

**Summary of sections mentioning
“Medical Director”
in the:
Revision to State Operations Manual (SOM)
Appendix PP Guidance to Surveyors for
Long Term Care Facilities**

This summary was prepared by using the search term “Medical Director” in the original 696 page document. Only 5 pages of the resulting 22 pages are in the Medical Director section. For ease of reference, the term **“Medical Director”** has been boldfaced and underlined.

The summary should not be regarded as all inclusive. Some references will have been inadvertently overlooked, especially if “Medical Director” was spelt incorrectly in the original document.

The summary is designed to be saved on a Smartphone so you will have the regs immediately available. Colorado Ch 5 is appended at the end.

To get an overview, read the index p2-4 and the main Medical Director Section p16-20. Page number in the original 696 page document precedes each section.

Italicized red print indicates that the guidance is new.

Comments are welcome. Please email to Malcolm Fraser at denvermeddir@gmail.com

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(iii) The SNF or NF must have a designated medical director who is responsible for implementing care policies and coordinating medical care, and who is directly

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Attending Physician - changing

GUIDANCE §§483.10(d)(1)-(5)

The right to choose a personal physician does not mean that a resident is required to do so. It also does not mean that the physician the resident chose is obligated to provide service to the resident. *If a resident or his or her representative declines to designate a personal physician or if a physician of the resident's choosing fails to fulfill their responsibilities, as specified in §483.30, F710, Physician Services, or elsewhere as required in these regulations, facility staff may choose another physician after informing the resident or the resident's representative.* Before consulting an alternate physician, the **Medical Director** *must have a discussion with* the attending physician. Only after a failed attempt to work with the attending physician or mediate differences *may* facility *staff* request an alternate physician.

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Abuse

***§483.12(a)* The facility must—**

***§483.12(a)(1)* Not use verbal, mental, sexual, or physical abuse, corporal punishment, or involuntary seclusion;**

GUIDANCE

NOTE: For purposes of this guidance, “staff” includes employees, the medical director, consultants, contractors, and volunteers. Staff would also include caregivers who provide care and services to residents on behalf of the facility, students in the facility's nurse aide training program, and students from affiliated academic institutions, including therapy, social, and activity programs.

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Consent

483.10(b)(3)-(7) [F551] for concerns related to the exercise of the resident's rights by the resident representative.

NOTE: CMS is not requiring facilities to adopt a specific approach in determining a resident's capacity to consent. However, the facility administration, nursing and **Medical Director** may wish to consider establishing an ethics committee, that includes legal consultation, in order to assist in the development and implementation of policy related to aspects of quality of life and/or care, advance directives, intimacy and relationships.

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Medications - harm

- ‘ 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).

...identified as a concern, , whether he/she notified the practitioner, Director of Nurses, and/or Medical Director and what was the response; and what is the facility’s process for notifying the pharmacist when initiating a medication for a change in the resident’s condition, such as when there are expressions or indications of distress, or other changes in a resident’s psychosocial status.

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Medications - unnecessary

Facility Review

It may be necessary to interview the Medical Director regarding medications that are not required to treat the resident’s medical symptoms result in the resident being subdued, sedated, or withdrawn or limited in his/her functional capacity.

Determine whether the Quality Assessment & Assurance committee is aware of psychotropic medication used to address resident behavioral symptoms, whether there is sufficient, qualified staff trained to provide interventions for behavioral symptoms, and supervision of staff to assure that medications are only used to treat a medical symptom and do not have the effect of convenience or discipline.

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POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION.....

- ‘ 42 CFR 483.70(h), F841-Responsibilities of Medical Director
- ‘ 42 CFR 483.75 (g)(2)(ii)- F867- QAA Activities

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Refusal for Care

If unable to resolve situations where a resident’s refusal for care poses a risk to the resident’s or others’ health or safety, the facility administration, nursing and Medical Director may wish to convene an ethics meeting, which includes legal consultation, in order to determine if the facility can meet the resident’s needs, or if the resident should be transferred or discharged.

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If a facility does not permit a resident who went on therapeutic leave to return, the facility must meet the requirements for a facility-initiated discharge at F622. Because the facility was able to care for the resident prior to therapeutic leave, documentation related to the basis for discharge must clearly show why the facility can no longer care for the resident.

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Care Plan

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)

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Hospice

If there is a conflict between the hospice and the resident's attending physician/practitioner regarding the care plan, there must be communication between the hospice and the nursing home regarding the issue. This communication should be timely and include the hospice Medical Director and the nursing home Medical Director as well as other pertinent hospice and facility staff, as needed..

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Treatment Protocol

A facility should be able to show that its treatment protocols are based upon current professional standards of practice and are in accord with the facility's policies and procedures as developed with the Medical Director's review and approval.

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Therapy

Administrative Review

The facility must develop resident care policies in collaboration with the Medical Director, director of nurses, and as appropriate, physical/occupational therapy consultant. This includes policies on restorative/rehabilitative treatments/services, based on professional standards of practice, including who may provide specific treatments and modalities according to applicable State law and/or practice acts. Refer to F841, Medical Director. These policies should also address equipment use, cleaning, and storage.

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Indwelling *Urinary* Catheter Use

If the facility provides care for a resident with an indwelling catheter, in collaboration with the Medical Director and director of nurses, and based upon current professional standards of practice, resident care policies and procedures must be developed and implemented that address catheter care and services, including but not limited to:

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TECHNICAL AND NUTRITIONAL ASPECTS OF FEEDING TUBES

It is important that staff providing care and services to the resident who has a feeding tube are aware of, competent in, and utilize facility protocols regarding feeding tube nutrition and care. These protocols are required to be developed with the Medical Director in order to assure staff implement and provide care and services according to resident needs and professional standards of practice.

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Resident Care Policies and Respiratory Care

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:

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Dialysis

Dialysis and Medical Director

A nursing home, that provides dialysis treatments, in collaboration with the nursing home Medical Director and the dialysis facility, must develop dialysis specific policies/procedures, based upon current standards of practice. This includes the care of a resident receiving dialysis services whether in the facility or at an offsite location. (Refer to F841 – Responsibilities of Medical Director.) At a minimum, these policies must include, but are not limited to the followin

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Physician Services

F710

§483.30 Physician Services

A physician must personally approve in writing a recommendation that an individual be admitted to a facility. Each resident must remain under the care of a physician. A physician, physician assistant, nurse practitioner, or clinical nurse specialist must provide orders for the resident's immediate care and needs.

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Fax (Physician) Orders/Signatures

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.*

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(PHYSICIAN PROGRESS NOTES) -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?*

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Physician Supervision

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 condition.*

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Elopement

DEFICIENCY CATEGORIZATION §483.40

An example of Severity Level 4 Non-compliance: Immediate Jeopardy to Resident Health or Safety includes, but is not limited to:

- ‘ *The surveyor was able to determine through an interview with a certified nurse aide (CNA), that the resident often became anxious and agitated in the evenings and attempted to leave the facility on multiple occasions over the last three months. Last week, he left the facility for 30 minutes before being found by facility staff. While outside the nursing home, he fell, resulting in several abrasions and a laceration on his forehead and right knee, which required transfer to acute care. Review of the resident’s record neglected to provide documentation of potential underlying causes for his anxiety and agitation. Nor did his care plan include any interventions to reduce his expressions of distress and deter elopement. This was confirmed through interviews with the social worker, director of nursing, and **Medical Director**. The attending physician also confirmed that the IDT had not discussed potential causes for the resident’s anxiousness and agitation and had not developed interventions to resolve these concerns.*

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PHARMACEUTICAL SERVICES PROCEDURES

The pharmacist, in collaboration with the facility and **Medical Director**, helps develop and evaluate the implementation of pharmaceutical services procedures that address the needs of the residents, are consistent with state and federal requirements, and reflect current standards of practice.

The pharmacist is responsible for helping the facility obtain and maintain timely and appropriate pharmaceutical services that support residents’ healthcare needs, *goals, and quality of life* that are consistent with current standards of practice, and that meet state and federal requirements. This includes, but is not limited to, collaborating with the facility and **Medical Director** to:

- ‘ Develop, implement, evaluate, and revise (as necessary) the procedures for the provision of all aspects of pharmaceutical services, *including procedures to support resident quality of life such as those that support safe, individualized medication administration programs*;
- ‘ Coordinate pharmaceutical services if and when multiple pharmaceutical service providers are utilized (e.g., pharmacy, infusion, hospice, prescription drug plans [PDP])

- ‘ Develop intravenous (IV) therapy procedures if used within the facility (consistent with state requirements) which may include: determining competency of staff and facility- based IV admixture procedures that address sterile compounding, dosage calculations, IV pump use, and flushing procedures;
- ‘ Determine (in accordance with or as permitted by state law) the contents of the emergency supply of medications and monitor the use, replacement, and disposition of the supply;

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POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

- ‘ 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.*

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Drug Regimen Review

F756

§483.45(c) Drug Regimen Review.

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

§483.45(c)(2) *This review must include a review of the resident’s medical chart.*

§483.45(c)(4) The pharmacist must report any irregularities to the attending physician **and the facility’s Medical Director** and director of nursing, and these reports must be acted upon.

- (i) *Irregularities include, but are not limited to, any drug that meets the criteria set forth in paragraph (d) of this section for an unnecessary drug.*
- (ii) *Any irregularities noted by the pharmacist during this review must be documented on a separate, written report that is sent to the attending physician and the facility’s Medical Director and director of nursing and lists, at a minimum, the resident’s name, the relevant drug, and the irregularity the pharmacist identified.*
- (iii) *The attending physician must document in the resident’s medical record that the*

identified irregularity has been reviewed and what, if any, action has been taken to address it. If there is to be no change in the medication, the attending physician should document his or her rationale in the resident's medical record.

INTENT §483.45(c)(1), (2), (4), and (5)

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

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Transitions in Care

Transitions in care such as a move from home or hospital to the nursing home, or vice versa, increase the risk of medication-related issues. Medications may be added, discontinued, omitted, or changed. It is important, therefore, to review the medications. Currently, safeguards to help identify medication issues *around transitions in care and throughout a resident's stay* include:

- ‘ The pharmacist performing the medication regimen review, *which includes a review of the resident's medical record*, at least monthly;
- ‘ *The pharmacist reporting any irregularities in a separate written report to the attending physician, Medical Director, and director of nursing; and*
- ‘ *The attending physician reviewing and acting on any identified irregularities.*

Transitions in Care (contd)

MRR policies and procedures should also address, but not be limited to:

- ‘ *MRRs for residents who are anticipated to stay less than 30 days;*
- ‘ *MRRs for residents who experience an acute change of condition and for whom an immediate MRR is requested after appropriate staff have notified the resident's physician, the Medical Director, and the director of nursing about the acute change.*

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Pharmacists Findings

The pharmacist's findings are considered part of each resident's *medical* record *and as such are available to the resident/representative upon request*. If documentation of the findings is not in the active record, it is maintained within the facility and is readily available for review.

Establishing a consistent location for the pharmacist's findings and recommendations can facilitate communication with the attending physician, the director of nursing, the remainder of the *IDT*, the Medical Director, the resident and his or her legal representative, *the* ombudsman, and surveyors.

Response to Irregularities Identified in the MRR

The medical record must show documentation that the attending physician reviewed any irregularities identified by the pharmacist. For those issues that require physician intervention,

the *attending* physician either accepts and acts upon the report and recommendations or rejects all or some of the report *and should document his or her rationale of why the recommendation is rejected in the resident's medical record*. It is not acceptable for *an attending* physician to

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Pharmacy Letter/MRR- Attending Physician

The facility should have a procedure for how to resolve situations where:

- ‘ *The attending physician does not concur with or take action on identified irregularities, and;*
- ‘ *The attending physician is also the Medical Director.*

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F756, the surveyor's investigation will generally show that:

- ‘ The pharmacist failed to identify or report medications in a resident's regimen that could (as of the review date) be causing or associated with new, worsening, or progressive signs and symptoms; *or*
- ‘ The pharmacist failed to identify and report the absence of any explanation as to why or how the benefit of a medication(s) with potential for clinically significant adverse consequences outweighs the risk; *or*
- ‘ *The attending physician failed to document that he or she reviewed the pharmacist's identified irregularities and/or failed to document the action taken or not taken to address the irregularities; or*

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Pharmacy Letter/MRR and Medical Director follow up

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 noncompliance that demonstrate severity at Level 4 include, but are not limited to:

- ‘ Despite identifying irregularities with the potential for serious harm or death *in a resident's medication regimen*, the pharmacist did not report the irregularities to the attending physician, *DON, and Medical Director* or action was *not* taken on the irregularities reported.

Examples of Level 3, Actual harm (physical or psychosocial) that are not immediate jeopardy, include, but are not limited to:

- ‘ The *attending* physician failed to act in response to the pharmacist's MRR which identified the indefinite continuation of an antidepressant in a resident who had no history of depression, who had been placed on the antidepressant without an evaluation to confirm presence of depression, and whose function and mood were not monitored while getting the medication for months. The resident experienced clinically significant adverse consequences such as falls *without serious injury*, constipation, or change in weight.

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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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Diagnostic Services/Physician Notification

F777

§483.50(b)(2) The facility must—

- (i) Provide or obtain radiology and other diagnostic services only when ordered by **a physician; physician assistant; nurse practitioner or clinical nurse specialist in accordance with State law, including scope of practice laws.**
- (ii) Promptly notify the **ordering physician, physician assistant, nurse practitioner, or clinical nurse specialist of results that fall outside of clinical reference ranges in accordance with facility policies and procedures for notification of a practitioner or per the ordering physician's orders.**

GUIDANCE §483.50(b)(2)(i)(ii)

For purposes of this requirement “promptly” means that results shall be relayed, with little or no delay to the ordering physician, physician assistant, nurse practitioner, or clinical nurse specialist according to facility policies and procedures for notification and the medical orders.

Facility policies and procedures should be developed in consultation with the Medical Director and follow current standards of practice. Such policies may include defining categories where follow-up is required, the urgency of reporting specific concerns, and a process for monitoring the effectiveness of communication to ensure that communication was received, and delegation by the ordering provider to a qualified on-call individual as appropriate.

If results were not acted upon in a timely manner by the physician; physician assistant; nurse practitioner; clinical nurse specialist; or by facility staff as ordered, consider additional review for possible deficient practices under Medical Director, Nursing Services, Quality of Care or Quality of Life requirements. 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.

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Dental/Oral 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.

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Resident Care Policies

§483.70(h), F841, 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

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Competency - staff

PROCEDURES §483.70(f)

If there is reason to doubt the qualifications *or competencies* of **any personnel, including** temporary, agency *and contracted individuals*, *verify qualifications* with the appropriate *State registry or practitioner professional licensing body*.

NOTE: Only cite F839 for any staff not referenced above or if any professional staff is not licensed, certified, or registered in accordance with applicable State laws. This includes any physician or practitioner including the Medical Director that does not hold a valid license to practice in the State where the Nursing Home is located.

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Hospice

NOTE: *The nursing home regulations at F710 - Physician Supervision), requires that “The facility must ensure that another physician supervises the medical care of residents when their attending physician is unavailable.” According to the hospice CoPs at §418.64(a) and (a)(3) Standard: Physician services, “The hospice Medical Director, physician employees, and contracted physician(s) of the hospice, in conjunction with the patient's attending physician, are responsible for the palliation and management of the terminal illness and conditions related to the terminal illness...(3) If the attending physician is unavailable, the Medical Director, contracted physician, and/or hospice physician employee is responsible for meeting the medical needs of the patient.”*

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Main Medical Director Section

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.*

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Medical Director is the Attending Physician

*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 expectations and facilitating feedback to physicians and other health care practitioners regarding their performance and practices;*

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- ‘ *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.*

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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

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Facility Termination

If CMS or the State Medicaid Agency involuntarily terminates the facility's participation in the Medicare and/or Medicaid programs, the facility's notifications must be no later than the date specified by CMS or the State Medicaid Agency. Notice must still be given if the facility remains open but CMS or the State Medicaid Agency involuntarily terminates the facility's participation in the Medicare and/or Medicaid programs.

In addition, the administrator or someone acting on behalf of the administrator should notify in writing, prior to the impending closure of the facility, the:

- ‘ Facility's **Medical Director**;
- ‘ Residents' primary physician;
- ‘ CMS Regional Office (RO); and
- ‘ State Medicaid Agency.

Although not required, facilities are encouraged to provide notice to other entities that are impacted, such as employees, union representatives, vendors, community partners, hospitals, home health agencies, dialysis facilities and other providers as early as possible.

*The facility's notifications should be developed with input from the facility's **Medical Director** and other management staff, and include details from the closure plan for the safe and orderly transfer, discharge or adequate relocation of all residents.*

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Facility Closure

*When conducting an onsite survey prior to the impending closure, tour the facility and interview staff including the **Medical Director**, residents, and family. Determine their involvement in and/or knowledge of the facility closure plans and the resident transfer procedures. Determine through observation, interview, and record review, as applicable:*

- ‘ That the delivery of resident care and services are continuing to be provided, monitored and supervised based upon the assessed needs and choices of each resident. If problems are noted it may be necessary to further investigate and review other quality of care regulations as appropriate. Do not cite quality of care issues under the Facility Closure regulations;
- ‘ Whether written notices were provided timely and that the notice included the expected date of the resident's transfer to another facility or other setting; and

- *How the facility involved the resident, his/her legal representative or other responsible party, and the resident's primary physician to determine the resident's goals, preferences and needs in planning for the services, location and setting to which they will be mov*

P604/696

Hospice

§483.70(o)(3) Each LTC facility arranging for the provision of hospice care under a written agreement must designate a member of the facility's interdisciplinary team who is responsible for working with hospice representatives to coordinate care to the resident provided by the LTC facility staff and hospice staff. The interdisciplinary team member must have a clinical background, function within their State scope of practice act, and have the ability to assess the resident or have access to someone that has the skills and capabilities to assess the resident.

The designated interdisciplinary team member is responsible for the following:

- A. (i) Ensuring that the LTC facility communicates with the hospice Medical Director, the patient's attending physician, and other practitioners participating in the provision of care to the patient as needed to coordinate the hospice care with the medical care provided by other physicians.*
- B. If there is a conflict between orders given by hospice and the resident's attending physician/practitioner, there must be communication between the nursing home and the hospice regarding the issue.*

This communication should include the nursing home Medical Director and the hospice Medical Director as well as other pertinent staff as needed.

Notifying Hospice Regarding Clinical Changes

If there is a conflict between the nursing home and the hospice regarding the course of hospice care or level of service, there must be communication between the nursing home and the hospice regarding the issue. This communication should include the nursing home Medical Director and the hospice Medical Director as well as other pertinent staff, as needed.

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Quality Assurance

F868

§483.75(g) Quality assessment and assurance.

§483.75(g)(1) A facility must maintain a quality assessment and assurance committee consisting at a minimum of:

- (i) The director of nursing services;**
- (ii) The Medical Director or his/her designee;**
- (iii) At least three other members of the facility's staff, at least one of who must be the administrator, owner, a board member or other individual in a leadership role; and**
- (iv) The infection preventionist.**

[483.75(g)(1)(iv) Implemented beginning November 28, 2019(Phase 3)]

§483.75(g)(2) The quality assessment and assurance committee reports to the facility's governing body, or designated person(s) functioning as a governing body regarding its activities, including implementation of the QAPI program required under paragraphs (a)

through (e) of this section. The committee must:

- (i) Meet at least quarterly and as needed to coordinate and evaluate activities under the QAPI program, such as identifying issues with respect to which quality assessment and assurance activities, including performance improvement projects required under the QAPI program, are necessary.**

DEFINITIONS §483.75(g)(1)-(2)

“Non-physician practitioner (NPP)”: *A nurse practitioner (NP), clinical nurse specialist (CNS), or physician assistant (PA).*

GUIDANCE §483.75(g)(1)-(2)

QAA Committee

QAA committee responsibilities include identifying and responding to quality deficiencies throughout the facility, and oversight of the QAPI program when fully implemented. Additionally, the committee must develop and implement corrective action, and monitor 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 ..
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Infection Control

INFECTION CONTROL POLICIES AND PROCEDURES

The facility must develop and implement written policies and procedures for the provision of infection prevention and control. The facility administration and Medical Director should ensure that current standards of practice based on recognized guidelines are incorporated in the resident care policies and procedures.

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Infection Prevention and Control Program Incidents

SYSTEM OF RECORDING IPCP INCIDENTS

A facility must develop and implement a system for recording incidents identified under the facility's IPCP and the corrective actions taken by the facility based on the investigation of the incidents. A facility-identified incident (e.g., HAI) may include the spread of disease due to errors in infection prevention and control. The facility's system should include defining, identifying, analyzing, and reporting incidents related to failures in infection control practices to the director of nursing, Medical Director, and the QAA committee. These may include but are not limited to the following:

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QAPI concerns re Medical Director

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.

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Infection Control

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.*

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Antibiotic Stewardship

Antibiotic Stewardship Program

As summarized by the CDC⁶³, the core elements for antibiotic stewardship in nursing homes include:

- ‘ *Facility leadership commitment to safe and appropriate antibiotic use;*
- ‘ *Appropriate facility staff accountable for promoting and overseeing antibiotic stewardship;*
- ‘ *Accessing pharmacists and others with experience or training in antibiotic stewardship;*
- ‘ *Implement policy(ies) or practice to improve antibiotic use;*
- ‘ *Track measures of antibiotic use in the facility (i.e., one process and one outcome measure);*
- ‘ *Regular reporting on antibiotic use and resistance to relevant staff such as prescribing clinicians and nursing staff; and*
- ‘ *Educate staff and residents about antibiotic stewardship.*

*The facility must develop an antibiotic stewardship program which includes the development of protocols and a system to monitor antibiotic use. This development should include leadership support and accountability via the participation of the **Medical Director**, consulting pharmacist, nursing and administrative leadership⁶³ and individual with designated responsibility for the infection control program if different.*

The Antibiotic Stewardship Program in Relation to Pharmacy Services

The assessment, monitoring, and communication of antibiotic use shall occur by a licensed pharmacist in accordance with §483.45(c), F756, Drug Regimen Review. A pharmacist must perform a medication regimen review (MRR) at least monthly, including review of the medical

record and identify any irregularities, including unnecessary drugs.

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F881, the surveyor’s investigation will generally show that the facility failed to do any one or more of the following:

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

XX

The END