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Department of Health &
Human Services (DHHS)
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Transmittal

Date:

SUBJECT: Guidance to Surveyors of Long Term Care Facilities

I. SUMMARY OF CHANGES: State Operations Manual, Appendix PP, F520, Quality Assessment and Assurance – Guidance to Surveyors is entirely replaced with new Guidance, attached.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: Upon Issuance
IMPLEMENTATION DATE: Upon Issuance

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	Appendix PP/F520, Quality Assessment and Assurance

III. FUNDING: Medicare contractors shall implement these instructions within their current 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.

F520

(Rev. XX)

§483.75(o) *Quality Assessment and Assurance*

(1) *A facility must maintain a quality assessment and assurance committee consisting of –*

- (i) *The director of nursing services;*
- (ii) *A physician designated by the facility; and*
- (iii) *At least 3 other members of the facility's staff.*

(2) *The quality assessment and assurance committee –*

- (i) *Meets at least quarterly to identify issues with respect to which quality assessment and assurance activities are necessary; and*
- (ii) *Develops and implements appropriate plans of action to correct identified quality deficiencies.*

(3) *State or the Secretary may not require disclosure of the records of such committee except insofar as such disclosure is related to the compliance of such committee with the requirements of this section.*

(4) *Good faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions.*

INTENT: 483.75(o) Quality Assurance and Assessment

The intent of this requirement is that:

- *The facility has an ongoing quality assessment and assurance (QAA) committee that includes designated key members and that meets at least quarterly; and*
- *The committee identifies quality deficiencies and develops and implements plans of action to correct these quality deficiencies, including monitoring the effect of implemented changes and making needed revisions to the action plans.*

Definitions

Definitions are provided to clarify terms related to the requirement for a quality assessment and assurance committee.

- *“Quality Assessment” is an evaluation of a process and/or outcomes of a process to determine if a defined standard of quality is being achieved.*
- *“Quality Assurance” is the organizational structure, processes, and procedures designed to ensure that care practices are consistently applied and the facility meets or exceeds an expected standard of quality. Quality assurance includes the implementation of principles of continuous quality improvement.*
- *“Quality Deficiencies” are potential markers of quality that the facility considers to be in need of investigating and which, after investigation, may or may not represent a deviation from quality that results in a potential or actual undesirable outcome. The term “quality deficiency” in this regulation is meant to describe a deficit or an area for improvement. This term is not synonymous with a deficiency cited by surveyors.*
- *“Quality Improvement (QI)” is an ongoing interdisciplinary process that is designed to improve the delivery of services and resident outcomes.*

NOTE: Many facilities have changed their terminology for the QAA processes to “quality improvement (QI).” However, in these guidelines, we will continue to use the designation of QAA, as specified in the requirement. The elements are comparable regardless of the terminology.

Overview

QAA is a management process that is ongoing, multi-level, and facility-wide. It encompasses all managerial, administrative, clinical, and environmental services, as well as the performance of outside (contracted or arranged) providers and suppliers of care and services. Its purpose is continuous evaluation of facility systems with the objectives of:

- *Keeping systems functioning satisfactorily and consistently including maintaining current practice standards;*
- *Preventing deviation from care processes from arising, to the extent possible;*
- *Discerning issues and concerns, if any, with facility systems and determining if issues/concerns are identified; and*
- *Correcting inappropriate care processes.*

Several studies conducted under the auspices of the U.S. Department of Health and Human Services have examined quality of care and quality of life in nursing homes.^{1,2}

These studies have concluded that QAA committees provide an important point of accountability for ensuring both quality of care and quality of life in nursing homes. The QAA committees represent key internal mechanisms that allow nursing homes opportunities to deal with quality deficiencies in a confidential manner.

Resources are available that recommend processes and standards to develop and enhance quality improvement programs. Some Web site resources include:

- *American Medical Directors Association (www.amda.com);*
- *American Health Care Association (www.ahca.org);*
- *American College of Physicians Quality Indicators for Assessing Care of Vulnerable Elders (www.acponline.org/sci-policy/acove/);*
- *American Geriatric Society (www.americangeriatrics.org);*
- *Agency for Healthcare Research and Quality (www.ahrq.gov);*
- *Medicare Quality Improvement Community (www.Medqic.org);*
- *American Association of Homes and Services for the Aging (www.aahsa.org); and*
- *The American Health Quality Association (www.ahqa.org).*

NOTE: References to non-CMS sources or sites on the Internet are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services. CMS is not responsible for the content of pages found at these sites. The URL addresses were current as of the date of this publication.

The guidance below includes sections that describe facility responsibilities to meet the various aspects of the QAA requirement, including:

- *The composition of the QAA committee and the minimum frequency of committee meetings;*
- *The committee's monitoring of systems and identification of concerns with the quality of facility systems; and*
- *Modification and correction of facility systems, when needed, including monitoring the effect of action plans.*

QAA COMMITTEE FUNCTIONS

Key aspects of the QAA requirements include the specifications that the facility must have a QAA committee, that this committee must include certain staff members, and that the

committee must meet at least quarterly. The QAA committee is responsible for identifying whether quality deficiencies are present (potential or actual deviations from appropriate care processes or facility procedures) that require action. If there are quality deficiencies, the committee is responsible for developing plans of action to correct them and for monitoring the effect of these corrections. These functions of the QAA committee are described below.

Committee Composition and Frequency of Meetings

The regulation states that the QAA committee must include the director of nursing, a physician, and three other staff. These additional members may include:

- The administrator (facilities with effective QAA committees include members who have knowledge of facility systems and the authority to change those systems, including the administrator or assistant administrator due to their responsibility to manage the facility, and make changes to facility systems);*
- The medical director (part of the medical director's responsibility (see F501)) is to guide the facility's development and implementation of resident care policies and coordination of medical care. If the medical director is not a committee member, exchange of information with the medical director enhances the functioning of the QAA committee);*
- Staff with responsibility for direct resident care and services, such as nursing aides, therapists, staff nurses, social workers, activities staff members; and*
- Staff with responsibility for the physical plant, such as maintenance, housekeeping, and laundry staff.*

NOTE: Facilities may have a larger committee than required by the regulation. Consideration should be given as to how committee information is provided to consultants who may not be members of the committee, but whose responsibilities include oversight of departments or services.

Meetings of the QAA committee must be held at least quarterly or more often as the facility deems necessary to fulfill committee functions and operate effectively. The Committee should maintain a record of the dates of all meetings and the names/titles of those attending each meeting.

Identification of Quality Deficiencies

Facilities can collect and analyze data about their performance from various sources that may help them to identify quality deficiencies. These may include information from reports such as open and closed record audits, facility logs and tracking forms, incident reports, consultants' reports, and other reports as part of the QAA function. Quality deficiencies related to facility operations and practices are not only related to those that cause negative outcomes, but also may be directed toward enhancing quality of care and

quality of life for residents. The committee responds to quality deficiencies and serves a preventative function by reviewing and improving systems.

Records of the committee meetings identifying quality deficiencies, by statute, may not be reviewed by surveyors unless the facility chooses to provide them. However, the documents the committee used to determine quality deficiencies are subject to review by the surveyors.

NOTE: A State or the Secretary may not require disclosure of the records of the QAA committee except insofar as such disclosure is related to the compliance of the QAA committee with the regulations.

If concerns, especially repeat survey deficiencies, have not been identified by the facility's QAA committee, this may be an indication that the committee is not performing the functions required by this regulation.

Development of Action Plans

In order to fulfill the regulatory mandate, the facility's QAA committee, having identified the root causes which led to their confirmed quality deficiencies, must develop appropriate corrective plans of action. Action plans may include, but are not limited to, the development or revision of clinical protocols based on current standards of practice, revision of policies and procedures, training for staff concerning changes, plans to purchase or repair equipment and/or improve the physical plant, and standards for evaluating staff performance.

Implementation of Action Plans and Correction of Identified Quality Deficiencies

The facility's action plans to address quality deficiencies may be implemented in a variety of ways, including: staff training and deployment of changes to procedures; monitoring and feedback mechanisms; and processes to revise plans that are not achieving or sustaining desired outcomes. The committee may delegate the implementation of action plans to various facility staff and/or outside consultants.

ENDNOTES

¹ *Institute of Medicine (2001). Improving the Quality of Long-Term Care. Washington, DC: National Academy Press.*

² *Office of Inspector General (2003) Quality Assurance Committees in Nursing Homes, Baltimore, MD: U.S. Department of Health and Human Services (OEI-01-01-00090).*

INVESTIGATIVE PROTOCOL

QUALITY ASSESSMENT AND ASSURANCE

Objectives

- *To determine if the facility has a QAA committee consisting of the director of nursing, a physician designated by the facility, and at least three other staff members; and*
- *To determine if the QAA committee:*
 - *Meets at least quarterly (or more often, as necessary);*
 - *Identifies quality deficiencies; and*
 - *Develops and implements appropriate plans of action to address identified quality deficiencies.*

Use

Use this protocol for all initial and standard surveys. Also, use it as necessary on revisits and abbreviated standard surveys (complaint investigations).

Procedures

During Offsite Survey Preparation (see Appendix P, Task 1), the survey team must review information about the facility prior to the survey. Sources include, at a minimum:

- *Quality Measure/Quality Indicator Reports;*
- *The OSCAR 3 Report (includes a 4-year history of the facility's deficiencies from standard surveys, revisits, and complaint surveys). The survey team should determine if the facility has had repeat deficiencies as well as recent serious deficiencies (Levels F and H and above); and*
- *Information from the State ombudsman.*

The regulation states that good faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions. The facility is not required to release the records of the QAA committee to the surveyors to review, and the facility is not required to disclose records of the QAA committee beyond those that demonstrate compliance with the regulation (F520). However the facility may choose such disclosure if it is the facility's only means of showing the composition and functioning of the QAA committee. If the facility has provided the records for surveyor review, this information may not be used to cite deficiencies unrelated to the QAA committee requirement. It is recommended that surveyors not review QAA records (if provided) until after they complete their investigations of other tags.

If the survey team's review of the QAA committee records reveals that the committee is making good faith efforts to identify quality deficiencies and to develop action plans to correct quality deficiencies, this requirement (F520) should not be cited. However, if the survey team had already independently (not through use of the records) identified noncompliance in the same areas as those that have been selected by the QAA committee, the team is expected to cite the noncompliance for the other requirements.

Throughout the survey, the survey team may become aware of other concerns regarding the delivery of care and services that may reflect that the QAA committee is not functioning in identifying ongoing and current quality deficiencies.

During the daily meetings, the team discusses concerns about facility compliance that they are identifying through observations, interviews, and record reviews. The information from the entrance conference about the composition and meetings of the QAA committee is reviewed and relayed to the team.

The team coordinator assigns a surveyor to obtain information from the person the facility has designated as responsible for the QAA committee. The surveyor should interview this designated person to determine:

- How the committee identifies current and ongoing issues for committee action. This could include how they monitor the provision of care and services on an ongoing basis, and how they ascertain from residents and/or their families information regarding the facility's provision of care and services, in addition to facility staff throughout the various departments, and outside consultants and/or suppliers and providers of care;*
- The methods the committee uses to develop action plans; and*
- How current action plans are being implemented, including: staff training; deployment of changes to procedures; monitoring and feedback mechanisms that have been established; and, for any plans that are not achieving or sustaining desired outcomes to correct the deficiencies, the process underway for revision to these plans.*

The assigned surveyor should interview staff in various departments to determine if they know how to bring an issue to the attention of the QAA committee.

If, during the course of the survey, the survey team identifies noncompliance at a particular requirement, the assigned surveyor should interview the designated person responsible for the QAA committee to determine whether the committee knew of or should have known of the issues related to the noncompliance. The assigned surveyor should determine if the committee had considered the quality deficiency and if it was determined that an action plan was needed. If so, the surveyor determines whether the committee developed and implemented any action plans to address these concerns. The survey team should verify that the action plans that are described are actually implemented, and that staff are providing care and services according to the directives of these action plans.

DETERMINATION OF COMPLIANCE (Task 6, Appendix P)

NOTE: Although the literature of QAA and QI provides various definitions of the facility's achievement of quality, surveyors will need to determine the facility's compliance based on the language of this regulation.

Synopsis of Regulation (F520)

This requirement has two aspects: the facility must have a committee composed of certain key members that meets at least quarterly (or more often, as necessary); and the committee functions to develop and implement appropriate plans of actions to correct identified quality deficiencies.

Criteria for Compliance

The facility is in compliance if:

- It has a functioning QAA committee, consisting of the director of nursing, a physician, and at least three other staff members, that meets at least quarterly; and*
- The committee:*
 - Identifies quality deficiencies; and*
 - Develops and implements appropriate plans of actions.*

If not, cite F520.

Noncompliance for F520

After completing the investigative protocol, the survey team determines whether or not compliance with the regulation exists. Examples of noncompliance may include, but are not limited to, the following:

- Lack of a physician member of the committee;*
- The committee met only twice during the previous year;*
- The action plan to correct a quality deficiency regarding food temperatures was not being followed by staff in the dietary department, and food was not being served at proper temperatures; or*
- An action plan was developed to correct a problem with inadequate assessment of root causes of falls. Staff did not implement the plan, and residents continued to experience serious falls.*

- *An action plan that was developed to correct the issue of resident falls did not take account of the root cause of the falls being overuse of sedative type medications. The plan was to increase the use of restraints which was an inappropriate action plan.*

DEFICIENCY CATEGORIZATION (Part V, Appendix P)

Once the survey team has determined that noncompliance exists, the team will select the appropriate level of severity for the deficiency using the guidance below.

The survey team must identify a relationship between noncompliance at other regulatory requirements and the facility's failure to have a functional QAA committee. The key elements for severity determination for F520 are as follows:

1. *Presence of harm/negative outcome(s) or potential for negative outcomes because of a failure of the QAA committee structure or function*

Actual or potential harm/negative outcome for F520 may include, but is not limited to:

- *Failure of the QAA committee to identify and implement an action plan to reduce of medication errors committed by agency staff, resulting in the noncompliance for medication errors based on the resident receiving the wrong medication, which resulted in the resident experiencing insulin shock; or*
- *Failure of the QAA committee to develop an action plan to address assessment of the cause of a pattern of recent falls of several residents, resulting in noncompliance at the accident requirement based on several residents sustaining avoidable falls with bruises but no fractures.*

2. *Degree of harm (actual or potential) related to the noncompliance*

Identify how the facility practices caused, resulted in, allowed, or contributed to the actual or potential for harm:

- *If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; and*
- *If harm has not yet occurred, determine how likely is the potential for serious injury, impairment, death, compromise, or discomfort to occur to the resident.*

3. *The immediacy of correction required*

Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for Tag F520. First, the team must rule out whether Severity Level 4,

Immediate Jeopardy to a resident's health or safety, exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q.)

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety

Immediate Jeopardy is a situation in which the facility's noncompliance with one or more requirements of participation:

- Has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident; and*
- Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventive or corrective measures.*

NOTE: The death or transfer of a resident who was harmed or injured as a result of facility noncompliance does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to correct the noncompliance which allowed or caused the immediate jeopardy.

In order to select Severity Level 4 for this regulation, the surveyor must be able to identify the relationship between the facility's noncompliance cited at Severity Level 4 at other regulatory tags, and the failure of the QAA Committee to function effectively. In order to select Severity Level 4 at F520, both of the following must be present:

- Deficiency(ies) has been cited at Severity Level 4 in other tags that are related to QAA committee failure; and*
- The facility does not have a QAA committee, or the facility's QAA committee failed to develop and implement appropriate plans of action to correct identified quality deficiencies.*

Severity Level 3: Actual Harm that is Not Immediate Jeopardy

In order to select Severity Level 3 for this regulation, the surveyor must be able to identify the relationship between the facility's noncompliance cited at Severity Level 3 at other regulatory tags, and the failure of the QAA Committee to function effectively. In order to select Severity Level 3 at F520, both of the following must be present:

- Deficiency(ies) has been cited at Severity Level 3 in other tags that are related to QAA committee failure; and*
- The facility does not have a QAA committee, or the facility's QAA committee failed to develop and implement appropriate plans of action to correct identified quality deficiencies.*

Severity Level 2: No Actual Harm with Potential for More than Minimal Harm that is Not Immediate Jeopardy

In order to select Severity Level 2 for this regulation, the surveyor must be able to identify the relationship between the facility's noncompliance cited at Severity Level 2 at other regulatory tags, and the failure of the QAA Committee to function effectively. In order to select Severity Level 2 at F520, both of the following must be present:

- Deficiency(ies) has been cited at Severity Level 2 in other tags that are related to QAA committee failure; and*
- The facility does not have a QAA committee, or the facility's QAA committee failed to develop and implement appropriate plans of action to correct identified quality deficiencies.*

Severity Level 1: No Actual Harm with Potential for Minimal Harm

Severity Level 1 should be selected if any of the following circumstances are present:

- The facility does not have a QAA committee, and there have been no other deficiencies cited above Severity Level 1; or*
- The facility has a QAA committee that has failed to meet the regulatory specifications for the composition of the committee and/or the frequency of committee meetings, and there have been no deficiencies cited above Severity Level 1; or*
- The facility's QAA committee meets regulatory specifications for committee membership and frequency of meetings, and deficiencies have been cited at Severity Level 1 in other tags. In order to select Severity Level 1 in this case, the surveyor must be able to identify the relationship between the facility's noncompliance cited at Severity Level 1 at other tags, and the failure of the QAA committee to function effectively.*