Detailed Overview of New and Updated Regulatory Guidance

The Centers for Medicare & Medicaid Services (CMS) recently issued QSO-22-19-NH, which outlines revisions to the following:

- Surveyor Guidance for some Phase 2 & and all Phase 3 Requirements of Participation (RoP);
- Arbitration Agreement Requirements;
- Investigating Complaints & Facility Reported Incidents; and
- Psychosocial Outcome Severity Guide.

CMS also issued an advance copy of the State Operations Manual to clarify specific regulatory requirements and provide information on how compliance will be assessed. **Surveyors will begin using this guidance to identify noncompliance on October 24, 2022.**

Below are the regulations that are impacted. AHCA has provided a summary of significant changes for each area to assist members with review and identification of potential action for facilities to consider related to the guidance.

§483.10 Resident Rights

- Right to Receive Visitors
- Respect & Dignity
- Self-Determination
- Medicare, Medicaid Coverage, Liability Notice

§483.12 Freedom from Abuse, Neglect, and Exploitation

- Coordination with QAPI Program

§483.15 Admission, Transfer and Discharge

§483.21 Comprehensive Person-Centered Care Plans

§483.25 Quality of Care

- Trauma Informed Care

§483.35 Nursing Services

- Sufficient Staff

§483.45 Pharmacy Services

- Controlled Medications

- Unnecessary Drugs and Psychotropic Drugs

§483.60 Food and Nutrition Services

§483.70 Administration
- Binding Arbitration Agreements
- Mandatory Submission of Staffing (PBJ)

§483.75 Quality Assurance and Performance Improvement
- QAA Committee

§483.80 Infection Control
- Infection Prevention & Control Program & Antibiotic Stewardship Program
- Infection Preventionist Qualifications/Role

§483.85 Compliance and Ethics

§483.90 Physical Environment
- Resident Rooms/Bedrooms
- Resident Call System

§483.95 Training Requirements
- Communications Training
- Resident's Rights and Facility Responsibilities
- QAPI Training
- Infection Control Training
- Compliance and Ethics Training
- Behavioral Health Training

In addition, a summary of changes to the following documents is provided with more details in the links.

Potential Inaccurate Diagnosis and/or Assessment
- Addresses situations where practitioners or facilities may have inaccurately diagnosed/coded a resident with schizophrenia in the resident assessment instrument.

Mental Health/Substance Use Disorder (SUD)
- Addresses rights and behavioral health services for individuals with mental health needs and SUDs.

Psychosocial Outcome Severity Guide
- Clarifies the application of the "reasonable person concept" and severity levels for deficiencies.

State Operations Manual Chapter 5

- Clarifies timeliness of state investigations and communication to complainants to improve consistency across states.

Please contact Crystal Bowens or Holly Harmon with any questions at regulatory@ahca.org.

§483.10 Resident Rights-Right to Receive Visitors

Specific Regulatory Area:

- F563-483.10(f)(4)(ii)-(v) The resident has a right to receive visitors of his or her choosing at the time of his or her choosing, subject to the resident's right to deny visitation when applicable, and in a manner that does not impose on the rights of another resident.

Overview of Guidance: §483.10(f)(4)(ii)-(v)

CMS revised guidance related to visitation restrictions by importing parts of the recent COVID-19 guidance to prevent community-associated infection or the spread of communicable disease in response to the current Public Health Emergency (PHE), such as deferring visitation for visitors with signs and symptoms of transmissible infections according to CDC guidelines and/or local health department recommendations. The revised guidance stresses the importance of adhering to the core principles of infection prevention to reduce the risk of infectious disease transmission during visits, as well as offering considerations for facilities to modify visitation practices during a communicable disease outbreak.

The guidance also outlines an additional reasonable clinical and safety restriction that may be necessary through facility policy, procedure, or practice to protect the health and security of all residents and staff, such as denying access or providing supervised visitation to individuals who have a history of bringing illegal substances into the facility. Visitation and illegal substance use is addressed again in this section to add a facility should not act as an arm of law enforcement and cases may warrant a referral to local law enforcement if they determine illegal substance have been brought into the facility by a visitor.

Potential Action by Facility: Review policies, procedures, communications with residents, families and staff for consistency with updated guidance.

Links: More details can be found in Appendix PP-State Operations Manual, starting on page 28.

§483.10 Resident Rights-Respect and Dignity

Specific Regulatory Area:

- F557-483.10(e)(2)-Respect and Dignity-The right to retain and use personal possessions, including furnishings, and clothing, as space permits, unless to do so would infringe upon the rights or health and safety of other residents.

Overview of Guidance: §483.10(e)(2)

CMS added an additional example of non-compliance with this requirement to include facility staff searching a resident's body or personal possessions without the resident's or, if applicable, the resident's representative's consent and further added a facility should not act as an arm of law enforcement and cases may warrant a referral to local law enforcement.

Potential Action by Facility: Review policies, procedures, communications with residents, families and staff for consistency with updated guidance.

Links: More details can be found in Appendix PP-State Operations Manual, starting on page 20.

§483.10 Resident Rights – Self-Determination

Specific Regulatory Area:

- F61-483.10(f)-Self-determination

Overview of Guidance: §483.10(f)(1)-(3), (8)

CMS updated guidance to state that if a facility changes its policy to prohibit smoking (including electronic cigarettes), it should allow current residents who smoke to continue smoking in an area that maintains the quality of life for these residents and considers non-smoking residents. The smoking area may be an outside area provided that residents remain safe. Residents admitted after the facility changes its policy must be informed of this policy at admission.

Potential Action by Facility: Review policies, procedures, communications with residents, families and staff for consistency with updated guidance.

Links: More details can be found in Appendix PP-State Operations Manual, starting on page 25.

§483.10 Resident Rights-Medicare, Medicaid Coverage, Liability Notice

Specific Regulatory Area:

- F582-483.10(g)(17)-(18) Medicare, Medicaid Coverage, Liability Notice

Overview of Guidance: CMS updated the guidance to provide more details regarding beneficiary notices (Notice of Medicare Non-Coverage (NOMNC) and Skilled Nursing Facility Advanced Beneficiary Notice of Non-coverage (SNF ABN)) to include information on the forms, circumstance of whether to initiate the forms or not, and when they should be given to the resident.

Potential Action by Facility: Review and updated where needed, current processes to ensure compliance with the timing and process for issuing beneficiary notices.

Links: More details can be found in Appendix PP-State Operations Manual, starting on page 56.

§483.12 Freedom from Abuse, Neglect, and Exploitation

Specific Regulatory Area: §483.12 Freedom From Abuse, Neglect, and Exploitation

Overview of Guidance: Changes to Guidance re: Abuse; Determination of Past Non-Compliance; Neglect; Investigative Summary for Abuse and Neglect Investigation of Allegations of Abuse; Deficiency Categorization.

Abuse

- New guidance clarifies that although a resident-to-resident altercation should be reviewed as a potential situation of abuse, surveyors should not assume every resident-to-resident altercation results in abuse.
    - New language provides an example of infrequent arguments or disagreements that occur during course of normal social interactions would not constitute abuse.
    - Clarifies that the surveyor must determine if the incident meets the definition of abuse.
- Related to Allegations of Sexual Abuse, specific sections of cross-referenced tags F609 and F610 are included [§§ 483.12(b)(5), 483.12(c)(1) and (c)(4), and §§ 483.12(c)(2), (c)(3), and (c)(4)]:
    - Specifies the facility must develop and implement written policies and procedures that ensure reporting of crimes;
    - The facility must meet all required time frames for such reporting (§483.12(c)(1);
    - The facility must have evidence that all alleged violations are thoroughly investigated;
    - The results of the investigation must be provided to the administrator or designated representative and other officials in accordance with State law, including the State Survey Agency within five working days of the incident and if appropriate, corrective action has been taken.
- When determining past non-compliance related to sexual abuse, the surveyor should thoroughly investigate each instance to determine if the facility took all appropriate actions to correct the noncompliance and determine the date on which the facility had returned to substantial compliance.
- Specifies when a facility has identified abuse, the facility must immediately take all appropriate steps to remediate the noncompliance and protect resident from additional abuse. This includes: (1) Taking steps to prevent further potential abuse; (2) Reporting the alleged violation and investigation within require timeframes; (3) Conducting a thorough investigation of the alleged violation; (4) Taking appropriate corrective action; and (5) Revising the resident's care plan if the resident's medical, nursing, physical, mental, or psychosocial needs or preferences change as a result of an indicant of abuse.

Neglect

- Additional guidance included to provide clarity about when neglect has occurred.

- Specifies that noncompliance at tags such as F686 (Skin Integrity, Pressure Ulcers) and F689 (Accidents) do not automatically indicate noncompliance at F600 for neglect and examples are provided supporting this statement.
- The guidance notes "…a citation for neglect would require additional evidence that identifies that the facility knew, or should have known, to provide the staff, supplies, services, policies, training, or staff supervision and oversight to meet the resident's needs, but continued to fail to take action necessary to avoid the potential for harm or actual harm to the resident."
- "Neglect occurs when the facility is aware of, or should have been aware of, goods or services that a resident(s) requires but the facility fails to provide them to the resident(s), *that has resulted in or may result in physical harm, pain, mental anguish, or emotional distress. Neglect includes cases where the facility's indifference or disregard for resident care, comfort or safety, resulted in or could have resulted in, physical harm, pain, mental anguish, or emotional distress*." (new language *in italics*)
- Cross references requirements at §483.10 Resident Rights, §483.24 Quality of Life, and §483.25 Quality of Care in guidance related to Identification of Goods and Services Required by Residents**.** NOTE: when a facility does not have the goods and services a resident requires to avoid physical harm, pain, mental anguish, or emotional distress, this is likely to result in a finding of Neglect.
- An additional example is added to the list of individual failures that result in neglect: "Failure to implement an effective communication system across all shifts for communicating necessary care and information between staff, practitioners, and resident representatives."

Investigative Summary for Abuse and Neglect Investigation of Allegations of Abuse

- Surveyors are expected to refer to the Investigative Protocol for F607- Policies and Procedures Related to Allegations of Retaliation by the Facility Against a Covered Individual, for an allegation of retaliation.
- Specific language is identified for the survey team to use when citing Deficient Practice Statement on the Form CMS-2567.

Deficiency Categorization §483.12(a)(1)

- Expanded language related to the Psychosocial Outcome Severity Guide is included in this section. The guidance emphasizes the importance of applying the reasonable person concept in determining the psychosocial outcome or potential outcome that an event may have had on a reasonable person in the resident's position. Three examples are provided that the survey team should consider when determining the psychosocial impact of an event on a resident: (1) The resident may consider the facility to be their "home," where there is an expectation that he/she is safe, has privacy, and will be treated with respect and dignity. (2) The resident trusts and relies on facility staff to meet his/her needs. 3) The resident may be frail and vulnerable. The survey team is not limited to these three examples.

A significant statement in the guidance is: "However, when a nursing home resident is treated in any manner that does not uphold a resident's sense of self-worth and individuality, it dehumanizes the resident and creates an environment that perpetuates a disrespectful and/or potentially abusive situation for the resident(s)."

This guidance emphasizes that there are situations that are likely to cause psychosocial harm that may sometimes take months or years to manifest and have long-term effects on the resident and his/her relationship with others. A list of examples is provided about the type of abuse that could manifest itself much later and the survey team is not limited to this list of examples.

The guidance states: "In incidents in which one resident abuses another resident, if a reasonable person would likely suffer actual harm as a result of the incident, the incident should not be cited below Severity Level 3 (Actual Harm)."

- This updated guidance adds five examples of Severity Level 4 Noncompliance. In addition, the following statement is added to the three original examples "Based on the resident's behavior, it can be determined that the resident experienced severe psychosocial harm as a result of …" . Each sentence references either sexual abuse, mental abuse, or neglect.
- There is one new example provided at Severity Level 3 Noncompliance. Resident 1 slapped Resident 2 in the face. Resident 2 did not suffer any injuries other than some redness in the area that was slapped. Resident 2 was moderately cognitively impaired and did not remember the incident. The survey team then interviewed the son of Resident 2. The son said his father would have been mad after an incident like this [being slapped in the face]. The statement to support the finding of Severity Level 3 noncompliance is: "Therefore, by using the reasonable person concept, the survey team would conclude that Resident 2 would have experienced psychosocial harm (e.g., anger directed at the action or at a person) as a result of the physical abuse since there is an expectation that the resident would not be slapped in the face in the facility."
- One example is provided for Severity Level 2 Considerations Noncompliance No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy. During an interview, Resident 2 stated to survey staff that she does not get along with Resident 1. According to staff interviews, Resident 1 had spoken unkindly to Resident 2 when they were seated at the same table. To prevent Resident I from verbally abusing Resident 2, staff would redirect them to sit at separate tables. Interviews with other residents reflected that one weekend, temporary staff had seated Resident 1 and Resident 2 at the same table for a group activity. Resident 1 called Resident 2 a derogatory name. Review of records for Resident 1 and Resident 2 showed no documentation related to altercations. Although Resident 2 did not have a reaction to being called a derogatory name, "it can be determined that the reasonable person would experience no actual harm with the potential for more than minimal psychosocial harm as a result of the verbal abuse."

Potential Actions by Facility:

- **Ensure all facility policies include any relevant information from the updated guidance**. For example, updating the resident's care plan if the resident's medical, nursing, physical, mental, or psychosocial needs or preferences change as a result of an incident of abuse.
- **Ensure facility actions related to resolving resident and family issues/concerns/allegations, educating staff, communicating with families and others (as relevant) are clearly recorded.**
- **Confirm the facility has clear communication processes in place to ensure all relevant information is reported and recorded**. Following is an example used in the guidance for determining Immediate Jeopardy in an instance of neglect: "The facility failed to protect a resident from sexual abuse resulting in serious psychosocial harm. A resident, with moderate confusion and who was dependent on staff for care, reported to staff that she was "touched down there" and identified the alleged perpetrator. However, staff, who thought the resident was confused, did not report her allegation to facility administration and failed to provide protection for the resident allowing ongoing access to the resident by the alleged perpetrator."
- **Be aware of the expansion and potential implications of the Neglect section of guidance.**
- **Be aware of the expansion and the potential implications of the portions of the Psychosocial Outcome Severity Guide specifically included in the Deficiency Categorization for §483.12(a)(1).**

Links: More details can be found in Appendix PP-State Operations Manual, starting on page 68.

§483.12-Freedom from Abuse, Neglect, and Exploitation – Coordination with QAPI Program

Specific Regulatory Area:

- F607-483.12(b)(4) – Establish coordination with the QAPI program required under §483.75

Background: Long term care facilities are required to develop written policies and procedures that define how staff will communicate and coordinate situations of abuse, neglect, misappropriation of resident property, and exploitation with the QAPI program under §483.75.

Overview of Guidance:

The quality assessment and assurance (QAA) committee should track and take corrective action in cases of physical or sexual abuse.

Potential Action by Facility:
Review policies and procedures for communication and coordination with the QAPI program and instances of abuse, neglect, misappropriation of resident property, and exploitation. This can include the QAA committee identifying quality deficiencies or concerns with the implementation of action plans to correct these deficiencies (F867).

Links: More details can be found in Appendix PP-State Operations Manual starting on page 142.

§483.15 Admission, Transfer, and Discharge

Specific Regulatory Area:

- F622-§483.15(c)-Transfer and Discharge

Overview of Guidance: As part of the surveyor's investigation, they must determine whether a transfer or discharge is resident, or facility initiated. CMS clarified in the new guidance the determination that a transfer or discharge is facility-initiated does not equate to noncompliance if the requirements in this regulatory section are met; however, CMS has outlined areas for surveyors to focus on such as situations where residents sign out of the facility, leave against medical advice (AMA), or communicate they are not ready to leave the facility following the completion of therapy.

CMS updated guidance to clarify once a resident is admitted, residents have a right to remain in the facility unless the discharge or transfer meets one of the specified exceptions in §§483.15(c)(1)(i)(A)-(F) and discharging outside of these limited circumstances is a violation.

CMS updated guidance for situations where a resident Medicare coverage may be ending and outlined what the facility must do to comply with regulation as the resident cannot be discharged for nonpayment while determination on the resident's Medicaid eligibility is pending.

Updated guidance related to emergency transfers to acute care defines the scenario as a facility-initiated transfer, not a discharge and the resident must be permitted to return to the facility unless the facility initiates the discharge when the resident is in the hospital following the emergency transfer, then the facility must have evidence that the resident's status at the time the resident seeks to return to the facility meets the required criteria (§483.15(c)(1)(i)(A) through (D)). The resident also has the right to return to the facility pending an appeal of any facility-initiated discharge unless the return endangers the health or safety of the resident or other individuals in the facility. The facility must document the danger that the failure to transfer or discharge would pose. Residents who are sent to the acute care setting for routine treatment/ planned procedures must also be allowed to return to the facility.

Additional clarifications were made in guidance regarding the information that must be conveyed to the receiving provider when a resident is transferred or discharged. Additions include all special instructions, transmission-based precautions such as contact, droplet, or airborne, and all other information necessary to meet the resident's needs. For residents being discharged (return not expected), the facility must convey all of the information required, along with a copy of the required information.

Potential Action by Facility: Review policies, procedures, communications with residents, families and staff for consistency with updated guidance. Pay particular attention to residents signing out of the facility or leaving AMA, when Medicare coverage ends and when residents are transferred to acute setting and not permitted to return.

Links: More details can be found in Appendix PP-State Operations Manual, starting on page 178.

§483.21-Comprehensive Person-Centered Care Plan

Specific Regulatory Area:

- F658 & F659-§483.21(b)(3) Comprehensive Care Plans

Overview of Guidance: CMS added to guidance on services provided related to care plan and reporting practitioners not adhering to professional standards of quality (such as misdiagnosis with antipsychotic use).

Under F658, CMS noted awareness of situations where practitioners have potentially misdiagnosed residents with a new diagnosis of schizophrenia which would exclude the resident from long stay antipsychotic quality measure, if noncompliance exists in the practitioner not adhering to professional standards, it may require referrals by the facility and/or survey team to State Medical Boards or Board of Nursing.

Under F659, CMS also added that services provided or arranged "in accordance with the residents plan of care".

Potential Action by Facility: Review policies, procedures, communications with residents, families, staff, practitioners for consistency with updated guidance.

Links: More details can be found in Appendix PP-State Operations Manual, starting on page 242.

§483.25-Quality of Care - Trauma-Informed Care

Specific Regulatory Area:

- F699-§483.25(m) Trauma-Informed care

Overview of Guidance: Deliver care and services that meet professional standards and are delivered using approaches that are culturally competent and account for experiences and preferences and address the needs of trauma survivors by minimizing triggers and/or re-traumatization. This guidance defines culture, cultural competence, trauma, and trauma informed care. Principles pertaining to trauma-informed care adapted from SAMHSA include safety, trustworthiness and transparency, peer support and mutual self-help, collaboration, empowerment, voice, and choice.

- Assessment: Facilities should use a multi-pronged approach to identify resident's history of trauma and cultural preferences. Ask resident about triggers that may be stressors or may prompt recall of previous traumatic events and screening and assessment tools (e.g., RAI), admission assessment, history and physical, social history/assessment and others.
- Trauma: Residents may include military veterans, survivors of large-scale nature/human-caused disasters, Holocaust survivors, survivors of physical, sexual, and/or mental abuse, violent crime, history of imprisonment, homelessness, suffered traumatic loss of loved one. History and physical assessment by physician can reveal clues to resident's history of trauma, scars or other signs of abuse should be explored to determine the cause if resident is comfortable/agreeable with discussing them, numerical tattoos may indicate WWII Holocaust survivors, history of trauma may have diagnosis of anxiety, depression, substance abuse issues including alcoholism, may abuse prescription medications/street drugs. Evidence of physical and/or psychological trauma can be revealed during comprehensive social history/assessment by social worker.
- Triggers: Facility must identify triggers which may re-traumatize residents with trauma history. Transition to living in institutional setting may trigger profound re-traumatization. Common triggers include lack of privacy or confinement in crowded or small space, loud noises, bright/flashing lights, certain sights such as those used in abuse, sounds, smells, physical touch.
- Culture: Increasing changing demographics has led to need to provide culturally competent care that includes racial and ethnic diversity, religious preferences, sexual orientation, and gender identity.
- Cultural Competencies: Help staff communicate effectively with residents/families and provide care that is appropriate to culture and individual.
- Care Planning to Address Past Trauma: Facility should collaborate with resident trauma survivors, resident's family, friends, other healthcare professionals (as appropriate) to develop and implement individualized interventions. Consider establishing support group run by qualified professional(s) or allowing the support group to meet in a facility. When trauma survivors are reluctant to share history, the facility is still responsible to try to identify triggers which may cause re-traumatization and develop care plan interventions which minimize or eliminate the effect of the trigger. Examples of triggers and interventions to minimize are shared in guidance. Trauma-specific interventions should recognize the interrelation between trauma and symptoms of trauma such as substance abuse, eating disorders, depression, and anxiety. Interventions generally recognize

survivors' need to be respected, informed, connected, and hopeful regarding their own recovery and may need access to support groups either in facility or in community if appropriate and feasible.

- Care Planning to Address Cultural Preferences: When admitting a resident, facility has determined that it can provide care and services that resident requires. Create and sustain an environment that humanizes and promotes resident's well-being and feeling of self-worth and self-esteem. Staff must understand the cultural preferences of individuals and how it impacts the delivery of care. Staff must demonstrate proficiency in communicating with residents to ensure critical information can be conveyed and must include sufficient guidance for staff, including temporary staff, on how to communicate and deliver care to residents.
- Monitoring Delivery of Care and Services: Must monitor effects of their approaches to ensure they are implemented as intended and have the desired effect to achieve measurable objectives and resident's goals for care.
- Key Elements of Noncompliance: Facility failed to do any one of the following: identify cultural preferences of resident who are trauma survivors, identify resident's history of trauma, and/or triggers which may cause re-traumatization, or consistently use approaches that are culturally competent and/or trauma-informed.

Potential Action by Facility: Review policies, procedures, communications with residents, families, staff, practitioners for consistency with new guidance.

- Review delivery of care and services to determine if culturally competent and trauma-informed in accordance with standards of practice accounting for residents' experience and preferences to eliminate/mitigate triggers that may cause re-traumatization.
- Identify method(s) of comprehensively assessing each resident and new admission for possible past traumas that will need to be addressed and interventions specific to reduce potential re-traumatization.
- Ensure staff are educated in interventions and trigger identification as well as how best to communicate effectively with residents who do not speak the same language or are culturally different.
- Engage appropriate parties when needed (families, friends, practitioners, etc.) to provide care and services that are culturally competent, and trauma informed.

AHCA Resource: Trauma Informed Care Training

Links: More details can be found in Appendix PP-State Operations Manual, starting on page 418.

§483.35 Nursing Services – Sufficient Staff

Specific Regulatory Area:

- F725-483.35- Nursing Services-(a)(1)-(2) Sufficient Staff

Overview of Guidance: CMS provided clarification on sufficient staff relative to state minimum staffing requirements and use of PBJ data to identify concerns with staffing.

CMS updated the guidance to reflect that compliance with State staffing standards is not necessarily determinative of compliance with Federal staffing standards that require a sufficient number of staff to meet all the residents' basic and individualized care needs. A facility may meet a state's minimum staffing requirement and still need more staff to meet the needs of its residents. The facility is required to provide licensed nursing staff 24 hours a day, 7 days a week. Surveyors will utilize the PBJ Staffing Data Report available through the CASPER reporting system to identify concerns with staffing.

Potential Action by Facility: Review policies, procedures, communications with residents, families, staff for consistency with updated guidance, including how sufficient staffing is determined for the facility and ensuring PBJ data is accurate and submitted timely.

Links: More details can be found in Appendix PP-State Operations Manual, starting on page 455.

§483.45 Pharmacy Services-Controlled Medications

Specific Regulatory Area:

- F755-483.45(a) and (b)(1), (2), and (3) -Controlled Medications

Overview of Guidance: §483.45(b)(2)-(3) Controlled Medications

CMS updated guidance with a reference to the Food and Drug Administration (FDA) and manufacturer instructions that recommend consumers dispose of used fentanyl patches by folding the patch in half with the sticky sides together and flushing the patch down the sink or toilet. In areas where state or local laws restrict flushing of pharmaceuticals, nursing homes may use drug disposal products or systems for fentanyl patches and other controlled medications; or as long as the facility can show that the product or system minimizes accidental exposure or diversion.

Potential Action by Facility: Review policies, procedures, communications with staff for consistency with updated guidance.

Links: More details can be found in Appendix PP-State Operations Manual, starting on page 528.

§483.45 Pharmacy Services-Unnecessary Drugs and Psychotropic Drugs

Specific Regulatory Area:

- F757-§483.45 (d)Unnecessary Drugs and F758-§483.45(c)(3) and(e)Psychotropic Drugs

Overview of Guidance: CMS added definitions for Dose, Duplicate Therapy, and Excessive dose. Additionally, CMS added a statement that as part of a facility's QAPI program, a facility may track its use of certain classes of medications, such as antipsychotics, through reports from the long-term care pharmacist which could identify trends and reduce adverse events.

CMS updated guidance to reflect the medical record must show documentation of the diagnosed condition for which a psychotropic medication is prescribed. CMS outlines risks associated with the use of psychotropic medications and indicate that the requirements pertaining to psychotropic medications apply to the four categories of drugs (anti-psychotic, anti-depressant, anti-anxiety, and hypnotic) without exception. CMS provides a list of other medication classifications that affect brain activity and indicates that they fall under psychotropic requirements when the documented use appears to be a substitution for another psychotropic medication rather than for the original or approved indication.

Additionally, CMS provides guidance regarding dose reductions for psychotropic medications to minimize withdrawal and addresses how to meet compliance with the Gradual Dose Reduction requirements.

Potential Action by Facility: Review policies, procedures, communications with residents, families, staff, practitioners for consistency with updated guidance. Consider enhanced tracking of certain medication classes as part of QAPI, ensure documentation captures the reason medications are prescribed, and examine the use of non-psychotropic medications that still affect brain activity under the psychotropic medication requirements.

Links: More details can be found in Appendix PP-State Operations Manual, starting on page 545.

§483.60-Food and Nutrition Services

Specific Regulatory Area:

- F812-**§**483.60(i) Food procurement, Store/Prepare/Serve-Sanitary

Overview of Guidance: CMS added content to the definition of food distribution and added a new definition for food service.

Guidance was updated to provide information on the risks that foodborne illnesses cause and how illnesses are impacted by unsafe food handling practices. They also outlined how to identify focus on effective food safety systems used to identify hazards and referenced additional resources.

CMS outlined when hairnets must be worn by staff (cooking, preparing, or assembling food, such as stirring pots or assembling the ingredients of a salad), as well as when the use of gloves is necessary (directly touching ready-to-eat food and serving residents who are on transmission-based precautions).

CMS also provided clarification in the guidance to include that dining locations include any area where one or more residents eat their meals. These can be located adjacent to the kitchen or a distance from the kitchen, such as residents' rooms and dining rooms on other floors or areas of the building.

In addition, CMS listed other areas of focus related to food preparation and service for surveyors to monitor, such as staff distributing meals without first properly washing their hands and serving food to residents after collecting soiled plates and food waste, without proper hand washing.

Potential Action by Facility: Review policies, procedures, staff practices for consistency with updated guidance, including food procurement, storage, preparation, and serving.

Links: More details can be found at Appendix PP-State Operations Manual, starting on page 628.

§483.70-Administration – Binding Arbitration Agreements

Specific Regulatory Area:

- F847- §483.70(n) – Binding Arbitration Agreements – Entering into Binding Arbitration Agreements
- F848-§483.70(n) – Binding Arbitration Agreements – Arbitrator/Venue Selection and Retention of Agreements

Overview of Guidance: The interpretive guidance (IGs) implements the regulation governing the use of arbitration agreements by facilities, which regulation went into effect on September 16, 2019. In doing so, the IGs divide the regulation's various requirements into two completely new tags and provide CMS' first ever surveyor guidance regarding this regulation's meaning and intended enforcement. Notably, the IGs expressly state that they apply to arbitration agreements entered on or after September 16, 2019.

The first new tag (F847) implements the regulation's prohibition against making entry into an arbitration agreement a condition of admission or continued residency, as well as the regulation's requirement regarding a facility's obligation to explain the agreement to a resident or their representative, the requirement that a facility obtain an acknowledgement of such understanding by the resident or their representative, the requirement that such an agreement provide a 30-day right of rescission, and the prohibition against including any language in the agreement that prohibits or discourages the resident or anyone else from communicating with government officials. The stated intent of the new tag is to ensure that facilities inform residents or their representatives of the nature and implications of any proposed arbitration agreement in order to inform their decision on whether to enter into such agreements. For example, the new tag states that facilities should take every step to meet the resident's needs (e.g., literacy level and language proficiency). The new tag also addresses those instances in which an arbitration agreement is included within a larger document such as an admissions agreement.

The second new tag (F848) implements the regulation's requirements that arbitration agreements provide for the selection of a neutral arbitrator and a convenient venue. For example, in connection with the regulation's requirement that arbitration agreements provide for the selection of a neutral arbitrator, the new tag states that a facility "should promptly disclose to the resident or his or her representative the extent of any relationship which exists with an arbitrator or arbitration services company, including how often the facility has contracted with the arbitrator or arbitration service, and when the arbitrator or arbitration service has ruled for or against the facility."

Potential Action by Facility: Review policies, procedures, language of agreements, communications with residents, families, staff for consistency with new guidance, in particular, if facility continued to use arbitration agreements on or after September 16, 2019.

Links: More details can be found in Appendix PP-State Operations Manual, starting on page 680 for F847 and page 690 for F848.

§483.70 Administration – Mandatory Submission of Staffing (PBJ)

Specific Regulatory Area:

- F851-483.70(q)- Mandatory submission of staffing information based on payroll data in a uniform format

Overview of Guidance: The surveyors will be using PBJ data from the Certification and Survey Provider Enhanced Reports (CASPER) report to determine if the facility submitted the required staffing. The facility's failure to submit PBJ data will be reflected on their CASPER report and result in a deficiency citation.

Potential Action by Facility: Review process for ensuring PBJ data is accurate and submitted timely, including backup coverage.

Links: More details can be found in Appendix PP-State Operations Manual, starting on page 711.

§483.75 Quality Assurance and Performance Improvement

Specific Regulatory Area:

- F865-F868-483.75 – Quality Assurance and Performance Improvement

Background: Long term care facilities are required to develop, implement, and maintain an effective, comprehensive, data-driven Quality Assurance and Performance Improvement (QAPI) program. This program must be ongoing, comprehensive, and address the full range of care and services provided by the facility.

Overview of Guidance: The updated guidance clarifies the purpose of QAPI as:

- Ensuring care delivery systems function consistently, accurately, and incorporate current and evidence-based practice standards where available;
- Preventing deviation from care processes to the extent possible;
- Identifying issues and concerns with facility systems, as well as identifying opportunities for improvement; and
- Developing and implementing plans to correct and/or improve identified areas.

The guidance highlights that the QAPI program must address all systems of care and management practices, utilize best practices to measure quality of care and the facilities goals, and reflect the unique services and care provided. Furthermore, the responsibilities of the governing body/executive leadership are outlined.

Information is provided on what types of evidence a facility can provide to demonstrate compliance with the QAPI requirements and what constitutes good faith attempts by the facility to correct quality of care issues.

Furthermore, guidance is provided on what disclosures to the surveyors may be necessary to show compliance.

A number of terms such as quality indicators, quality assurance, and performance improvement have been defined.

Under F867 several new policies and procedures are required. Below is additional information highlighting these.

- Feedback: Each facility must establish and implement written policies and procedures for feedback. Feedback must be collected from direct care staff, other staff, residents, and resident representatives, as well as other sources. Feedback should be collected for both problem areas as well as opportunities for improvement. Feedback should also include the provision of feedback to direct care staff, other staff, residents, and resident representatives.

- Data Collection Systems and Monitoring: Facilities must collect and monitor data reflecting its performance, including adverse events. The Facilities policies and procedures must address how data will be identified, frequency with which it will be collected, and collection methodology.

- Performance Indicators: Facilities must have policies and procedures in place for monitoring and evaluating performance indicators. These policies and procedures must include what frequency the facility develops, monitors, and evaluates its performance indicators.

- Systematic Analysis and Action: Facilities must have policies and procedures with address how it will use systematic approaches to determine underlying problems and how corrective actions will be designed to impact change at a systems level. The policies and procedures must also address how the facility will monitor the effectiveness of its performance improvement activities and ensure sustainability of improvements.

- Establishing Priorities: Facilities must establish priorities for their performance improvement activities.

- Medical Errors and Adverse Events: Facilities must establish policies and procedures that allow for systematically identifying and investigating medical errors and adverse events. These policies and procedures must include how the facility will analyze and use data to develop activities to prevent further medial errors and adverse events.

  Instances of abuse, neglect, and misappropriation of resident property and exploitation (see §483.5) were added to the list of potentially preventable events related to care.

  Education must be provided to staff, residents, resident representatives, and family members on medical errors and adverse events.

- Performance Improvement Projects: Facilities must conduct performance improvement projects, with a minimum of one annually.

- Quality Assessment and Assurance (QAA): The QAA committee functions under the facilities governing body and is responsible for developing and implementing appropriate plans of actions to correct deficiencies identified, regularly review, and analyze data under QAPI and drug regimen review and act on available data to make improvements.

Regulatory requirements of §483.75(c) and §483.75(c)(1)-(4) have been relocated from F866 to F867.

Under F865 facilities maybe be cited if they fail to do one of the following:

- Maintain documentation and evidence of its ongoing QAPI program;
- Present its QAPI plan to the Federal and/or State surveyors during recertification survey or upon request;
- Present QAPI evidence necessary to demonstrate compliance with these requirements;
- Develop, implement and maintain an effective, comprehensive QAPI program, that addresses the full range of services the facility provides; or
- Ensure governing body oversight of the facility's QAPI program and activities.

Under F867 facilities may be cited for deficient practices is they fail to do any one of the following:

- Include in its policies and procedures how it obtains and uses feedback from residents, resident representatives, and staff to identify high-risk, high-volume, or problem prone issues as well as opportunities for improvement;
- Develop and implement policies and procedures which include how it ensures data is collected, used and monitored for all departments;
- Develop and implement policies and procedures for how the facility develops, monitors and evaluates performance indicators and the frequency for these activities;
- Develop policies and procedures for how it will identify, report, and track, adverse events, and high risk, high volume, and/or problem-prone concerns;
- Establish priorities for its improvement activities, that focus on high-risk, high-volume or problem-prone areas, as well as resident safety, choice, autonomy, and quality of care;
- Ensure the QAA Committee developed and implemented action plans to correct identified quality deficiencies;
- Measure the success of actions implemented and track performance to ensure improvements are realized and sustained;
- Track medical errors and adverse events, analyze their causes, and implement preventive actions and mechanisms;
- Conduct at least one PIP annually that focuses on high-risk or problem prone areas, identified by the facility, through data collection and analysis; or
- Ensure the QAA Committee regularly reviews and analyzes data collected under the QAPI program and resulting from drug regimen reviews, and act on the data to make improvements.

Under F868, it is important that the QAA committee is reporting its activities to the governing body. For smaller facilities, if the administrator is on the QAA committee, they are already apprised of the QAPI activities.

Potential Action by Facility: Review policies, procedures, communications with residents, families, staff for consistency with updated guidance including comprehensive examination of QAPI program and associated activities.

Links: More details can be found in Appendix PP-State Operations Manual starting on page 713.

§483.75 Quality Assessment and Assurance – Infection Preventionist

Specific Regulatory Area:

- F868- §483.75(g)(1)(iv)-QAA Committee

Overview of Guidance: Infection preventionist participation on the quality assessment and assurance committee and must report to the committee on the IPCP on a regular basis. Reporting should occur at the same frequency as the QAA committee meetings. The IP reporting at QAA meetings may include facility process and outcome surveillance, outbreaks and control measures, occupational health communicable disease illness, and antibiotic stewardship program related to antibiotic use and resistance data. For the IP to be considered an active participant they should attend each QAA meeting and if they cannot attend another staff member should report on the IP's behalf, but this does not change or absolve the IP's responsibility to fulfill the role of QAA committee member or reporting on the IPCP.

Potential Action by Facility: Review role of IP and engagement in the QAA committee consistent with guidance.

AHCA Resource: Infection Preventionist Specialized Training

Links: More details can be found in Appendix PP-State Operations Manual, starting on page 733.

§483.80-Infection Control – Infection Prevention & Control

Specific Regulatory Area:

- F880-§483.80 – Infection Prevention and Control

Overview of Guidance: CMS added a section on staff that includes all facility staff (direct and indirect care functions), contracted staff, consultants, volunteers, others who provide care and services to residents on behalf of the facility, and students in the facility's nurse aide training programs or from affiliated academic institutions. Define standard precautions to prevent the spread of infection and explain their application during resident care activities. Define transmission-based precautions. C. difficile, Legionellosis and MDROs definitions added.

More active screening may include the completion of a screening tool or questionnaire which elicits information related to recent exposures or current symptoms. That information is reviewed by the facility staff and the visitor is either permitted to visit or excluded. At a minimum, the IPCP must include: a system for preventing, identifying, reporting, investigating, and control infections and communicable disease that covers all residents, staff, contractors, consultants, volunteers, visitors, others who provide care and services to residents on behalf of the facility, and students in the facility's nurse aide training programs or from affiliated academic institutions.

- Infection Control Policies and Procedures: Must include define and explain standard precautions and their application during resident care activities. Define transmission-based precautions (i.e., contact precautions, droplet precautions, airborne precautions) and explain how and when they should be utilized, as consistent with accepted national standards. Environmental cleaning and disinfection – routine cleaning and disinfection of frequently touched or visibly soiled surfaces in communal areas, resident rooms, and at the time of discharge and routine cleaning and disinfection of resident care equipment including equipment shared among residents (e.g., blood pressure cuffs, rehabilitation therapy equipment, blood glucose meters, etc.).
- Water Management: Facilities must be able to demonstrate its measures to minimize the risk of Legionella and other opportunistic pathogens in building water systems such as by having a documented water management program. Water management must be based on nationally accepted standards. An assessment to identify where Legionella and other opportunistic waterborne pathogens could grow and spread, and measures to prevent the growth of opportunistic waterborne pathogens, and how to monitor them. Control measures may include visible inspections, use of disinfectant, and temperature. Monitoring controls include testing protocols for control measures, acceptable ranges, and documenting results of testing. Water management should include established ways to intervene when control limits are not met. CMS does not require water cultures for Legionella or other opportunistic waterborne pathogens as part of routine program validation, although there may be instances when it is needed. If there is a case of healthcare-associated legionellosis or an outbreak of an opportunistic waterborne pathogen causing disease the facility should contact the local/state public health authority and follow their recommendations.
- MDRO Colonization and Infection: Contact precautions are used for resident infected or colonized with MDROs when a resident has wounds, secretions, or excretions that are

unable to be covered or contained and on units or in facilities where, despite attempts to control the spread of the MDRO, ongoing transmission is occurring. Refer to the CDC's Enhanced Barrier Precautions.

- Droplet Precautions: If it becomes necessary for a resident who requires droplet precautions to share a room with a resident who does not have the same infection, the facility should make decisions regarding resident placement on a case-by-case basis after considering infection risks to other residents in the room and available alternatives. A resident who is on droplet precautions for the duration of the illness (e.g., influenza), should wear a facemask (surgical or procedure facemask) when leaving their room.
- Blood Glucose Monitors: If the facility failed to clean and disinfect blood glucose meters per device and disinfectant manufacturer's instructions for use, they are used for more than one resident, and there is a resident with a known bloodborne pathogen in the facility the surveyor must cite noncompliance under this tag and using Appendix Q determine immediate jeopardy. The survey agency must notify appropriate local/state public health authority of this practice.

Potential Action by Facility: Review policies, procedures, communications with residents, families, staff for consistency with updated guidance including comprehensive review of facility Infection Prevention & Control Program.

AHCA Resources: Infection Preventionist Specialized Training and Water Management Training

Links: More details can be found in Appendix PP-State Operations Manual, starting on page 736.

§483.80- Infection Control - IP&C Program and Antibiotic Stewardship Program

Specific Regulatory Area:

- F881-483.80(a)- Infection Prevention and Control Program & 483.80(a)(3) Antibiotic Stewardship Program

Overview of Guidance: CMS added a section on monitor/review response to antibiotics, and laboratory results when available, to determine if the antibiotic is still indicated or adjustments should be made (e.g., antibiotic time-out).

Facilities should provide feedback to prescribing practitioners regarding antibiotic data to improve prescribing practices and resident outcomes. Require antibiotic orders to include the indication, dose, and duration.

For surveyor concerns on antibiotic stewardship program (ASP), surveyors must include at least one resident on an antibiotic in resident sample to assess whether the resident(s) is being prescribed antibiotic(s) unnecessarily and whether they were any negative outcomes such as adverse drug event.

Potential Action by Facility: Review policies, procedures, communications with residents, families, staff for consistency with updated guidance including examination of facility antibiotic stewardship program. If not already doing, provide feedback to prescribing practitioners when response to antibiotics or laboratory results do not indicate their utilization.

AHCA Resources: Infection Preventionist Specialized Training

Links: More details can be found in Appendix PP-State Operations Manual, starting on page 769.

§483.80 Infection Control – IP Qualifications/Role

Specific Regulatory Area:

- F882-§483.80(b) Infection Preventionist Qualifications/Role

Overview of Guidance: Ensure designation of a qualified individual(s) onsite who is responsible for implementing programs and activities to prevent and control infections. IPCP program includes IPC, antibiotic stewardship program.

IP is responsible for IPCP, but other staff play important roles. Example: Staff must appropriately implement standard precautions (e.g., hand hygiene and transmission-based precautions). Antibiotic stewardship program (ASP) includes leadership support and accountability via participation of medical director, consulting pharmacist, nursing, and administrative leadership, requiring IP to utilize and work collaboratively with these team members to implement ASP. IP is responsible for ensuring ASP program meets requirements at 483.80(a)(3).

IP should review/approve IPC training topics and content as well as ensure staff are trained on IPCP. IP is not required to perform the IPCP training since some facilities have designated staff development personnel.

IP Primary Professional Training: Must be professionally trained in nursing, medical technology, microbiology, epidemiology, or other related field, earned certificate/diploma or degree in nursing, professional trained medical technologist with at least an associate's degree in medical technology or clinical laboratory microbiology, professionally trained microbiologist with at least bachelor's degree in microbiology, professionally trained epidemiologist with at least bachelor's in epidemiology, or examples of other field appropriate for IP include physician, pharmacists, physician's assistant.

IP Qualifications: Qualified by education, training, experience, or certification with knowledge to perform role and remain current with infection prevention and control issues and be aware of national organizations' guidelines as well as those from national/state/local public health authorities (e.g., emerging pathogens). IP should have background and ability to fully carry out requirements of IP based on needs of resident population, such as interpreting clinical and laboratory data. Experience examples include identification of infection disease processes, surveillance, and epidemiologic investigation, preventing and control transmission of infectious agents.

IP Hours of Work: IP hours per week can vary based on facility and resident population, number of hours required to fulfil the role must be at least part-time and should be determined by facility assessment to determine resources needed for IPCP and ensure resources are provided for IPCP to be effective. Based upon assessment, determine if IP should be dedicated solely to IPCP. Consider resident census, resident characteristics, types of units (e.g., respiratory care units, memory care, skilled nursing, complexity of services it offers, outbreaks, seasonality of infections) in determining amount of IP hours needed. IP must have the time necessary to

accurately assess, develop, implement, monitor, and manage IPCP for facility addressing training requirements and participate in required committees including QAA.

IP must physically work onsite in facility and cannot work off-site as consultant or perform IP work at separate location such as corporate office or affiliated short term acute care facility.

Specialized Training in IPC: IPC training must be sufficient to perform the role of IP. Specialized training in IPC may include care for residents with invasive medical devices, resident care equipment (e.g., ventilators), and treatment such as dialysis and high-acuity conditions. As resident population changes, IP should re-evaluate knowledge and skills and may need to obtain additional training for the change in facility scope of care. IP must have obtained specialized training beyond initial professional training or education prior to assuming role. Training can occur through more than one course, but IP must provide evidence of training through certificate(s) of completion or equivalent documentation.

Potential Action by Facility: Review IP role, responsibilities, specialized training, qualifications, work hours/location, for consistency with new guidance. Consider IP backup when primary IP is not available.

AHCA Resources: Infection Preventionist Specialized Training

Links: More details can be found in Appendix PP-State Operations Manual, starting on page 774.

§483.85 Compliance and Ethics

Specific Regulatory Area:

- F895-§483.85 Compliance and Ethics

Background: Medicare and Medicaid participating nursing facilities have been required to have a compliance and ethics program since March 23, 2013, under the Affordable Care Act. However, there was no regulatory mechanism to enforce the requirement until CMS issued its revised 2016 Requirements of Participation (ROP), which included the requirements for the compliance and ethics program at §483.85. Survey and enforcement of these standards was delayed due to the pandemic but will begin on October 24, 2022.

Overview of Guidance: Facilities must have a comprehensive compliance and ethics program meeting all requirements stated below. Surveyors will be reviewing the facilities, written policies and procedures and interviewing both staff and the high-level personnel overseeing the program to determine if this program is in place. They will look for examples of the compliance program in action, evidence of the annual review and that the organization has completed due diligence on the high-level personnel overseeing the program.

CMS indicates that facilities should integrate their compliance and ethics program and their QAPI program at 483.75(g)(2)(iii). Specifically, CMS states that facilities should integrate the information and data they collect, or which arises out of their compliance and ethics program into their QAPI program. The QAPI officer should work with the compliance officer to determine if there are trends or patterns of systematic problems.

The annual training must be delivered in accordance with the compliance and ethics training requirements in 483.95(f).

As a refresher, the CMS regulations include eight required components of a compliance and ethics program, three additional components for organizations operating five or more facilities, and a required annual review. CMS also expects all facilities to use their facility assessment to evaluate the needs of their C&E programs, including identifying risk areas, developing, and maintaining the program and determining resources.

The eight primary components of the C&E program are as follows:

1. Written compliance and ethics standards, policies, and procedures "reasonably capable of" reducing the prospect of criminal, civil and administrative violations and promote quality of care.
    a. Designating an appropriate contact to whom individuals may report suspected violations.
    b. Establishing an alternate method of reporting suspected violations anonymously without fear of retribution.

c. Disciplinary standards that set out the consequences for committing violations for the entire staff, individuals providing services under a contractual arrangement, and volunteers, consistent with the volunteers' expected roles.

2. Assignment of "high level" individual(s) (*e.g.*, Chief Executive Officer ("CEO"), Board Member, Division Director, etc.) with the overall responsibility to oversee compliance with the C&E program's standards, policies, and procedures.

3. Sufficient resources and authority to individual(s) overseeing the program to "reasonably assure compliance" with standards, policies, and procedures.

4. Due care not to delegate substantial discretionary authority to individuals who the operating organization knew, or should have known through due diligence, had a propensity to engage in criminal, civil, and administrative violations under the Social Security Act.

5. Effective communication of program standards, policies, and procedures to the entire staff.

   a. Requirements include, but are not limited to, mandatory participation in training as set forth at §483.95(f) or orientation programs or disseminating information that explains in a practical manner what is required under the program.

6. Reasonable steps to achieve compliance with the program's standards, policies, and procedures, including auditing and monitoring systems, as well as reporting mechanisms and a non-retaliation policy.

7. Consistent enforcement of the program standards, policies and procedures through appropriate disciplinary mechanisms including, as appropriate, discipline for individual'(s) failure to detect and report a violation to the program contact.

8. Ensuring all "reasonable steps" are taken to "respond appropriately" to a violation and to "prevent further similar violations" including any necessary modification to the program.

The three supplemental components required of operating organizations with five or more facilities are as follows:

9. Conducting annual and mandatory program training that meets the requirements set forth in § 483.95(f).

10. Designating a compliance officer whose "major responsibility" is to oversee the program, and who reports to the "governing body." *Note: The compliance officer cannot be "subordinate to the general counsel, chief financial officer or chief operating officer."*

11. Designating a compliance liaison at each of the organization's facilities.

Finally, the operating organization of every facility is required to review its C&E program annually. The review must reflect changes in all applicable laws or regulations and within the operating organization and its facilities to improve its performance in deterring, reducing, and

detecting violations under the Act and in improving quality of care. Facilities should make sure to document the annual review, even if no changes or revisions are made.

Potential Action by Facility: Comprehensively review facility compliance & ethics program for consistency with new guidance including policies, procedures, training & communication with staff and integration with QAPI program.

Links: More details can be found in Appendix PP-State Operations Manual, starting on page 786.

§483.90 Physical Environment – Resident Rooms/Bedrooms

Specific Regulatory Area:

- F910 and F911-483.90(e)- Physical Environment: Resident Rooms/Bedrooms

Overview of Guidance: CMS is urging providers to consider making changes to their physical environment to allow for a maximum of double occupancy in each room and explore ways to allow for single occupancy rooms as outlined in QSO-22-19-NH.

CMS outlines the advantages to limiting rooms to double or single occupancy, including:

1. Allowing for more resident privacy for daily activities such as dressing and visiting with friends and family (§483.10(h)).
2. Encourages a homelike environment (§483.10(i)).
3. Improving infection control and prevention by reducing the risks associated with multiple residents in the same room and making it easier to isolate or quarantine residents who are infectious.

Potential Action by Facility: Evaluate possible physical environment changes. Maintain compliance with existing regulation for newly constructed, re-constructed, or newly certified after Nov. 28, 2016, cannot accommodate more than two residents in a bedroom.

Links: More details can be found in Appendix PP-State Operations Manual, starting on page 801 and in QSO-22-19-NH .

§483.90 Physical Environment – Resident Call System

Specific Regulatory Area:

- F919-483.90- Physical Environment- (g)(1)(2) Resident Call System

Overview of Guidance: Additions were made to specify that the facility must be adequately equipped to allow residents to call for staff assistance through a communication system which relays the call directly to a staff member or to a centralized staff work area from–§483.90(g)(1) Each resident's bedside; and §483.90(g)(2) Toilet and bathing facilities.

The call system must be accessible to residents while in their bed or other sleeping accommodations within the resident's room. The call system must be accessible to the resident at each toilet and bath or shower facility. The call system should be accessible to a resident lying on the floor.

Potential Action by Facility: Evaluate current call system in facility to ensure consistent with updated guidance.

Links: More details can be found in Appendix PP-State Operations Manual, starting on page 808.

§483.95-Training Requirements – General

Specific Regulatory Area:

- F940-§483.95- Training Requirements-General

Overview of Guidance: Facilities are required to develop, implement, and maintain an effective training program for all staff. Training needs change over time based on resident population and facility assessment.

Consider competencies and skill sets for all new and existing staff, individual provider services under a contractual agreement, and volunteers must be consistent with their expected roles. Facility staff includes (direct and indirect care functions), contracted staff, and volunteers (training topics as appropriate to role). F940 would be cited as a result of the facility's failure to implement trainings for multiple training topics included at §483.95.

Potential Action by Facility: Review current training program for all staff and determine if consistent with new guidance, including being current with resident population and facility assessment.

Links: More details can be found in Appendix PP-State Operations Manual, starting on page 813.

§483.95-Training Requirements – Communications Training

Specific Regulatory Area:

- F941- §483.95(a)- Communication Training – A facility must include effective communications as a mandatory training for direct care staff.

Overview of Guidance: Communication includes teletypewriters, telecommunications device for the deaf, cellular phones, and accessibility such as reasonable access and privacy for electronic communications like email or internet-based interpersonal video communications. Topics for training should meet the needs of the resident population, needs of staff, and correspond with facility assessment. Facilities must inform residents in a language they can understand of their total health status and provide notice of rights and services both orally and in writing in language the resident understands. Staff includes all staff providing direct care services (training topics as appropriate to role).

If there is a concern by surveyors about effective communication they will utilize interviews and review training records to determine ongoing in-service training, admission of non-English speaking residents, how the facility assessment reflects needs of direct care staff training of non-English speaking residents, alternative means of communication, ethnic and cultural differences reflected in communications, how well staff communicate with residents, processes in place to communicate with residents with language/communication barriers during emergencies, facility training of direct care staff on non-verbal communication or residents, and training of direct care staff on identifying and understanding their own non-verbal communication.

Potential Action by Facility: Review current communication training and determine if consistent with new guidance, update accordingly. Observe staff communications with residents and how residents' communication needs are being met.

Links: More details can be found in Appendix PP-State Operations Manual, starting on page 815.

§483.95-Training Requirements – Resident's Rights and Facility Responsibilities

Specific Regulatory Area:

- F942-§483.95(b) Resident's Rights and Facility Responsibilities

Overview of Guidance: Facility staff understand and foster the rights of all residents. Staff includes all facility staff (direct and indirect care functions), contracted staff, volunteers (training topics as appropriate to role). Facilities must develop and implement an ongoing education program on all resident rights and facility responsibilities for care of residents as outlined in §483.10. Education programs should incorporate learning objectives, performance standards, and evaluation criteria.

Staff performance assessments should evaluate the ability to integrate knowledge and skills specific to the requirements at 483.10. Process for validating that the training was completed, whether in a group setting or an individual basis.

Probing questions from surveyors may include interview of staff to determine if they received training regarding the rights of residents and facility responsibilities, observe staff interactions with residents, review training documentation provided by facility related to resident rights and facility responsibilities, and interview staff from various departments and disciplines about their knowledge of resident rights and facility responsibilities.

Potential Action by Facility: Review current education program on rights of the resident and responsibilities of facility to properly care for residents to determine if consistent with new guidance, update accordingly. Observe staff interactions with residents and evaluate resident rights are being met.

Links: More details can be found in Appendix PP-State Operations Manual, starting on page 818.

§483.95-Training Requirements – QAPI Training

Specific Regulatory Area:

- F944-§483.95(d) Quality Assurance and Performance Improvement-Training

Overview of Guidance: Facility must conduct mandatory training, for all staff, on the facility's QAPI program, that includes goals and various elements of the program, including how the facility intends to implement the program. Training should include the staff's role in the facility's QAPI program and how to communicate concerns, problems, or opportunities for improvement to the facility's QAA Committee.

As updates are made to the QAPI program, the facilities training should also be updated, and staff trained on updates. Training should support current scope and standards of practice through the curricula which detail learning objectives, performance standards, and evaluation criteria, including a process for tracking staff participation in the required training.

Probing questions from state surveyors may include verification that the facility has a mandatory requirement that all staff receive QAPI training, method for verifying attendance at mandatory QAPI training, did all staff attend mandatory training, does training program inform staff of current elements and goals of QAPI program, are staff aware of what the QAPI program entails and how the facility intends to implement and monitor the program, are staff aware of how to bring ideas or concerns to the attention of the QAA committee, and how does the facility determine when training content requires updating to be consistent with current professional standards and guidelines.

Potential Action by Facility: Review current QAPI program training and determine if consistent with new guidance, update accordingly. Observe training application into practice, including bringing concerns and issues to QAA committee and updating QAPI training as needed.

Links: More details can be found in Appendix PP-State Operations Manual, starting on page 821.

§483.95-Training Requirements – Infection Control Training

Specific Regulatory Area:

- F945-§483.95(e) Infection Control-Training

Overview of Guidance: Facilities must develop, implement, and permanently maintain an effective training program for all staff that includes training on standards, policies, and procedures for the infection prevention and control program as described at 483.80(a)(2) that is appropriate and effective and determined by staff need. Staff includes all facility staff (direct and indirect care functions), contracted staff, and volunteers (training topics as appropriate to role).

Changes to the facility resident population, community infection risk, national standards, staff turnover, facility's physical environment, or facility assessment may necessitate ongoing revisions to the facility's training program. Training should support current scope and standards of practice through curricula that includes learning objectives, performance standards, evaluation criteria, and address potential risks to staff, residents, and volunteers if procedures are not followed.

Training at a minimum must include: the surveillance system designed to identify possible communicable disease or infection before they can spread to others, when and to whom possible incidents of communicable disease or infection should be reported, how and when to use standard precautions including proper hand hygiene practices and environmental cleaning and disinfection practices, how and when to use transmission-based precautions for a resident including type and its duration of use depending upon the infection agent or organism, occupational health policies including circumstances under which the facility must enforce work restrictions and when to self-report illness or exposures to potentially infectious materials, and proper infection prevention and control practices when performing resident care activities as it pertains to staff roles responsibilities and situations.

Probing questions for surveyors include did observations or interviews with staff indicate a training need, did staff report not receiving training, what process does the facility have to engage staff to express concerns and request training, does the facility respond to staff concerns and requests for training, review training coursework to determine if content meets professional standards/guidelines and covers facility policy and procedures for infection prevention and control, does facility implement the training program and ensure staff are instructed to meet requirements of infection control, verification that all staff participate in infection prevention and control training with a process in place to track participation.

Potential Action by Facility: Review current infection control training and determine if consistent with new guidance, update accordingly. Review process for staff to share concerns and requests for training including how those concerns and requests are addressed.

Links: More details can be found in Appendix PP-State Operations Manual, starting on page 823.

§483.95-Training Requirements – Compliance and Ethics Training

Specific Regulatory Area:

- F946-§483.95(f) Compliance and Ethics-Training

Overview of Guidance: Training for all facility staff (direct and indirect care functions), contractual services, volunteers consistent with expected roles. Operating organization (individual or entity that operates a facility) must provide training program or another practical manner to effectively communicate the standards, policies, and procedures of the compliance and ethics program to entire staff. For operating organizations that operate five or more facilities, annual training for staff must be conducted.

Training should support current scope and standards of practice through curricula that includes learning objectives, performance standards, and evaluation criteria with a process to track staff participation in training.

Probing questions from surveyors may include does the facility provide training or effectively communicate the standards policies and procedures of the compliance and ethics program, does facility have system for tracking staff attendance at trainings, and for organizations with five or more facilities is annual compliance and ethics training provided.

Potential Action by Facility: Review current compliance and ethics training and determine if consistent with new guidance, update accordingly. Confirm staff attendance tracking at trainings.

Links: More details can be found in Appendix PP-State Operations Manual, starting on page 824.

§483.95-Training Requirements- Behavioral Health Training

Specific Regulatory Area:

- F949-§483.95(i) Behavioral Health-Training

Overview: Facility must develop, implement, and maintain effective training program for all staff that includes at a minimum training on behavioral health care and services (consistent with 483.40) that is appropriate and effective as determined by staff need and facility assessment that includes all staff (direct and indirect care functions), contracted staff, and volunteers (training topics as appropriate to role). Changes to resident population, staff turnover, facility physical environment, and modifications to facility assessment may require ongoing revisions to training program.

Training should support current scope and standards of practice through curricula that details learning objectives, performance standards, and evaluation criteria with processes in place to track staff participation at trainings. Training should include at minimum person-centered care and services that reflect the resident's goals for care, interpersonal communication that promotes mental and psychosocial well-being, meaningful activities that promote engagement and positive meaningful relationships, environment and atmosphere conducive to mental and psychosocial well-being, individualized non-pharmacological approaches to care, care specific to individual needs of resident that are diagnosed with mental psychosocial or substance use disorder or history of trauma and/or post-traumatic stress disorder or other behavioral health conditions, and care specific to the individual needs of residents that are diagnosed with dementia.

Probing questions from surveyors may include does staff demonstrate skills needed to promote highest practicable level of function for residents with identified behavioral health care needs, can staff explain concepts learned in training, how does facility assure all staff interacting with residents are trained, how does facility assure that all staff including contractors and volunteers are training to interact with residents with specific behavioral health care needs, is training program designed to address residents' specific behavioral health care needs, does facility track staff participation in training, does facility monitor effectiveness of training, how are changes implemented to training program if desired outcomes are not achieved, is training curriculum based on results of facility assessment.

Potential Action by Facility: Review current behavioral health training and determine if consistent with new guidance, update accordingly. Confirm staff attendance tracking at trainings and that training is updated as changes in resident population, staff turnover, facility physical environment, and modifications to facility assessment occur.

Links: More details can be found in Appendix PP-State Operations Manual, starting on page 829.

Potential Inaccurate Diagnosis and/or Assessment

Specific Regulatory Area(s):

- F641-§483.20(g)-Accuracy of Assessment
- F658-§483.21(b)(3)(i)-Services Provided to Meet Professional Standards
- F758-§483.45(e)(1)-Free from Unnecessary Psychotropic Meds/PRN Use

Overview of Guidance: CMS revised guidance to investigate situations where practitioners or facilities may have potentially inaccurately diagnosed and/or coded a resident with schizophrenia in the resident assessment instrument. CMS believes that incorrect diagnosis may be causing unnecessary prescribing of antipsychotic medications and inaccurate long-stay antipsychotic quality measure.

CMS added a "note" in all three regulatory areas that indicated they are "aware of situations where practitioners have potentially misdiagnosed residents with a condition for which antipsychotics are an approved use (e.g., new diagnosis of schizophrenia) which would then exclude the resident from the long-stay antipsychotic quality measure. For these situations, determine if non-compliance exists related to the practitioner not adhering to professional standards of quality for assessing and diagnosing a resident. This practice may also require referrals by the facility and/or the survey team to State Medical Boards or Boards of Nursing" and they are "aware of situations where practitioners have potentially misdiagnosed residents with a condition for which antipsychotics are an approved use (e.g., new diagnosis of schizophrenia) which would then exclude the resident from the long-stay antipsychotic quality measure."

Potential Action by Facility: Focus review of any new diagnoses of schizophrenia and/or evaluating accurate assessment and diagnosis of residents.

Links: More details can be found in Appendix PP-State Operations Manual, on pages 212, 241, and 558.

Mental Health/Substance Use Disorder (SUD)

Specific Regulatory Area(s):

- F689-§483.25(d)-Accidents
- F740-§483.40-Behavioral Health Services
- F741-§483.40(a), (a)(1) & (a)(2), Sufficient staff, Competent Staff-Behavioral health needs

Overview of Guidance: In efforts to improve guidance related to meeting the unique health needs of residents with mental health needs and substance abuse disorder (SUD), CMS clarified that when facilities care for residents with these conditions, policies and practices must not conflict with resident rights or other requirements of participation.

CMS clarified that facility staff should have knowledge of signs and symptoms of possible substance use, and be prepared to address emergencies (e.g., an overdose) by increasing monitoring, administering naloxone, initiating cardiopulmonary resuscitation (CPR) as appropriate, and contacting emergency medical services.

CMS provided resources and non-pharmacological interventions, specific to residents living with mental disorders or substance use disorders, to assist providers in identifying alternative approaches to care to support this population.

CMS updated guidance related to substance use disorder in the following regulations:

- **Accidents** – Safety for residents with substance use disorder (related to elopement or overdose potential).
- **Behavioral Health Services** – Added to definition of SUD and included that SUD should be part of the facility assessment. Also, included activities for residents living with mental health and SUD may different based on needs, care plans must address needs of residents with SUD, and outlined areas a behavioral contract may address.
- **Sufficient/Competent Staff-Behavioral Health** – Added SUD to the intent, defined "substance use disorder," included SUD in guidance related to the need for sufficient staff and skills and competency of staff. Also, included in the list of non-pharmacological interventions for SUD is assisting with access to counseling.

Potential Action by Facility: Review policies, procedures, communications with residents, families, staff, practitioners for consistency with updated guidance, including those related to meeting mental health needs of residents to ensure there is not a conflict with residents' rights. Include SUD in facility assessment and ensure sufficient and competent staff are available to meet residents' needs.

Links: More details can be found in Appendix PP-State Operations Manual, on pages 325, 481, and 490.

Psychosocial Outcome Severity Guide

Specific Regulatory Area:

- F600- §483.12- Freedom from Abuse, Neglect, and Exploitation: Psychosocial Outcome Severity Guide

Overview of Guidance: CMS has made significant revisions to the guidance for abuse and neglect in Appendix PP. *Please refer to our member update on guidance updates related to Freedom from Abuse, Neglect and Exploitation for more details on changes.*

CMS updated the Psychosocial Outcome Severity Guide to assist in applying the reasonable person concept and determining the severity of the psychosocial outcome or potential outcome the deficiency may have had on a reasonable person in the residents' position (i.e., what degree of actual or potential harm would one expect a reasonable person in the resident's similar situation to suffer as a result of the noncompliance).

The guidance offers criteria by which applying the reasonable person concept should be considered as well as a list of situations that are likely to cause psychological harm. It also provides an update of specific examples of non-compliance as it related to the distinct levels of severity.

Form Updates: CMS added definitions for "fear," "psychosocial," and "reasonable person concept," updated the purpose of the document to provide examples of how psychosocial outcomes impact severity levels, provided instructions to surveyors on how to determine the severity of psychosocial outcomes, and how to apply the reasonable person concept. CMS also provided examples of psychosocial outcomes in consideration of severity levels.

Potential Action by Facility: Ensure all facility policies include any relevant information from the updated guidance. Be aware of the expansion and the potential implications of the portions of the Psychosocial Outcome Severity Guide specifically included in the Deficiency Categorization for §483.12(a)(1).

Links: More details can be found in Appendix PP-State Operations Manual, starting on page 86 and Psychosocial Outcome Severity Guide (This is an advanced copy that may change once released).

State Operations Manual-Chapter 5: State Investigations of Complaint Allegations

Overview of Guidance: CMS indicated that the revised guidance in Chapter 5 will strengthen the oversight of nursing home complaints and Facility Reported Incidents (FRIs) and aims to improve consistency across the State agencies in their communication to complainants. The revised guidance includes the following:

- Ensures that SAs have policies and procedures that are consistent with Federal requirements;
- Revises timeframes for investigation, to ensure that serious threats to residents' health and safety are investigated immediately;
- Requires that allegations of abuse, neglect, and exploitation be tracked in CMS' system;
- Requires that the SA report all suspected crimes to law enforcement if it has not yet been reported; and
- Removes the term "substantiate" from the SOM and instructs surveyors to specify whether non-compliance was identified during a complaint investigation.

Exhibit 23 of the SOM was revised to conform to the changes in Chapter 5. In addition, exhibits 358 and 359 provide sample templates that may be used for FRIs. These templates ensure SAs have the information needed to review and prioritize the incident for investigation.

*CMS noted that it will assess the SA's backlog and establish a target implementation date for meeting the new investigation timelines as established with this revision of Chapter 5 of the SOM at a later date, depending on the status of the PHE, and/or unique circumstances occurring in the SAs.

Links: More details can be found in QSO-22-19-NH. Advanced copies of the following documents have been released: (May be subject to change) State Operations Manual: Chapter 5-Complaint Procedures, SOM Exhibit 23-ACTS Required Fields, SOM Exhibit 358-Sample Form for Facility Reported Incidents, SOM Exhibit 359-Follow-up Investigation Report