The team coordinator must follow the steps below:

1. *Obtain the PBJ Staffing Data Report.*

2. *Identify if the facility triggered for "Failed to Submit Data for the Quarter."*
    a. *If the facility failed to submit the required PBJ Staffing Data, F851 must be cited as a Severity and Scope of "F".*

***NOTE:** It should be an **extremely rare** circumstance when a facility is not cited if the PBJ data report indicates the facility did not submit PBJ data for the quarter. If there are questions or the team thinks the facility should not be cited, the team coordinator must email NHStaffing@cms.hhs.gov for assistance. CMS will respond by the end of the next business day and copy the CMS location.*

Additionally, if facilities have questions on submitting PBJ data, refer them to the CMS Electronic Staffing Data Submission Payroll-Based Journal Policy Manual for submission guidelines. Please see the following link for more information: *https://www.cms.gov/medicare/quality/nursing-home-improvement/staffing-data-submission*

For questions related to *PBJ*, providers, or other stakeholders should email NHStaffing@cms.hhs.gov.

KEY ELEMENTS OF NONCOMPLIANCE
To cite deficient practice at F851, the surveyor's investigation will generally show that the facility failed to do any one of the following:

- *Submit the required staffing information based on payroll data in a uniform format; **or***

- Complete data for the entire reporting period, such as hours paid for all required staff, each day; **or**

- Provide accurate data; **or**

- Provide data by the required deadline.

Note: Noncompliance at F851 focuses on the submission of staffing data. If the surveyor identifies concerns related to *registered nurse (RN) coverage eight hours a day, licensed nurse (LN) coverage 24-hour a day, or* sufficient staffing, surveyors *should* investigate these concerns using the Sufficient and Competent Staff Critical Element Pathway, and guidance at §483.35 Nursing Services (F725 & F727).

F865
(Rev. 211; Issued: 02-03-23; Effective: 10-21-22; Implementation: 10-24-22)

§483.75(a) Quality assurance and performance improvement (QAPI) program. Each LTC facility, including a facility that is part of a multiunit chain, must develop, implement, and maintain an effective, comprehensive, data-driven QAPI program that focuses on indicators of the outcomes of care and quality of life. The facility must:

§483.75(a)(1) Maintain documentation and demonstrate evidence of its ongoing QAPI program that meets the requirements of this section. This may include but is not limited to systems and reports demonstrating systematic identification, reporting, investigation, analysis, and prevention of adverse events; and documentation demonstrating the development, implementation, and evaluation of corrective actions or performance improvement activities;

§483.75(a)(2) Present its QAPI plan to the State Survey Agency no later than 1 year after the promulgation of this regulation;

§483.75(a)(3) Present its QAPI plan to a State Survey Agency or Federal surveyor at each annual recertification survey and upon request during any other survey and to CMS upon request; and

§483.75(a)(4) Present documentation and evidence of its ongoing QAPI program's implementation and the facility's compliance with requirements to a State Survey Agency, Federal surveyor or CMS upon request.

§483.75(b) Program design and scope.
A facility must design its QAPI program to be ongoing, comprehensive, and to address the full range of care and services provided by the facility. It must:

§483.75(b)(1) Address all systems of care and management practices;

§483.75(b)(2) Include clinical care, quality of life, and resident choice;

§483.75(b)(3) Utilize the best available evidence to define and measure indicators of quality and facility goals that reflect processes of care and facility operations that have been shown to be predictive of desired outcomes for residents of a SNF or NF.

§483.75(b) (4) Reflect the complexities, unique care, and services that the facility provides.

§483.75(f) Governance and leadership.
The governing body and/or executive leadership (or organized group or individual who assumes full legal authority and responsibility for operation of the facility) is responsible and accountable for ensuring that:

§483.75(f)(1) An ongoing QAPI program is defined, implemented, and maintained and addresses identified priorities.

§483.75(f)(2) The QAPI program is sustained during transitions in leadership and staffing;
§483.75(f)(3) The QAPI program is adequately resourced, including ensuring staff time, equipment, and technical training as needed;

§483.75(f)(4) The QAPI program identifies and prioritizes problems and opportunities that reflect organizational process, functions, and services provided to residents based on performance indicator data, and resident and staff input, and other information.

§483.75(f)(5) Corrective actions address gaps in systems, and are evaluated for effectiveness; and

§483.75(f)(6) Clear expectations are set around safety, quality, rights, choice, and respect.

§483.75(h) Disclosure of information.
A State or the Secretary may not require disclosure of the records of such committee except in so far as such disclosure is related to the compliance of such committee with the requirements of this section.

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

INTENT
These requirements are intended to ensure that long-term care facilities (including multi-unit chains) implement a comprehensive QAPI program which addresses all the care and unique services a facility provides.

DEFINITIONS
"Governing body" refers to individuals such as facility owner(s), Chief Executive Officer(s), or other individuals who are legally responsible to establish and implement policies regarding the management and operations of the facility.

"Indicators" are measurement(s) of performance related to a particular care area or service.

"Quality Assurance and Performance Improvement (QAPI)" is the coordinated application of two mutually-reinforcing aspects of a quality management system: Quality Assurance (QA) and Performance Improvement (PI). QAPI takes a systematic, interdisciplinary, comprehensive, and data-driven approach to maintaining and

improving safety and quality in nursing homes while involving residents and families in practical and creative problem solving.

"Quality Assurance (QA)" is the specification of standards for quality of service and outcomes, and systems throughout the organization for assuring that care is maintained at acceptable levels in relation to those standards. QA is on-going, both anticipatory and retrospective in its efforts to identify how the organization is performing, including where and why facility performance is at risk or has failed to meet standards.

"Performance Improvement (PI)" (also called Quality Improvement - QI) is the continuous study and improvement of processes with the intent to improve services or outcomes, and prevent or decrease the likelihood of problems, by identifying areas of opportunity and testing new approaches to fix underlying causes of persistent/systemic problems or barriers to improvement. PI in nursing homes aims to improve processes involved in health care delivery and resident quality of life. PI can make good quality even better.

GUIDANCE

QAPI is a type of quality management program which takes a systematic, interdisciplinary, comprehensive, and data-driven approach to maintaining and improving safety and quality. An interdisciplinary approach encompasses all managerial, and clinical, services, which includes care and services provided by outside (contracted or arranged) providers and suppliers.

The purpose of a QAPI program is to ensure continuous evaluation of facility systems with the objectives of:

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

Program and Documentation
Each facility must develop, implement, and maintain an effective, comprehensive, data-driven QAPI program that focuses on indicators of the outcomes of care and quality of life.

The facility must maintain and be able to provide documentation and evidence of its ongoing QAPI program, which meets the requirements of §483.75.

Demonstration of compliance includes, but is not limited to:

- Evidence of systems and reports demonstrating identification, reporting, investigation, analysis and prevention of adverse events;
- Data collection and analysis at regular intervals; and
- Documentation demonstrating development, implementation and evaluation of corrective actions or performance improvement activities.

Upon the request of a State Survey Agency, Federal surveyor or CMS, the facility must present evidence, including documentation, of its ongoing QAPI program's implementation and the facility's compliance with requirements.

QAPI Plan

A QAPI plan is the written plan containing the process that will guide the nursing home's efforts in assuring care and services are maintained at acceptable levels of performance and continually improved. The plan describes how the facility will conduct its required QAPI and QAA committee functions. The facility is required to develop a QAPI plan and present its plan to federal and state surveyors at each annual recertification survey and upon request during any other survey, and to CMS upon request.

The QAPI plan should describe the scope of the QAA committee's responsibilities and activities, and the process addressing how the committee will conduct the activities necessary to identify and correct quality deficiencies. Each nursing home, including facilities which are a part of a multi-chain organization, should tailor its QAPI plan to reflect the specific units, programs, departments, and unique population it serves, as identified in its facility assessment.

The QAPI plan should describe how the facility will ensure care and services delivered meet accepted standards of quality, identify problems and opportunities for improvement, and ensure progress toward correction or improvement is achieved and sustained.

The QAPI plan should describe the process for identifying and correcting quality deficiencies. Key components of the process include:

- Tracking and measuring performance;
- Establishing goals and thresholds for performance measurement;
- Identifying and prioritizing quality deficiencies;
- Systematically analyzing underlying causes of systemic quality deficiencies;
- Developing and implementing corrective action or performance improvement activities; and
- Monitoring or evaluating the effectiveness of corrective action/performance improvement activities, and revising as needed.

Program Design and Scope

Each facility must have a QAPI program that is ongoing, comprehensive and capable of addressing the full range of care and services it provides. At a minimum, the program must:

- Address all systems of care and management practices;
- Include clinical care, quality of life and resident choice;
- Utilize the best available evidence to define measure indicators of quality and facility goals that reflect processes of care and facility operations that have been shown to be predictive of desired outcomes for residents; and
- Reflect the complexities, unique care and services that the facility provides.

Effective QAPI programs address systems of care and management practices. Systems of care (or care delivery systems) are the processes in place to achieve an expected clinical outcome. Nursing homes have many systems of care which intersect and involve multiple disciplines and departments. For example, the system for prevention of pressure ulcers also involves the system for ensuring adequate nutrition, as well as the systems for identification of changes in condition and infection prevention. In order to ensure all aspects of these systems of care occur consistently, accurately, timely, and with the intended outcome, an effective program includes methods for monitoring the systems.

In addition to systems of care, the facility should monitor important management practices such as resident finances and personal funds, admission and discharge practices, and other services that impact quality of life and resident rights. The QAPI program should address quality of life and resident choice by identifying the unique needs and preferences of the varying demographics of residents residing in the facility (i.e., young and/or culturally diverse residents) and seeking ongoing input and feedback from their residents.

Governance and Leadership

The Governing Body and/or executive leadership (or organized group or an individual who assumes full legal authority and responsibility for operation of the facility), must ensure the QAPI Program:

- Is defined, implemented and ongoing;
- Addresses identified priorities;
- Is sustained through transitions in leadership and staffing;
- Has adequate resources, including staff time, equipment, and technical training as needed;
- Uses performance indicator data, resident and staff input, and other information to identify and prioritize problems and opportunities;
- Implements corrective actions to address gaps in systems and evaluates actions for effectiveness; and
- Establishes clear expectations around safety, quality, rights, choice and respect.

Disclosure of Information

The survey process is intended to be an objective assessment of facility compliance with the requirements of participation. This assessment is guided by facility performance and outcomes as reported by Quality Measures (QMs) and Minimum Data Set (MDS) data, as well as complaints and surveyor observations, interviews, and record reviews. The surveyor task to review-QAPI/QAA is intended to occur at the end of the survey, after completion of investigation into all other requirements to ensure that concerns are identified by the survey team independent of the QAPI/QAA review. Surveyors must use critical thinking and investigatory skills to identify noncompliance, rather than using information provided during the QAPI/QAA review as a source to identify deficiencies.

Surveyors may only require a facility to disclose QAA committee records if they are used to determine the extent to which the facility is compliant with the provisions for QAPI/QAA.

Protection from disclosure is generally afforded documents generated by the QAA committee, such as minutes, internal papers, or conclusions. However, if those documents contain the evidence necessary to determine compliance with QAPI/QAA regulations, the facility must allow the surveyor to review and copy them. The **key point** is that the facility must provide satisfactory evidence that it has, through its QAA committee, identified its own high risk, high volume, and problem-prone quality deficiencies, and is making a "good faith attempt" to correct them.

Examples of when disclosure may be necessary to determine compliance:

- If the facility's infection control data indicates that staff may not have responded in a timely and effective manner to address an outbreak of a communicable disease, the facility must allow the surveyor to review and copy QAA committee minutes and related documentation so that the surveyor is capable of evaluating the facility's QAPI/QAA compliance.

- If the surveyor's staff interviews and record reviews reveal the facility has a past history of failing to follow care instructions and recommendations from clinical specialists when residents obtain specialty care outside the facility, the facility must allow the surveyor to review and copy QAPI/QAA documentation. Under these circumstances, review of the QAPI/QAA documentation is necessary to evaluate whether the QAA Committee identified a problem with failure to follow care instructions and recommendations from outside specialists and, if it did, whether the QAA Committee adequately addressed the problem.

NOTE: Prior to conducting the QAPI/QAA review, the survey team must conduct a thorough investigation of all issues identified, including expanding the sample as necessary to determine the scope of the issue.

Reports and Logs

Incident and accident reports, wound logs, infection control logs, or other reports or records used to track adverse events are not protected from disclosure. Surveyors may request these documents as part of their normal investigation of other areas of concern throughout the survey to support their findings.

Surveyor Access to QAPI/QAA Material and Confidentiality of Patient Safety Work Products

CMS supports and encourages nursing homes to work on a confidential basis with an Agency for Healthcare Research and Quality (AHRQ) approved Patient Safety Organization (PSO) to obtain technical assistance in identifying, analyzing and preventing quality deficiencies and adverse events. The Federal Patient Safety and Quality Improvement Act of 2005 (PSQIA), Public Law 109-41, established a voluntary reporting system designed to enhance the data available to assess and resolve patient safety and health care quality issues. PSQIA has afforded privileged and confidential status to "patient safety work product" (PSWP). PSWP includes data, reports, records, memoranda, analysis, or written and oral statements assembled and developed for reporting to a PSO and have been submitted to a PSO approved and listed by the Department of Health and Human Services (HHS), AHRQ.

PSQIA and the Patient Safety Rule only limit the disclosure of PSWP. Neither PSQIA nor the Patient Safety Rule limit the disclosure of non-PSWP, including its disclosure to a Federal, state or local government for public health surveillance, investigation or health oversight. The preamble to the final Patient Safety Rule states:

> "Information is not patient safety work product if it is collected to comply with external reporting, such as…certification or licensing records for compliance with health oversight agency requirements;…complying with required disclosures by particular providers or suppliers pursuant to Medicare's Conditions of participation or conditions of coverage…" (73 FR 70742-70743, November 21, 2008).

Ultimately, it is the nursing home's final decision as to whether to enter into a relationship with a PSO and to create a patient safety evaluation system (PSES) which is the collection, management, or analysis of information for reporting to or by a PSO. Additionally, the nursing home should determine what information to place within the PSES, considering a number of factors, including how they will demonstrate compliance with the Long-term Care Requirements for Participation, in particular, the QAPI/QAA requirements. A nursing home must be prepared to meet its obligation to provide surveyors access to QAPI/QAA program information to demonstrate compliance without disclosing PSWP as that term is defined in 42 CFR Part 3, the regulation implementing the Federal PSQIA. There is no barrier under the PSQIA for nursing homes to maintain duplicate systems, one consisting of patient safety work product within a protected patient safety evaluation system, and another to demonstrate compliance with local, State or Federal requirements.

Surveyors should consider the following key points:

- Surveyors assessing QAPI/QAA compliance must ask nursing homes to provide evidence of QAPI/QAA compliance.
- Surveyors must **never** ask or demand that a nursing home show them "patient safety work product." If a nursing home states that all relevant QAPI/QAA material has been placed in its PSES, or is protected PSWP, surveyors must ask to see the agreement the nursing home has with an AHRQ-approved PSO, to confirm that it has an approved protected PSES.
- If a nursing home has placed all evidence related to QAPI/QAA compliance in its PSES as patient safety work product and does not also maintain a separate non-confidential system to provide evidence of compliance, or is unable to remove evidence of such compliance from its PSES, it may not be able to demonstrate its compliance to the surveyor.

Sanctions and Good Faith Attempts
If the facility, through its QAA committee, has identified and made a good faith attempt to correct the same issue identified by the survey team during the survey, the facility will not be cited for QAA (it may however, still be cited with deficiencies related to actual or potential issues at other tags).

To establish that the facility's QAA committee has made a good faith attempt to correct an identified quality deficiency, a facility must do more than just subjectively assert it has made a good faith attempt; rather, the facility's actions, taken as a whole, must evidence a good faith attempt to identify and correct quality deficiencies.

To evaluate good faith attempts, surveyors will have to determine if the facility became aware of the issue as soon as it should have and where the facility is within the correction process. Additional areas of inquiry include, but are not limited to, the following: was the issue a high-risk, high-volume, or problem-prone issue the facility should have been tracking? Was there a negative outcome to a resident which should have alerted the facility to the issue? What steps did the facility take when it became aware of the issue? Has there been enough time to implement changes and to evaluate the effectiveness of those changes? Do the facility's efforts demonstrate diligence and a genuine attempt to correct the issue? Identifying and correcting problems requires the facility to:

- Collect data from various sources related to high risk, high volume, and problem-prone issues such as medical errors and adverse events;
- Analyze the data collected to identify performance indicators signaling deviation from expected performance;
- Study the issue to determine underlying causes and contributing factors;
- Develop and implement corrective actions; and
- Monitor data related to the issue to determine if they are sustaining corrections, or if revisions are necessary.

If the survey team has identified a current issue which will be cited at S/S level of E or above, or has identified substandard quality of care, the surveyor conducting the

QAPI/QAA Review should consider if the facility's monitoring systems should also have identified the same issue.

The surveyor must take into consideration whether the QAA committee has had sufficient time through its monitoring systems to identify the issue, if it was a high risk, problem-prone issue they should have been monitoring, and whether there has been a reasonable amount of time to respond to the issue. Issues which are likely to cause serious harm, impairment, or death must be responded to immediately. If the facility has identified the issue through its QAA committee, the surveyor must then evaluate the extent to which their actions or plans to correct the issue demonstrate a "good faith attempt."

Surveyors must not use documentation provided by the facility during the QAPI/QAA review to identify additional concerns not previously identified by the survey team during the current survey, nor can they expand the scope or the severity of the problem based on information gleaned from this disclosure.

Facility Refusal to Provide Evidence of Compliance
To the extent a facility's QAPI/QAA information is necessary to demonstrate the facility's compliance with the requirements of 42 CFR § 483.75, a facility is required under 42 CFR § 483.75(h) to disclose this information to the State Agency and/or CMS. Refusal by a facility to produce evidence of compliance with QAPI/QAA will lead to citation of noncompliance with F865, requiring a plan of correction, and possible imposition of enforcement remedies up to and including termination of the facility's provider agreement (per 42 CFR §489.53). In the event of a facility refusal to produce evidence of compliance, the team coordinator should contact their State Agency supervisor.

INVESTIGATIVE PROCEDURE

Use the Facility Task Pathway for Quality Assurance and Performance Improvement (QAPI) and Quality Assessment and Assurance (QAA) Review,-along with the above interpretive guidelines when determining if the facility meets the requirements for, or when investigating concerns related to QAPI/QAA.

Surveyors should refer to the following when investigating concerns and citing non-compliance related to QAPI:

- F865: For concerns related to whether a facility has implemented and maintains a comprehensive QAPI program and plan, disclosure of records and governance and leadership.
- F867: For concerns related to how the facility obtains feedback, collects data, monitors adverse events, identifies areas for improvement, prioritizes improvement activities, implements corrective and preventive actions, and conducts performance improvement projects.