions or indications of distress improved as a result of the PRN medication?

Report of the resident's condition from facility staff to the attending physician or prescribing practitioner does not constitute an evaluation.

NOTE: The State Operations Manual outlines the following key elements of noncompliance related to psychotropic medications:

- "Failure to present to the attending physician or prescribing practitioner the need to attempt GDR in the absence of identified and documented clinical contraindications; or
- Use of psychotropic medication(s) without documentation of the need for the medication(s) to treat a specific diagnosed condition; or
- PRN psychotropic medication ordered for longer than 14 days, without a documented rationale for continued use; or
- Failure to implement person-centered, non-pharmacological approaches in the attempt to reduce or discontinue a psychotropic medication; or
- Administering a new PRN antipsychotic medication for which the resident had a previous PRN order (for 14 days) but the medical record does not show that the attending physician or prescribing practitioner evaluated the resident for the appropriateness of the new order for the medication. "

Regulatory Requirement

§483.55 Dental Services

The facility must assist residents in obtaining routine and 24-hour emergency dental care.

(a)*Skilled nursing facilities.* A facility (1) Must provide or obtain from an outside resource, in accordance with § 483.70(g), routine and emergency dental services to meet the needs of each resident;

(a3) 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;

- (a5) Must promptly, within 3 days, refer residents with lost or damaged dentures for dental services. If a 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.

(b)*Nursing facilities.* The facility (1) Must provide or obtain from an outside resource, in accordance with § 483.70(g), the following dental services to meet the needs of each resident:

(i) Routine dental services (to the extent covered under the State plan); and

(ii) Emergency dental services;

(b3) Must promptly, within 3 days, refer residents with lost or damaged dentures for dental services. If a 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;

(b4) 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; and

(Page 677 of final rule)

State Operations Manual

Intent: To ensure that residents obtain needed dental services, including routine dental services; to ensure the facility provides the assistance needed or requested to obtain these services; to ensure the resident is not inappropriately charged for these services; and if a referral does not occur within three business days, documentation of the facility's to ensure the resident could still eat and drink adequately while awaiting dental services and the extenuating circumstances that led to the delay.

Guidance: A dentist must be available for each resident. The dentist can be directly employed by the facility or the facility can have a written contractual agreement with a dentist. The facility may also choose to have a written agreement for dentist services from a dental clinic, dental school or a dental hygienist all of whom are working within Federal and State laws and under the direct supervision of a dentist.

For Medicare and private pay residents, facilities are responsible for having the services available, but may bill an additional charge for the services.

For Medicaid residents, the facility must provide all emergency dental services and those routine dental services to the extent covered under the Medicaid state plan. The facility must inform the resident of the deduction for the incurred medical expense available under the Medicaid state plan and must assist the resident in applying for the deduction.

If any resident is unable to pay for dental services, the facility should attempt to find alternative funding sources or delivery systems so that the resident may receive the services needed to meet their dental needs and maintain his/her highest practicable level of well-being. This can include finding other providers of dental services, such as a dental school or the provision of dental hygiene services on site at a facility.

The facility must assist residents in making arrangements for transportation to their dental appointments when necessary or requested. The facility should attempt to minimize the financial burden on the resident by finding the lowest cost or no cost transportation option to dental health care appointments.

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 facility staff 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.

Procedures: Review the resident's records for identification of the resident's dental needs and the resident's responsiveness to dental services.

§483.55 Dental Services

Suggested Checklist for Implementation

- Develop and implement a policy that identifies how dental services are provided to residents

- Develop and implement a policy identifying those instances when the loss or damage of partial or full dentures is the facility's responsibility. The policy should include the process for replacing the dentures.

NOTE: The State Operations Manual outlines the following key elements of noncompliance:

"To cite deficient practice, the surveyor's investigation will generally show that the facility:

For residents receiving Medicare and private pay residents:

- Failed to provide or obtain from an outside resource, in accordance with §483.70(g), routine and emergency dental services to meet the needs of each resident; or
- Did not assist the resident as necessary or requested to make appointments for dental services and/or arrange for transportation to and from the dental service location; or
- Did not promptly, within three business days, refer a resident with lost or damaged partial or full dentures and/or documented the extenuating circumstances that led to a delay; or
- Did not document what the facility did to ensure a resident with missing or damaged dentures could still eat and drink adequately while awaiting dental services; or
- Charged a resident for the loss or damage of partial or full dentures determined to by facility policy to be the facility's responsibility.

For residents receiving Medicaid:

- Failed to provide or obtain from an outside resource, in accordance with §483.70(g), routine (to the extent covered by the State plan) and emergency dental services for each resident; or
- Did not assist the resident as necessary or requested to make appointments for dental services or arrange for transportation to and from dental services locations; or
- Did not promptly, within three days, refer a resident with lost or damaged partial or full dentures and/or documented the extenuating circumstances that led to a delay; or
- Did not document what the facility did to ensure a resident with missing or damaged partial or full dentures could still eat and drink adequately while awaiting dental services; or
- Charged a resident for the loss or damage of partial or full dentures determined to by facility policy to be the facility's responsibility; or
- Failed to assist a resident(s) who are eligible to participate and/or wish to participate to apply for reimbursement of dental services as an incurred medical expense under the State plan; or
- Charged a Medicaid resident an added fee for routine dental services covered by the State plan or for emergency dental services."

Regulatory Requirement

§483.60 Food and Nutrition Services

(a)*Staffing.* The facility must employ sufficient staff with the appropriate competencies and skills 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) (*referenced below*).

(Page 678 of final rule)

Reference to § 483.70(e) ***Facility assessment.***

The facility must conduct and document a facility-wide assessment to determine what resources are necessary to care for its residents competently during both day-to-day operations and emergencies. The facility must review and update that assessment, as necessary, and at least annually. The facility must also review and update this assessment whenever there is, or the facility plans for, any change that would require a substantial modification to any part of this assessment. The facility assessment must address or include:

(1) The facility's resident population, including, but not limited to,

(i) Both the number of residents and the facility's resident capacity;
(ii) The care required by the resident population considering the types of diseases, conditions, physical and cognitive disabilities, overall acuity, and other pertinent facts that are present within that population;
(iii) The staff competencies that are necessary to provide the level and types of care needed for the resident population;
(iv) The physical environment, equipment, services, and other physical plant considerations that are necessary to care for this population; and
(v) Any ethnic, cultural, or religious factors that may potentially affect the care provided by the facility, including, but not limited to, activities and food and nutrition services.

(2) The facility's resources, including but not limited to,

(i) All buildings and/or other physical structures and vehicles;
(ii) Equipment (medical and non-medical);
(iii) Services provided, such as physical therapy, pharmacy, and specific rehabilitation therapies;
(iv) All personnel, including managers, staff (both employees and those who provide services under contract), and volunteers, as well as their education and/or training and any competencies related to resident care;
(v) Contracts, memorandums of understanding, or other agreements with third parties to provide services or equipment to the facility during both normal operations and emergencies; and
(vi) Health information technology resources, such as systems for electronically managing patient records and electronically sharing information with other organizations.

(3) A facility-based and community-based risk assessment, utilizing an all-hazards approach.

State Operations Manual

Intent: To ensure there is sufficient and qualified staff with the appropriate competencies and skill sets to carry out food and nutrition services.

Guidance: Cite F801 for concerns regarding the qualifications of the dietitian, other clinical nutrition professionals, or the food services director. For concerns regarding support personnel refer to F802, Sufficient Dietary Support Personnel.

In addition, cite F801 if staff, specifically the qualified dietitian or other clinically qualified nutrition professional did not carry out the functions of the food and nutrition services. While these functions may be defined by facility management, at a minimum they should include, but are not limited to:

- Assessing the nutritional needs of residents;
- Developing and evaluating regular and therapeutic diets, including texture of foods and liquids, to meet the specialized needs of residents;
- Developing and implementing person centered education programs involving food and nutrition services for all facility staff;
- Overseeing the budget and purchasing of food and supplies, and food preparation, service and storage; and,
- Participating in the quality assurance and performance improvement (QAPI), as described in §483.75, when food and nutrition services are involved.

The qualified dietitian or other clinically qualified nutrition professional can decide to oversee and delegate some of the activities listed above to the director of food and nutrition services.

Procedures: If the survey team finds concerns regarding a resident's food and/or nutritional status determine:

- If the practices of the dietitian, nutrition professional, and/or food services director contributed to the identified concerns. If so how?
- How facility management ensures that staff have the appropriate competencies and skills sets to carry out the functions of the food and nutrition service?
- If a food services director is employed by the facility, do they have frequent consultations with the dietitian or other nutrition professionals or consultants employed by the facility?

§483.60 Food and Nutrition Services

Suggested Checklist for Implementation

- Develop and implement policies and procedures to assess the nutritional needs of the resident population to determine the appropriate number and competencies of staff needed

- Develop and implement policies and procedures to identify who represents food and nutrition services at interdisciplinary team meetings

Regulatory Requirement

§ 483.70(e) Facility assessment

The facility must conduct and document a facility-wide assessment to determine what resources are necessary to care for its residents competently during both day-to-day operations and emergencies. The facility must review and update that assessment, as necessary, and at least annually. The facility must also review and update this assessment whenever there is, or the facility plans for, any change that would require a substantial modification to any part of this assessment. The facility assessment must address or include:

(1) The facility's resident population, including, but not limited to,

(i) Both the number of residents and the facility's resident capacity;
(ii) The care required by the resident population considering the types of diseases, conditions, physical and cognitive disabilities, overall acuity, and other pertinent facts that are present within that population;
(iii) The staff competencies that are necessary to provide the level and types of care needed for the resident population;
(iv) The physical environment, equipment, services, and other physical plant considerations that are necessary to care for this population; and
(v) Any ethnic, cultural, or religious factors that may potentially affect the care provided by the facility, including, but not limited to, activities and food and nutrition services.

(2) The facility's resources, including but not limited to,

(i) All buildings and/or other physical structures and vehicles;
(ii) Equipment (medical and non-medical);
(iii) Services provided, such as physical therapy, pharmacy, and specific rehabilitation therapies;
(iv) All personnel, including managers, staff (both employees and those who provide services under contract), and volunteers, as well as their education and/or training and any competencies related to resident care;
(v) Contracts, memorandums of understanding, or other agreements with third parties to provide services or equipment to the facility during both normal operations and emergencies; and
(vi) Health information technology resources, such as systems for electronically managing patient records and electronically sharing information with other organizations.

(3)A facility-based and community-based risk assessment, utilizing an all-hazards approach.

(Page 686 of final rule)

State Operations Manual

Intent: The intent of the facility assessment is for the facility to evaluate its resident population and identify the resources needed to provide the necessary care and services the residents require.

Guidance: While a facility may include input from its corporate organization, the facility assessment must be conducted at the facility level.

It should serve as a record for staff and management to understand the reasoning for decisions made regarding staffing and other resources, and may include the operating budget necessary to carry out facility functions.

To ensure the required thoroughness, individuals involved in the facility assessment should, at a minimum, include the administrator, a representative of the governing body, the medical director, and the director of nursing. The environmental operations manager, and other department heads (for example, the dietary manager, director of rehabilitation services, or other individuals including direct care staff should be involved as needed.

Although not required, facility staff are strongly encouraged to seek input from the resident/family council, residents, their representative(s), or families and incorporate that information as appropriate when formulating their assessment.

The facility must review and update this assessment annually or whenever there is, or the facility plans for, any change that would require a modification to any part of this assessment.

Procedures: If systemic care concerns are identified that are related to the facility's planning, review the facility assessment to determine if these concerns were considered as part of the facility's assessment process. Questions surveyors should consider include, but are not limited to, the following:

- How did the facility assess the resident population? Does this reflect the population observed?
- How did the facility determine the acuity of the resident population?
- How did the facility determine the staffing level?
- How did the facility determine what skills and competencies would be required by those providing care?
- Who was involved in conducting the facility assessment?
- How did the facility determine what equipment, supplies, and physical environment would be required to meet all resident needs?
- How did the facility develop its emergency plan?
- If a deficient practice is systemic and is observed at another tag, was this related to an incomplete facility assessment? How?

§ 483.70(e) Facility assessment

Suggested Checklist for Implementation

- Develop and implement policies and procedures to evaluate annually the needs of your facility's resident population. Include in the policies considerations of how to address changes in practice or services provided that would lead to the modification of the facility assessment.

- Develop and implement policies and procedures to identify the resources needed to provide the necessary care and services the residents require

NOTE: The State Operations Manual outlines the following key elements of noncompliance:

"To cite deficient practice, the surveyor's investigation will generally show that the facility failed to do any one of the following:

- Annually and as necessary, conduct, document, review and update a facility-wide assessment; or

- Address or include in the facility assessment the minimum requirements as described in sections (1)(i-v), (2)(i-vi), and (3) above."

Regulatory Requirement	State Operations Manual
§483.75 Quality Assurance and Performance Improvement **(a)** *Quality assurance and performance improvement (QAPI) program.* Each LTC facility, including a facility that is part of a multiunit chain, must develop, implement, and maintain an effective, comprehensive, data-driven QAPI program that focuses on indicators of the outcomes of care and quality of life. The facility must – **(2)** Present its QAPI plan to the State Survey Agency no later than 1 year after the promulgation of this regulation; (Page 691 of final rule)	**Intent:** These requirements are intended to ensure facilities develop a plan that describes the process for conducting QAPI/QAA activities, such as identifying and correcting quality deficiencies as well as opportunities for improvement, which will lead to improvement in the lives of nursing home residents, through continuous attention to quality of care, quality of life, and resident safety. **Guidance:** The facility is required to develop a QAPI plan and present its plan to federal and state surveyors at each annual recertification survey and upon request during any other survey, and to CMS upon request. The QAPI plan must describe in detail the scope of the QAA committee's responsibilities and activities, and the process addressing how the committee will conduct the activities necessary to identify and correct quality deficiencies. Each nursing home, including facilities which are a part of a multi-chain organization, should tailor its QAPI plan to reflect the specific units, programs, departments, and unique population it serves, as identified in its facility assessment. The QAPI plan must describe how the facility will ensure care and services delivered meet accepted standards of quality, identify problems and opportunities for improvement, and ensure progress toward correction or improvement is achieved and sustained. The QAPI plan must describe the process for identifying and correcting quality deficiencies. Key components of the process include: • Tracking and measure performance; • Establishing goals and thresholds for performance measurement; • Identifying and prioritizing quality deficiencies; • Systematically analyzing underlying causes of systemic quality deficiencies; • Developing and implementing corrective action or performance improvement activities; and • Monitoring or evaluating the effectiveness of corrective action/performance improvement activities, and revising as needed. **Procedures:** Use the Facility Task Pathway for Quality Assurance and Performance Improvement (QAPI) Plan and Quality Assessment and Assurance (QAA) Review, as appropriate, along with the above interpretive guidelines when determining if the facility meets the requirements for, or investigating concerns related to the QAPI plan. Prior to conducting the QAPI Plan/QAA review, the survey team should identify and validate systemic problems in the facility. This includes concerns identified from offsite preparation that represent repeat deficient practice, and concerns or issues identified throughout the survey.

Suggested Checklist for Implementation

- Develop and implement policies and procedures that describe how the facility will ensure care and services delivered meet accepted standards of quality, identify problems and opportunities for improvement, and ensure progress toward correction or improvement

Regulatory Requirement

§483.80 Infection Control

The facility must establish and maintain an infection prevention and control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of communicable diseases and infections.

(a)***Infection prevention and control program.***

The facility must establish an infection prevention and control program (IPCP) that must include, at a minimum, the following elements:

(1) 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 arrangement based upon the facility assessment conducted according to §483.70(e) and following accepted national standards;

(Page 695 of final rule)

State Operations Manual

Intent: The intent of this regulation is to ensure that the facility:

- Develops and implementsan ongoing infection prevention and control program (IPCP) to prevent, recognize, and control the onset and spread of infection to the extent possible and reviews and updates the IPCP annually and as necessary. This would include revision of the IPCP as national standards change;
- Establishes facility-wide systems for the prevention, identification, investigation and control of infections of residents, staff, and visitors. It must include an ongoing system of surveillance designed to identify possible communicable diseases or infections before they can spread to other persons in the facility and procedures for reporting possible incidents of communicable disease or infections
- Develops and implements written policies and procedures for infection control that, at a minimum:
    - ° Explain how standard precautions and when transmission-based precautions should be utilized, including but not limited to the type and duration of precautions for particular infections or organisms involved and that the precautions should be the least restrictive possible for the resident given the circumstances and the resident's ability to follow the precautions;
    - ° Prohibit staff with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease; and
    - ° Require staff follow hand hygiene practices consistent with accepted standards of practice.
    - Requires staff handle, store, process, and transport all linens and laundry in accordance with accepted national standards in order to produce hygienically clean laundry and prevent the spread of infection to the extent possible.

Guidance: The facility must establish and maintain an IPCP designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of communicable diseases and infections. This program must include, at a minimum, a system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, and visitors. The IPCP must follow national standards and guidelines.

Facilities are expected to tailor the emphasis of their IPCP for visitors to prevent transmission of infection to the resident from the visitor using reasonable precautions and national standards,

A facility must develop and implement a system for recording incidents identified under the facility's IPCP and the corrective actions taken by the facility based on the investigation of the incidents.

The facility's IPCP and its standards, policies and procedures must be reviewed at least annually to ensure effectiveness and that they are in accordance with current standards of practice for preventing and controlling infections; the IPCP must be updated as necessary. In addition, the facility population and characteristics may change over time, and the facility assessment may identify components of the IPCP that must be changed accordingly.

Procedures: Surveyors would use the Infection Control Facility Task to determine compliance with the infection control part of the survey. One surveyor should coordinate the review of the facility's overall infection prevention and control program **(**IPCP), however, each member of the survey team should assess for compliance throughout the entire survey when observing his/her assigned areas and tasks. The IPCP must be facility-wide and include all departments and contracted services. The surveyor should corroborate any concerns observed through interviews and record and/or document review.

Suggested Checklist for Implementation

Develop and implement an Infection Prevention and Control Program that provides:

- "A system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases that:
  - Covers all residents, staff, volunteers, visitors, and other individuals providing services under a contractual arrangement;
  - Is based on the individual facility assessment;
  - Follows accepted national standards;

- Written standards, policies and procedures that must include, but are not limited to:
  - A system of surveillance designed to identify possible communicable diseases or infections before they can spread to other persons in the facility;
  - When and to whome possible incidents of communicable disease or infections should be reported;
  - Standard and transmission-based precautions to be followed to prevent the spread of infections;
  - When and how isolation should be used for a resident; including but not limited to:
    - The type and duration of the isolation, depending upon the infectious agent or organism involved, and
    - A requirement that the isolation should be the least restrictive possible for the resident under the circumstances.
  - The circumstances under which the facility must prohibit employhees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease; and
  - The hand hygiene procedures to be followed by staff involved in direct resident contact.

- A system for recording incidents identified under the IPCP and corrective actions taken by the facility; and

- An antibiotic stewardship program."

NOTE: The State Operations Manual outlines the following key elements of noncompliance:

"To cite deficient practice, the surveyor's investigation will generally show that the facility failed to do any one or more of the following:

- Establish and maintain an IPCP designed to provide a safe, sanitary, and comfortable environment and to help prevent development and transmission of disease and infection;
- The IPCP must be reviewed at least annually and updated as necessary;
- Implement 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 arrangement, based on the facility assessment (see §483.70(e)) and follows accepted national standards;
- Develop and implement written IPCP standards, policies, and procedures that are current and based on national standards. These must include:
  - When and to whom possible incidents of communicable diseases should be reported;
  - Developing and implementing a system of surveillance to identify infections or communicable diseases;
  - How to use standard precautions (to include appropriate hand hygiene) and how and when to use transmission-based precautions (i.e., "isolation precautions"); and/or
  - Prohibiting staff with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit disease.
- Assure that staff handle, store, process and transport laundry to prevent the spread of infection; and/or
- Maintain a system for recording identified incidents, and taking appropriate corrective actions."

Regulatory Requirement	State Operations Manual
§483.80 Infection Control The facility must establish and maintain an infection prevention and control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of communicable diseases and infections. (a)***Infection prevention and control program.*** The facility must establish an infection prevention and control program (IPCP) that must include, at a minimum, the following elements: **(3)** An antibiotic stewardship program that includes antibiotic use protocols and a system to monitor antibiotic use. (Page 695 of final rule)	**Intent:** The intent of this regulation is to ensure that the facility: • Develops and implements protocols to optimize the treatment of infections by ensuring that residents who require an antibiotic, are prescribed the appropriate antibiotic; • Reduces the risk of adverse events, including the development of antibiotic-resistant organisms, from unnecessary or inappropriate antibiotic use; and • Develops, promotes, and implements a facility-wide system to monitor the use of antibiotics. **Guidance:** As part of their IPCP programs, facilities must develop an antibiotic stewardship program that promotes the appropriate use of antibiotics and includes a system of monitoring to improve resident outcomes and reduce antibiotic resistance. This means that the antibiotic is prescribed for the correct indication, dose, and duration to appropriately treat the resident while also attempting to reduce the development of antibiotic-resistant organisms. The facility must develop an antibiotic stewardship program which includes the development of protocols and a system to monitor antibiotic use. This development should include leadership support and accountability via the participation of the medical director, consulting pharmacist, nursing and administrative leadership, and individual with designated responsibility for the infection control program if different **Procedures:** Surveyors should use the Infection Control Facility Task to assess for compliance with the antibiotic stewardship program during the standard survey.

Suggested Checklist for Implementation

- "Develop and implement an infection prevention and control program that includes the following core elements for antibiotic stewardship in nursing homes:
  - Facility leadership commitment to safe and appropriate antibiotic use;
  - Appropriate facility staff accountable for promoting and overseeing antibiotic stewardship;
  - Accessing pharmacists and others with experience or training in antibiotic stewardship;
  - Implement policy(ies) or practice to improve antibiotic use;
  - Track measures of antibiotic use in the facility (i.e., one process and one outcome measure);
  - Regular reporting on antibiotic use and resistance to relevant staff such as prescribing clinicians and nursing staff; and
  - Educate staff and residents about antibiotic stewardship."

NOTE: The State Operations Manual outlines the following key elements of noncompliance:

"To cite deficient practice, the surveyor's investigation will generally show that the facility failed to do any one or more of the following:

- Develop and implement antibiotic use protocols to address the treatment of infections by ensuring that residents who require antibiotics are prescribed the appropriate antibiotics;
- Develop and implement antibiotic use protocols that address unnecessary or inappropriate antibiotic use thereby reducing the risk of adverse events, including the development of antibiotic-resistant organisms; and/or
- Develop, promote and implement a facility-wide system to monitor the use of antibiotics."

Regulatory Requirement	State Operations Manual
§483.90 Physical Environment The facility must be designed, constructed, equipped, and maintained to protect the health and safety of residents, personnel and the public. (i) **Other environmental conditions.** The facility must provide a safe, functional, sanitary, and comfortable environment for the residents, staff and the public. The facility must - **(5)** 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. (Page 703 of final rule)	**Guidance:** The use of oxygen in smoking areas and while smoking is forbidden. **Procedures:** As part of the overall review of the facility, look for signs of smoking by residents, staff, visitors, guests, and non-staff. Look for smoking areas both inside and outside of the facility. Review policies to determine if they have been developed and are being implemented in accordance with Federal, State and local laws and regulations in regards to smoking, smoking areas and smoking safety for both smoking and non-smoking residents.

Suggested Checklist for Implementation

- "Develop and implement policies and procedures that take into account the federal, state, and local laws regarding smoking. These should include, but not be limited to:
  - Outlining the facility's position on allowing residents and/or visitors to smoke while on the premises.
  - Outlining the areas in the facility where smoking is allowed and that would not adversely affect non-smoking residents.
  - Outlining the facility's position on the provision of smoking cessation services for residents.
  - Identifying how residents may access the smoking cessation services provided by the facility."

ADDENDUM A

Required Policies and Procedures for Reporting Suspicions of a Crime

The following table describes the different reporting requirements that are addressed under 42 CFR 483.12:

	F608 42 CFR 483.12(b)(5) and Section 1150B of the Act	F609 42 CFR 483.12(c)
What?	Any reasonable suspicion of a crime against a resident.	1) All alleged violations of abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property. 2) The results of all investigations of alleged violations.
Who is required to report?	Any covered individual, including the owner, operator, employee, manager, agent or contractor of the facility.	The facility.
To whom?	State Survey Agency (SA) and one or more law enforcement entities for the political subdivision in which the facility is located (i.e., police, sheriffs, detectives, public safety officers; corrections personnel; prosecutors; medical examiners; investigators; and coroners).	The facility administrator and to other officials in accordance with State law, including to the SA and the adult protective services where state law provides for jurisdiction in long-term care facilities.
When?	Serious bodily injury-Immediately but not later than 2 hours* after forming the suspicion No serious bodily injury-not later than 24* hours.	All alleged violations-Immediately but not later than: 1) 2 hours—if the alleged violation involves abuse or results in serious bodily injury. 2) 24 hours—if the alleged violation does not involve abuse and does not result in serious bodily injury.

** Reporting requirements under this regulation are based on real (clock) time, not business hours.*