CMS Manual System

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Department of Health & Human Services (DHHS)

Centers for Medicare & Medicaid Services (CMS)

Transmittal 169- Advanced Copy

Date:

SUBJECT: Revision to State Operations Manual (SOM) Appendix PP for Phase 2, F-Tag Revisions, and Related Issues

I. SUMMARY OF CHANGES: The revisions to the Centers for Medicare & Medicaid Services (CMS) Requirements for Participation under the Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities Final Rule caused many of the prior regulatory citations to be re-designated. As such, CMS was required to re-number the F-Tags used to identify each regulatory part. Those new F-Tags are described here

NEW/REVISED MATERIAL - EFFECTIVE DATE: Month XX, 2017
IMPLEMENTATION: Month XX,, 2017

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Entire Appendix, New F-Tags

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2016 operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	**Manual Instruction**
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

***Unless otherwise specified, the effective date is the date of service.**

Effective November 28, 2017

- *42 CFR 483.10(c)(2)-(3), F553 - Right to Participate Planning Care*
- *42 CFR 483.21(b)(1), F656- Develop/Implement Comprehensive Care Plan*
- *42 CFR 483.24, F675 - Quality of Life*
- *42 CFR 483.25(d), F689 - Accidents*
- *42 CFR 483.25(n)(1)-(4), F700- Special Care: Bedrails*
  42 CFR 483.35, 483.35(a), and 483.35(c)- F725 and F726 – Sufficient and Competent Staff
- *42 CFR 483.40(b)-(b)(1), F742- Treatment/Svc for Mental/Psychosocial Concerns*
- *42 CFR 483.70(h), F841-Responsibilities of Medical Director*
- *42 CFR 483.75 (g)(2)(ii)- F867- QAA Activities*

DEFICIENCY CATEGORIZATION

In addition to actual or potential physical harm, always consider whether psychosocial harm has occurred when determining severity level (See Appendix P, Section IV, E, Psychosocial Outcome Severity Guide).

Examples of Severity Level 4 Noncompliance Immediate Jeopardy to Resident Health or Safety include, but are not limited to:

- *The facility failed to identify the resident's medical symptom that warranted the use of a restraint. It was identified that a resident had repeated falls in his room usually after meals, when he attempted to transfer from his wheelchair to the bed. The clinical record documented that the resident repeatedly requested to be assisted to lie down after eating. Staff recorded that the belt restraint was being applied to prevent falls as he had fallen several times when attempting to stand up from the wheelchair after meals and lie down. Although the resident verbalized distress at being tied down in the wheelchair, staff stated they had informed the resident that they would put the resident in bed as soon as they finished taking care of the other residents in the dining room. It was documented that after staff left the room, the resident had attempted to stand up with the lap belt in place in the wheelchair, and as a result, the wheelchair tipped over and he sustained a fracture of his hand and had hit his head, resulting in hospitalization and treatment for multiple head and face lacerations and a subdural hematoma.*
- *The facility failed to identify bed rails as a physical restraint, failed to assess the resident for use of a bed rail, and failed to ensure that the bed rails did not pose a risk of injury from falls. A moderately cognitively impaired resident was admitted to the facility who required extensive assistance with bed mobility and transfer, and was not ambulatory. The staff recorded on admission that the resident was at high risk for falls and as a result, placed full bed rails on all open sides of the bed. No assessment was conducted related to the use of bed rails, or the use of restraints. Documentation in the record revealed that the resident crawled to the foot of her bed while the full bed rails were in a raised position, attempted to stand and walk, and fell off the right side of the bed. The resident was hospitalized for surgical repair of a femoral neck fracture.*

Examples of Severity Level 3 Noncompliance Actual Harm that is not Immediate Jeopardy include, but are not limited to:

- *The facility failed to assure that a restraint was an intervention to treat a medical symptom and was not being used for staff convenience. Facility staff had placed a*

- *Discontinues the use of the medication when the medical symptom is no longer being treated, unless reducing or eliminating the use of the medication may be clinically contraindicated.*

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

During the investigation, the surveyor may have determined that concerns may also be present with related outcome, process and/or structure requirements. The surveyor is cautioned to investigate these related requirements before determining whether non-compliance may be present. Some examples of related requirements that should be considered include the following:

- *42 CFR 483.10, 483.10(a)(1)-(2), 483.10(b)(1)-(2), F550- Resident Rights and Dignity*
- *42 CFR 483.10(c)(2)-(3), F553 - Right to Participate Planning Care*
- *42 CFR 483.21(b)(1), F656- Develop/Implement Comprehensive Care Plan*
- *42 CFR 483.35, 483.35(a), and 483.35(c)- F725 and F726 – Sufficient and Competent Staff*
- *42 CFR 483.40(b)-(b)(1), F742- Treatment/Svc for Mental/Psychosocial Concerns*
- *42 CFR 483.45(c), F756-Drug Regimen Review, Report Irregular, Act On*
- *42 CFR 483.45(d), F757- Drug Regimen is Free From Unnecessary Drugs*
- *42 CFR 483.45, F758- Psychotropic Medications*
- *42 CFR 483.70(h), F841-Responsibilities of Medical Director*
- *42 CFR 483.75 (g)(2)(ii)- F867- QAA Activities*

DEFICIENCY CATEGORIZATION

In addition to actual or potential physical harm, always consider whether psychosocial harm has occurred when determining severity level (See Appendix P, Section IV, E, Psychosocial Outcome Severity Guide).

Examples of Severity Level 4 Noncompliance Immediate Jeopardy to Resident Health or Safety includes, but is not limited to:

- *The facility administered a medication to a resident for staff convenience without a medical symptom identified. The resident was admitted to a secured area of the facility two months prior to the survey. During observations the resident was observed lying in a reclining chair, sleeping and staff had difficulty arousing the resident for meals. The staff had to provide one to one assistance to assist the resident to eat. The resident was unable to hold the utensils, and was being fed a pureed meal. The resident required a two-person assist to transfer from bed to chair and required total assistance for activities of daily living. The resident's record revealed that on admission, the resident was independent in mobility and ambulation and did not require assistance to eat. Staff interviewed stated that they had difficulty monitoring the resident as they were taking care of other residents. They stated that there were no identified interventions or activities to address these behaviors. As a result, staff requested a medication from the physician for the wandering behavior. The physician was interviewed and stated that the medication was being administered for wandering, but that he was not aware that the resident was sedated and the resident's decline in walking and activities of daily living. There was no other evidence in the resident's record or from interviews with staff and the physician that indicate a medical reason for the decline and sedating effect.*

assessment may identify psychosocial needs, such as fear, loneliness, anxiety, or depression. Interventions to address the needs must be included in the plan of care. (For concerns related to the provision of activities, refer to F679. For concerns regarding medically related social services, refer to F745.)

For concerns related to developing and implementing the care plan, refer to F656, Comprehensive Care Plans; and for revision of care plans refer to F657, Comprehensive Care Plan Revision.

Resident Care Policies

The facility in collaboration with the medical director must develop and implement resident care policies that are consistent with current professional standards of practice for not only pain management and symptom control, but for assessing residents' physical, intellectual, emotional, social, and spiritual needs as appropriate. In addition, if the facility has a written agreement with a Medicare-certified hospice, the policies must identify the ongoing collaboration and communication processes established by the nursing home and the hospice. (Refer to F841 - §483.70(h) Medical Director, or for the written agreement, to F849, 483.70(o) Hospice Services)

***NOTE**: If the resident has elected or is revoking the Medicare hospice benefit, a Significant Change in Status Assessment (SCSA) must be conducted as noted in the "Long Term Care Facility Resident Assessment Instrument User's Manual" (Version 3.0) Chapter 2:*

- *If a resident was admitted on the hospice benefit (i.e. the resident is coming into the facility having already elected the hospice benefit), the facility completes the required MDS admission assessment;*
- *If a terminally ill resident elects the hospice benefit after admission, a SCSA must be performed regardless of whether an MDS assessment was recently conducted on the resident. This is to ensure a coordinated care plan between the hospice and nursing home is in place; and*
- *A SCSA is required to be performed when a resident is receiving hospice services and decides to discontinue those services (revocation of the hospice benefit). (Refer to F637 significant change in status assessment)*

Hospice Care and Services Provided by a Medicare-certified Hospice

Hospice care and services are based upon a written agreement between the nursing home and the Medicare-certified hospice (hereafter referred to as hospice or hospice services). (See F849 - Hospice Services). This section discusses the collaborative services provided by the nursing home and the hospice for a resident who is receiving hospice care and services.

A nursing home resident at the end of life may choose to elect the Medicare hospice benefit, or may choose to continue to receive the care and services provided by the nursing home. The resident considering election of the hospice benefit must meet the hospice eligibility requirements. According to 42 CFR §418.20, in order to be eligible to elect hospice care under Medicare, an individual must be -

(a) Entitled to Part A of Medicare; and
(b) Certified as being terminally ill in accordance with §418.22.

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"Ventilator Assisted Individual (VAI)" *requires mechanical aid for breathing to augment or replace spontaneous ventilatory efforts to achieve medical stability or maintain life.* [2]

GUIDANCE § 483.25(i)

Changes in the respiratory system related to aging may lead to the development of and/or difficulty/challenges in treating diseases in the respiratory system, and may impact treatments/interventions. The Minimum Data Set (MDS) has identified the most frequent respiratory diseases/syndromes that a resident may have been admitted with or required after admission to a nursing home, including but not limited to pneumonia, asthma, chronic obstructive pulmonary disease (COPD), chronic lung disease (chronic bronchitis and restrictive lung diseases such as asbestosis), respiratory failure, shortness of breath (dyspnea) with exertion, or when sitting at rest, lying flat, or during an illness such as influenza. In addition, residents have been admitted with or previously had adult respiratory distress (ARD) syndrome, lung cancer, obstructive sleep apnea or a history of tuberculosis.

Various modalities/treatments for respiratory care identified on the MDS include respiratory treatments/therapy, oxygen therapy, the use of BiPAP/CPAP, tracheostomy and/or suctioning, and some facilities provide chest tube and mechanical ventilation services/care.

Based upon its facility assessment, the resident population, diagnosis, staffing, resources and staff skills/knowledge, the facility must determine whether it has the capability and capacity to provide the needed respiratory care/services for a resident with a respiratory diagnosis or syndrome that requires specialized respiratory care and/or services. This includes at a minimum, sufficient numbers of qualified professional staff, established resident care policies and staff trained and knowledgeable in respiratory care before admitting a resident that requires those services.

Resident Care Policies

The facility, in collaboration with the medical director, director of nurses, and respiratory therapist, as appropriate, must assure that resident care policies and procedures for respiratory care and services, are developed, according to professional standards of practice, prior to admission of a resident requiring specific types of respiratory care and services. (Also refer to F841, §483.70(h) Medical Director) The policies and procedures, based on the type of respiratory care and services provided, may include, but are not limited to:

- *Oxygen services, including the safe handling, humidification, cleaning, storage, and dispensing of oxygen;*
- *Types of respiratory exercises provided such as coughing/deep breathing and if provided therapeutic percussion/vibration and bronchopulmonary drainage;*
- *Aerosol drug delivery systems(nebulizers/metered-dose inhalers) and medications (preparation and/or administration) used for respiratory treatments;*
- *BiPAP/CPAP treatments;*
- *Delineation for all aspects of the provision of mechanical ventilation/tracheostomy care, including monitoring, oversight and supervision of mechanical ventilation, tracheostomy care and suctioning, and how to set, monitor and respond to ventilator alarms;*
- *Emergency care which includes staff training and competency for implementation of emergency interventions for, at a minimum, cardiac/respiratory complications, and*

- The facility should photocopy the faxed order, *if the faxed order is subject to fading over time*. The facsimile copy can be discarded after facility photocopies it.
- It is not necessary for a physician to re-sign the facsimile order when he/she visits the facility.

When rubber stamp signatures are authorized by the facility's *management*, the individual whose signature the stamp represents shall place in the administrative offices of the facility a signed statement to the effect that he/she is the only one who has the stamp and uses it. A list of computer codes*, identification numbers* and/or written signatures must be readily available and maintained under adequate safeguards. *Adequate safeguards may include, but are not limited to, locked in a drawer; locked in a location that is accessible only by appropriate staff as defined by the facility; or available on a protected electronic site accessible by appropriate staff as defined by the facility.*

PROBES §483.*30*(b)

- *Are physician progress notes written, signed and dated during each physician visit?*
- *For visits required by §483.30(c), do physician progress notes reflect a review of the resident's total program of care and current condition, including medications and treatments?*
- *Do physician progress notes reflect the physician's decisions about the continued appropriateness of the resident's current medical regimen?*
- *Does the physician sign and date all physician orders, during visits, with the exception of influenza and pneumococcal vaccines as outlined above?*
- *If the physician has not met the requirements of physician visits, how has the facility worked with the physician or sought alternate physician participation to assure that the resident receives appropriate care and treatment?*
- *If facility management allows for the use of rubber stamp signatures, are adequate safeguards in place to ensure the security of the stamps?*

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

If concerns regarding physician supervision of the resident's care are identified, investigate §483.30(a), F710.

For concerns related to admission orders, see §483.20(a), F635.

For concerns related to the frequency of physician visits, see §483.30(c), F712.

For concerns related to the medical director's follow-up on clinical issues or physician activities, see §483.70(h), F841.

Deficiency Categorization

Examples of Level 4, immediate jeopardy to resident health and safety, include, but are not limited to:

- *After a recent hospitalization, the facility failed to ensure the attending physician reviewed the hospital discharge summary or hospital progress notes. This lack of review of the resident's total program of care, including medications and treatments, resulted in the resident not receiving orders for new medications essential to the resident's medical*

treatment. As a result of the lack of essential medications, serious harm or death occurred or was likely to occur.

- *Facility staff contacted the physician on multiple occasions regarding the resident's elevated blood sugar levels. During a visit, the physician did not review the resident's recorded blood sugar values, or talk to the nurse regarding the resident's status or order changes to the resident's treatment regimen. The facility's failure to intervene when the physician was onsite or to seek alternate intervention resulted in the resident experiencing diabetic ketoacidosis which required hospitalization for management.*

Example of level 3, actual harm that is not immediate jeopardy, includes, but is not limited to:

- *The facility failed to ensure the physician completed a medical evaluation of a resident's condition and review the appropriateness of the resident's medical regimen. Specifically, a resident who had executed a Living Will at a time when he had capacity, indicated that it was his desire to refuse any treatment, other than comfort measures, in the event of an irreversible terminal illness from which there was no hope of recovery. Despite documentation from the pulmonologist that there was no expectation that the resident could survive without artificial means and contrary to the resident's wishes, the attending physician ordered, and the facility provided, aggressive, life-sustaining treatment including artificial ventilation and feeding. As a result, the resident received unwanted treatment in the facility.*

Examples of Level 2, no actual harm, with potential for than more than minimal harm, that is not immediate jeopardy, include, but are not limited to:

- *While the physician reviewed areas identified as high priority for the physician to address in the resident's program of care, the facility failed to ensure the physician reviewed the resident's total program of care or wrote, signed and dated progress notes with each visit.*
- *The facility failed to ensure physician progress notes that documented the physician's involvement in the assessment and care of residents were completed as required.*

Example of Level 1, no actual harm with potential for no more than a minor negative impact on the resident, includes, but is not limited to:

- *During a physician visit, the physician failed to sign and date new orders, however the orders were followed as intended and no adverse outcome was experienced by the resident.*

F712
§483.*30*(c) Frequency of physician visits
§483.*30*(c)(1) The residents must be seen by a physician at least once every 30 days for the first 90 days after admission, and at least once every 60 thereafter.

§483.*30*(c)(2) A physician visit is considered timely if it occurs not later than 10 days after the date the visit was required.

§483.*30*(c)(3) Except as provided in paragraphs (c)(4) and (f) of this section, all required physician visits must be made by the physician personally.

discomfort did not interfere with the resident's participating in activities or performing activities of daily living.
- As a result of failure to identify medications that should not be crushed for administration, a resident received a *newly ordered* medication that was crushed, contrary to the manufacturer's specifications. While the resident did not experience any harm, the potential for harm *to the resident* was present.

Severity Level 1: No Actual Harm with Potential for Minimal Harm
Severity Level 1 does not apply for this regulatory requirement because the failure of the facility to provide routine and emergency drugs and biologicals to its residents creates the potential for more than minimal harm. This provision, along with pharmaceutical procedures and services are essential aspects of both process and outcome requirements.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION
Examples of some of the related requirements that should be considered when *concerns have* been identified include the following:

- *42 CFR 483.12, F602, Right to be Free from Misappropriation/Exploitation*
  - *Determine if the facility diverted a resident's medication, including, but not limited to, controlled substances for staff use or personal gain. If it is determined that a resident's medications were diverted, the State Agency must make referrals to appropriate agencies, such as local law enforcement; Drug Enforcement Administration; State Board of Nursing; State Board of Pharmacy; the state Medicaid Fraud Control Unit, and possibly the State licensure board for Nursing Home Administrators.*
- 42 CFR 483.*35*, *F725,* Sufficient Staff *and F726, Competent Staff*
  - Determine if the facility had *competent* staff in sufficient numbers *available* to provide medications on a 24-hour basis to meet the needs of the residents, based upon the comprehensive assessment and care plan.
- 42 CFR 483.*70*(*h*), *F841,* Medical Director
  - Determine whether the medical director, in collaboration with the facility and the pharmacist, and based on current standards of practice, helped the facility develop procedures for the safe and accurate provision of medications to meet the needs of the residents.
- 42 CFR 483.75*(g), F867, Quality Assessment and Assurance*
  - *If concerns regarding pharmaceutical services have been identified, determine* whether the quality assessment and assurance committee has identified *and responded to* those concerns, as appropriate, *and* has developed, implemented, and monitored appropriate plans of action to correct identified quality deficiencies.
- 42 CFR 483.*70*(*i*), *F842, Medical* Records
  - Determine whether the facility has maintained clinical records, including medication administration, in accordance with accepted professional standards and practices that are complete, accurately documented, and readily accessible.

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Severity Level 1 does not apply for this regulatory requirement because the failure to perform the MRR according to the regulatory provisions creates the potential for more than minimal harm.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION
Examples of some of the related requirements that should be considered when *concerns have* been identified include the following:

- 42 CFR 483.*10*(*g*)*(14), F580,* Notification of Changes
  - Review whether *a member of the IDT* contacted the attending physician regarding a significant change in the resident's condition in relation to a potential adverse consequence of a medication, or a need to alter treatment significantly (i.e., a need to discontinue an existing form of treatment due to adverse consequences, or to commence a different form of treatment).
- 42 CFR 483.*45*(*d*), *F757,* Unnecessary *Drugs and 42 CFR 483.45*(*e*), *F758, Psychotropic Medications*
  - Review whether the resident is receiving any medications without an indication for use, in excessive dose or duration, with inadequate monitoring, or in the presence of any adverse consequences that indicate that the dose should be reduced or discontinued.
- 42 CFR 483.*30*(a), *F710,* Physician Supervision
  - Review whether the attending physician supervised the resident's medical treatment, including assessing the resident's condition, identifying the need for and continuing use of medication to address the resident's needs, and identifying and addressing adverse consequences related to medications.
- 42 CFR 483.*30*(b), *F711* Physician Visits *and 42 CFR 483.30(c), F712, Frequency of Physician Visits*
  - Review whether the attending physician or another designated practitioner reviewed the resident's total program of care including the beneficial and adverse effects of medications and treatment, and provided a relevant progress note at each visit.
- 42 CFR 483.*45(a), (b)(1)-(3)*, *F755,* Pharmacy Services
  - Review whether the licensed pharmacist has provided consultation regarding all aspects of pharmaceutical services.
- 42 CFR 483.*70*(*h*), *F841,* Medical Director
  - Review whether the medical director, when requested by the facility, interacted with the attending physician regarding an inadequate response to identified or reported potential medication irregularities and adverse consequences.

F757
§483.*45(d)* Unnecessary Drugs—General.
Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used—

§483.*45(d)(1)* In excessive dose (including duplicate *drug* therapy); or

§483.*45(d)(2)* For excessive duration; or

If during the course of this review, the surveyor needs to contact the attending physician regarding questions related to the medication regimen, it is recommended that the facility's staff have the opportunity to provide the necessary information about the resident and the concerns to the physician for his/her review prior to responding to the surveyor's inquiries.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

Examples of some of the related requirements that may be considered when *concerns have* been identified include the following:

- 42 CFR 483.*10(g)(14), F580,* Notification of Changes
  - Review whether the facility contacted the attending physician regarding a significant change in the resident's condition in relation to a potential adverse consequence of a medication, or if the resident has not responded to medication therapy as anticipated and/or indicated.
- 42 CFR 483.10 (*c*), *F552, Planning and Implementing Care*
  - Determine whether the resident was advised of her/his medical condition and therapy and was informed about her/his treatment including medications and the right to refuse treatments.
- 42 CFR 483.24(c), F679, Activities
  - Review whether the facility provides activities that address a resident's needs and may permit discontinuation or reduction of psychotropic medications. Review also whether adverse consequences of medications interfere with a resident's ability to participate in activities.
- 42 CFR 483.24(*a*), *F676, Activities of Daily Living*
  - Review whether the facility had identified, evaluated, and responded to a new or rapidly progressive decline in function, development or worsening of movement disorders, increased fatigue and activity intolerance that affected the resident's ADL ability in relation to potential medication adverse consequences.
- 42 CFR 483.*40, F740, Behavioral Health Services*
  - Review whether the facility had identified, evaluated, and responded to a change in behavior and/or psychosocial changes, including depression or other mood disturbance, distress, restlessness, increasing confusion, or delirium in relation to potential medication adverse consequences.
- 42 CFR 483.*30(a), F710,* Physician Supervision
  - Review if the attending physician supervised the resident's medical treatment, including assessing the resident's condition and medications, identifying the clinical rationale, and monitoring for and addressing adverse consequences.
- 42 CFR 483.*30(b), F711,* Physician Visits *and 42 CFR 483.30(c), F712, Frequency of Physician Visits*
  - Review if the attending physician or designee reviewed the resident's total program of care and wrote, signed, and dated progress notes covering pertinent aspects of the medication regimen and related issues.
- 42 CFR 483.*70(h), F841,* Medical Director
  - Review whether the medical director, when requested by the facility, interacted with the attending physician regarding a failure to respond or an inadequate response to identified or reported potential medication irregularities and adverse consequences;

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DEFINITIONS §483.50(a)(1)(i)

"Laboratory service " *as referenced in §493.2,* is any examination of materials derived from the human body for purposes of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings.

GUIDANCE §483.50(a)(1)(i)

If a facility provides its own laboratory services *or performs any laboratory tests directly (e.g., blood glucose monitoring, etc.)* the provisions of 42 CFR Part 493 apply and the facility must have a *current Clinical Laboratory Improvement Amendment (CLIA)* certificate appropriate for the level of testing performed within the facility.

Facilities collecting and/or preparing specimens and not performing testing are not considered to be providing laboratory services and do not need to meet the requirements of 42 CFR Part 493.

Surveyors should only verify that the facility has a current CLIA certificate and not attempt to determine compliance with the requirements in 42 CFR part 493; rather, refer questions or concerns to CLIA surveyors.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

If noncompliance with §483.50(a)(1)(i) has been identified, the surveyor may have identified concerns with related structure, process, and/or outcome requirements. If an additional concern has been identified, the surveyor must investigate the identified concern. Do not cite any related or associated requirements before first conducting an investigation to determine compliance or non-compliance with the related or associated requirement. Examples include, but are not limited to, the following:

- *§483.30 - Physician Services*
- *§483.35 - Nursing Services*
- *§483.70(g) - Use of Outside Resources*
- *§483.70(h) - Medical Director*
- *§483.75 - Quality Assessment and Performance Improvement*

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F770, the surveyor's investigation will generally show that the facility failed to do any one or more of the following:

- *Have a current CLIA certificate appropriate for the level of testing it performs;* ***OR***
- *Meet the needs of residents with regard to the quality and/or timeliness of providing laboratory services and reporting laboratory results:* ***OR***
- *Provide or obtain laboratory services, to meet the needs of its residents.*

F771

§483.50(a)**(1) The facility must provide or obtain laboratory services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.**

(ii) If the facility provides blood bank and transfusion services, it must meet the applicable requirements for laboratories specified in part 493 of this chapter.

Effective November 28, 2017

If facility staff failed to properly identify the resident receiving the blood/blood products or failed to monitor the status of the resident during and/or after a transfusion, it should be cited under Quality of Care at F684.

Nursing home surveyors should not evaluate compliance with the requirements in 42 CFR part 493. Questions or concerns must be referred to State Agency or Regional Office CLIA surveyors to determine whether or not the nursing home provided transfusion services in accordance with the requirements for specified in part 493. If it is verified by State Agency or Regional Office CLIA surveyors that requirements in part 493 were not met cite a deficiency under this Tag F771.

The facility must have procedures for preventing transfusion reactions and promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory that provided the blood or blood products and as appropriate, to Federal and State authorities.

If the facility provides transfusion services, determine whether they have policies, procedures, and protocols for:

- *(a) Transfusion processes that include adverse reaction identification and corrective actions to be taken;*
- *(b) Investigating all transfusion reactions; and*
- *(c) Reporting all transfusion reactions to the appropriate officials and agencies.*

Review the facility's procedures to ensure their process includes the positive identification of the blood or blood components to be transfused into the intended recipient.

*If a facility has not established policies as referenced above **do not** cite here but cite under §483.70(d) Governing body, F837. Also consider requirements at §483.70(h) Medical director, F841 for the responsibility to implement resident care policies.*

If a transfusion will be performed during the survey, observe the transfusion preparation process. Observe to determine whether or not a positive recipient verification and a second independent recipient verification were conducted prior to the initiation of the transfusion. If a surveyor has reason to suspect a resident is having an adverse reaction to a transfusion or the transfusion itself is not being properly administered, the surveyor shall immediately notify the facility Director of Nursing and the facility administrator.

Assure that blood and blood components are stored in a clean and orderly environment which ensures the integrity of the component. Whole blood, red blood cells, and thawed plasma shall be stored in accordance with §493.1103(c). If there are questions or concerns, consult with CLIA surveyors. If blood and blood components are not stored to ensure the integrity of these components do not cite here, cite under §483.45(h) - Storage of drugs and biologicals.

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F 771, the surveyor's investigation will generally show that the facility failed to:

- *Determine whether staff have assessed, care-planned, and provided services to manage a resident's oral/dental pain.*

§483.35(a), F725, Sufficient and Competent Nursing Staff

- *Determine whether based on the resident's needs the facility had qualified staff in sufficient numbers and with the required competencies to identify dental concerns and provide necessary routine resident dental care.*

§483.40(d), F745, Social Services

- *Determine whether the facility provided medically-related social services by addressing any unmet needs related to dental/denture or oral care.*

§483.45(d), F757, Unnecessary Medications

- *Determine if the resident is experiencing an adverse dental/oral consequence of a medication which indicated the dose should have been reduced or discontinued, or any combination of the reasons stated in §§483.45(d)(1)-(5).*

§483.70(f)(5), F842, Medical Records

- *Determine whether the resident's records accurately and completely document the resident's dental/oral status and the care and services provided in accordance with current professional standards and practices.*

§483.70(g), F840, Use of Outside Resources

- *Determine whether dental services provided met professional standards and principles and the timeliness of those services.*

§483.70(h), F841, Medical Director

- *Determine if the medical director was involved in the development of dental/oral health policies/procedures and the coordination of care both on-site as well as availability of off-site providers and addressed any quality concerns.*

F800
§483.60 *Food and nutrition services.*
The facility must provide each resident with a nourishing, palatable, well-balanced diet that meets *his or her* daily nutritional and special dietary needs*, taking into consideration the preferences of each resident.*

INTENT §483.*60* - *T*o ensure that facility staff support the nutritional well-being of the residents while respecting an individual's right to make choices about his or her diet.

GUIDANCE §483.*60*
This requirement *expects that there is ongoing* communication and coordination *among and* between *staff within all* departments to ensure that the resident assessment, care plan and actual food *and nutrition* service*s* meet *each resident's* daily nutritional and dietary needs *and choices.*

While it may be challenging to meet every residents' individual preferences, incorporating a residents' preferences and *dietary* needs will ensure residents are offered meaningful choices in *meals/*diets that are nutritionally adequate and satisfying to the individual. *Reasonable efforts to accommodate these choices and preferences must be addressed by facility staff.*

Also, cite this Tag if there *are overall* system*s* issue*s* relating to *how the facility manages and executes its* food *and nutrition* services.

Effective November 28, 2017

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION §483.*60*(h)(1)-(3)

During the investigation of F811, the surveyor may have identified concerns with additional requirements related to outcome, process, and/or structure requirements. The surveyor is cautioned to investigate these related requirements before determining whether non-compliance may be present at these other tags. Examples of some of the related requirements that may be considered when non-compliance has been identified include, but are not limited to, the following:

- §483.*10*, F*550*, *Resident Rights*
  - Determine if staff are attentive and responsive to the resident's requests, and if they provide assistance to eat in a manner that respects the resident's dignity, meets needs in a timely manner, and minimizes potential feelings of embarrassment, humiliation, and/or isolation related to inability to assist themselves with food or fluid intake.
- *§483.10(c), F552 and F578, Planning and Implementing Care*
  - *Determine if the facility addressed the resident's right to choose or refuse treatment, including receiving assistance to eat or drink by a paid feeding assistant.*
- §483.20(b), F*636*, Comprehensive Assessments
  - Review whether facility staff initially and periodically conducted a comprehensive, accurate assessment of the resident's ability to eat and drink with or without assistance and/or identified a condition that makes the resident ineligible for this service.
- §483.*21(b)(1)*, F*656*, Comprehensive Care Plans
  - Review whether facility staff developed *or implemented* a comprehensive care plan that was based on the assessment of the resident's conditions, needs, and behaviors, and was consistent with the resident's goals in order to provide assistance with nutrition and hydration as necessary.
- §483.*21(b)*(2)(iii), F*657,* Comprehensive Care Plan Revision
  - Determine if the care plan was reviewed and revised periodically, as necessary, related to eligibility to eat and drink with assistance of a paid feeding assistant.
- §§483.25*(g)(1)-(3),* F*692*, *Nutrition/Hydration Status*
  - Review if facility staff had identified, evaluated, and responded to a change in nutritional parameters, anorexia, or unplanned weight loss, dysphagia, and/or swallowing disorders in relation to the resident's ability to eat.
  - Review if facility staff had identified, evaluated, and responded to a change in the resident's ability to swallow liquids.
- §483.25 (b)*(4)*, F*676*, ADL Assistance for Dependent Residents
  - Determine if staff identified and implemented appropriate measures to provide food and fluids for the resident who cannot perform relevant activities of daily living.
- §483.*35*(a), F*725*, Sufficient Staff
  - Determine if the facility has qualified staff in sufficient numbers to provide assistance to eat or drink to those residents who require such assistance. For residents who are not eligible to receive assistance from paid feeding assistants, determine if there are sufficient *staff* to provide this assistance to these residents in a timely fashion.
- §483.*70(h),* F*841*, Medical Director
  - Determine whether the medical director collaborates with the facility to help develop, implement, and evaluate resident care policies and procedures based on current

Effective November 28, 2017

F841
§483.*70(h)* Medical director.
§483.*70(h)*(1) The facility must designate a physician to serve as medical director.

§483.*70(h)*(2) The medical director is responsible for—
(i) Implementation of resident care policies; and
(ii) The coordination of medical care in the facility.

DEFINITIONS §483.*70*(h)
"Medical director" *means* a physician who oversees the medical care and other designated care and services in a health care organization or facility. Under these regulations, the medical director is responsible for coordinating medical care and helping to implement and evaluate resident care policies that reflect current *professional* standards of practice.

"Physician*/practitioner" (physician assistant, nurse practitioner, clinical nurse specialist)* means the *individual* who has responsibility for the medical care of a resident.

"Current *professional* standards of practice" refers to approaches to care, procedures, techniques, treatments, etc., that are based on research and/or expert consensus and that are contained in current manuals, textbooks, or publications, or that are accepted, adopted or promulgated by recognized professional organizations or national accrediting bodies.

"Resident care policies" *refers to* the facility's overall goals, directives, and governing statements that direct the delivery of care and services to residents consistent with current *professional* standards of practice.

GUIDANCE §483.*70*(h)
If the medical director does not hold a valid license to practice in the State where the nursing home is located refer to F839 - §483.70(f) Staff qualifications. The facility must designate a physician to serve as medical director (unless waived per §488.56(b) by CMS).

The facility must identify how the medical director will fulfill his/her responsibilities to effectively implement resident care policies and coordinate medical care for residents in the facility. This may be included in the medical director's job description or through a separate facility policy. Facilities and medical directors have flexibility on how all the duties will be performed. However, the facility must ensure all responsibilities of the medical director are effectively performed, regardless of how the task is accomplished or the technology used, to ensure residents attain or maintain their highest practicable physical, mental, and psychosocial well-being. For example, some, but not all, duties may be conducted remotely using various technologies (e.g., phone, email, fax, telehealth, etc., that is compliant with all confidentiality and privacy requirements).

It is important that the medical director's responsibilities require *that he/she* be knowledgeable about current *professional* standards of practice in caring for long term care residents, and about how to coordinate and oversee *other* practitioners.

If the medical director is also an attending physician, there should be a process to ensure there are no concerns with the individual's performance as a physician (i.e., otherwise, the medical director is monitoring his/her own performance). If there are concerns regarding his/her performance, the facility's administration should have a process for how to address these situations.

While medical directors who work for multi-facility organizations, *such as* corporate or regional offices, may *be involved in* policy development, the *facility's individual policies must be based on the facility's unique environment and its resident's needs, and not based on a broad, multi-facility structure.*

Although the medical director is not required to sign policies, the facility must be able to show that the development, review, and approval of resident care policies included his/her input.

Medical director responsibilities must include their participation in:

- *Administrative decisions including recommending, developing and approving facility policies related to residents care. Resident care includes the resident's physical, mental and psychosocial well-being;*
- *Issues related to the coordination of medical care identified through the facility's quality assessment and assurance committee and other activities related to the coordination of care;*
- *Organizing and coordinating physician services and services provided by other professionals as they relate to resident care;*
- *Participate in the Quality Assessment and Assurance (QAA) committee or assign a designee to represent him/her. (Refer to F865).*

Note: Having a designee does not change or absolve the Medical Director's responsibility to fulfill his or her role as a member of the QAA committee, or his or her responsibility for overall medical care in the facility.

In addition, the medical director responsibilities should include, but are not limited to:

- *Ensuring the appropriateness and quality of medical care and medically related care;*
- *Assisting in the development of educational programs for facility staff and other professionals;*
- *Working with the facility's clinical team to provide surveillance and develop policies to prevent the potential infection of residents. Refer to Infection Control requirement at §483.80;*
- *Cooperating with facility staff to establish policies for assuring that the rights of individuals (residents, staff members, and community members) are respected;*
- *Supporting and promoting person-directed care such as the formation* of advance directives, end-of-life care, and provisions that enhance resident decision making, including choice regarding medical care options*;*
- Identifying performance expectation*s* and facilitating feedback to physicians and other health care practitioners regarding their performance and practices;

- Discussing and intervening (as appropriate) with a health care practitioner regarding medical care that is inconsistent with current standards of care; and
- *Assisting in developing* systems to monitor the performance of the health care practitioners *including* mechanisms for communicating and resolving issues related to medical care *and* ensuring that other licensed practitioners (e.g., nurse practitioners) who may perform physician-delegated tasks act within the regulatory requirements and within the scope of practice as defined by State law.

PROCEDURES §483.*70*(h)

If a deficiency has been identified regarding a resident's care, also determine if the medical director had knowledge or should have had knowledge of a problem with care, or physician services, or lack of resident care policies and practices that meet current professional standards of practice and failed:

- *To get involved or to intercede with other physicians or practitioners in order to facilitate and/or coordinate medical care; and/or*
- *To provide guidance for resident care policies.*

Interview the medical director about his/her:

- *Involvement in assisting facility staff with resident care policies, medical care, and physician issues;*
- Understanding of *his/her* roles, *responsibilities* and functions and the extent *to which he/she receives support from facility management* for these roles and functions;
- *Process for providing feedback to physicians and other health care practitioners regarding their performance and practices, including discussing and intervening (as appropriate) with a health care practitioner regarding medical care that is inconsistent with current professional standards of care;*
- Input into the facility's scope of services including the capacity to care for residents with complex or special care needs, such as dialysis, hospice or end-of-life care, respiratory support with ventilators, intravenous medications/fluids, dementia and/or related conditions, or problematic behaviors or complex mood disorders;
- *His/her participation or involvement in conducting the Facility Assessment and the Quality Assessment and Assurance (QAA) Committee.*

Interview facility leadership (e.g., Administrator, Director of Nursing, and others as appropriate) about how *they interact* with the medical director related to the coordination of medical care, the facility's clinical practices *and concerns or issues with other physicians or practitioners.*

Also, refer to §483.30 Physician Services for more information.

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F841, the surveyor's investigation will generally show that the facility failed to do any of the following:

- *Designate a physician to serve as medical director;* ***or***
- *Ensure the medical director fulfilled his/her responsibility for the implementation of resident care policies or the coordination of medical care in the facility.*

Effective November 28, 2017

DEFICIENCY CATEGORIZATION

- ***An example of Level 4, immediate jeopardy to resident health and safety, includes, but is not limited to:***
  - *The facility's medical director was aware of and did not intervene when a health care practitioner continued over several months to provide inappropriate medical care for infection prevention to a resident that was inconsistent with current professional standards of care. As a result this resident's health continued to decline, and was hospitalized with a severe infection.*

- ***An example of Level 3, Actual harm (physical or psychological) that is not immediate jeopardy, includes, but is not limited to:***
  - *The Director of Nursing repeatedly requested the medical director's assistance in coordinating medical care with attending physicians for residents receiving psychotropic medications. In particular there were several physicians who had a known history of failing to provide justification for continued use of these medications and not attempting a gradual dose reduction for the residents under his/her care. As a result of the medical director's failure to intervene, several residents continued to receive these medications without medical/clinical justification. Based on record review and interviews with residents, their representative's and staff, there was no supporting evidence to indicate that an Immediate Jeopardy situation existed. However, due to the continuation of the use of these psychotropic medications, the residents withdrew from activities and from eating in the dining room. This caused decreased appetite and substantial weight loss for several residents. Actual harm, both physical and psychosocial was indicated. Unnecessary Medications, was also cited for not ensuring the residents were receiving the lowest dose possible.*

- ***An example of Level 2 - No actual harm with a potential for more than minimal harm that is not immediate jeopardy, includes but is not limited to:***
  - *The administrator had made multiple requests for the medical director to meet with physicians to ensure that they were familiar with the facility's resident care policies. At the time of the survey the medical director was interviewed and stated that she had not yet had an opportunity to introduce herself to or meet with physicians. Although no actual harm occurred, due the medical director's failure to ensure implementation of resident care policies, the potential for more than minimal harm existed.*

Level 1 - Severity 1 does not apply for this regulatory requirement

F842

§483.20(f)(5) Resident-identifiable information.

(i) A facility may not release information that is resident-identifiable to the public.

(ii) The facility may release information that is resident-identifiable to an agent only in accordance with a contract under which the agent agrees not to use or disclose the information except to the extent the facility itself is permitted to do so.

§483.*70(i)* Medical records.

throughout the facility, and oversight of the QAPI program when fully implemented. Additionally, the committee must develop and implement corrective action, and monitor to ensure performance goals or targets are achieved, and revising corrective action when necessary.

The committee should be composed of staff who understand the characteristics and complexities of the care and services delivered by each unit, and/or department. The QAA Committee must be composed of, at a minimum:

- *The director of nursing (DON),*
- *The Medical Director or his/her designee, and*
- *At least three other staff, one of whom must be the facility's administrator, owner, board member, or other individual in a leadership role who has knowledge of facility systems and the authority to change those systems.*

Facilities may have a larger committee than required by the regulation. *Residents and families may provide a valuable perspective to committee efforts, although their participation is not required. Representation by staff with responsibility for direct care and services provides perspectives that are valuable in identifying, analyzing and correcting problems in resident care areas. Additionally, departments such as maintenance, housekeeping, laundry services, and other service areas such as the business office should be provided opportunities to participate in the committee, when relevant performance data is discussed.* Consideration should be given as to how committee information is provided to and from staff who may not be members of the committee, but whose responsibilities include oversight of departments or services.

As noted above, the Medical Director is a required member of the QAA committee. This requirement stems from the Medical Director's responsibility for the overall medical care provided and the implementation of all resident care policies in the facility. There should be evidence of meaningful participation by the Medical Director in the QAPI program, such as reporting on trends identified during oversight and review of reports such as the report of irregularities from the medication regimen review, and other oversight activities. For additional guidance related to the Medical Director's role, see 483.70(h), Medical Director, F841.

The Medical Director's designee must not be another required member, such as the DON, but may be a NPP. The designee must have knowledge of the facility's policies, procedures and practices so that he/she can fully participate and can add value to the QAA committee comparable to the medical director. Having a designee for the QAA committee, does not change or absolve the Medical Director's responsibility to fulfill his or her role as a member of the QAA committee, or his or her responsibility for overall medical care in the facility. In addition, there must be evidence of communication of the content of the meeting to the Medical Director, with his/her acknowledgement of this information. The Medical Director, in conjunction with the QAA committee, may arrange for real-time alternative methods of participation, such as videoconferencing and teleconference calls. For additional guidance related to the Medical Director's responsibilities, see 483.70(h) Medical Director, F841.

Frequency of Meetings

QAA committee meetings must be held at least quarterly or more often as necessary to fulfill the

Effective November 28, 2017

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION
For staff competency concerns, refer to the following F tags:

- *F725 or 726, §483.35(a),(c) for Nursing Services;*
- *F741, §483.40 for any Behavioral Health staff caring for residents with dementia or a history of trauma and/or post-traumatic stress disorder;*
- *F801, §483.60(a) for Food and Nutrition staff; and*
- *F839, §483.70(f), Administration for any other staff not referenced above.*

If the surveyor has concerns about 1) the overuse of transmission-based ("isolation") precautions, 2) the inappropriate transferring of rooms unnecessarily; or 3) the inappropriate use of PPE such as gloves when used unnecessarily, where residents indicate they are "untouchable," dirty or unclean, review under §483.10(a)(1), F550, Resident Rights (Dignity) or §483.24, F675, Quality of Life.

For concerns related to possible involuntary seclusion, refer to §483.12 (a)(1), F603.

Data from injectable, scheduled drug tracking should be regularly reviewed and discrepancies or unusual access patterns are investigated including whether residents should be screened for exposure to bloodborne pathogens (refer to 483.45, F755, Pharmacy Services for further information on reconciliation concerns).

For concerns related to the QAA committee's responsibility to identify or correct quality deficiencies, which may include systemic infection control concerns, refer to 483.75(g)(2)(ii), F867, QAA Activities.

For concerns related to the medical director's role in responsibility for care, refer to §483.70(h), F841, Medical Director.

F881
§483.*80(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:

§483.*80(a)(3) An antibiotic stewardship program that includes antibiotic use protocols and a system to monitor antibiotic use.*

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.*