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**Center for Clinical Standards and Quality/Quality, Safety & Oversight Group**

**Ref: QSO-23-09-Hospital**

**DATE:** March 9, 2023

**TO:** State Survey Agency Directors

**FROM:** Director, Quality, Safety & Oversight Group (QSOG)

**SUBJECT:** Revision to State Operations Manual (SOM), Hospital Appendix A - Interpretive Guidelines for 42 CFR 482.21, Quality Assessment & Performance Improvement (QAPI) Program

**Memorandum Summary**

- CMS is committed to consistent implementation and oversight of the QAPI requirements as a part of our **patient safety initiative**.
- **QAPI Guidance Released**: CMS is releasing the updated interpretive guidance for State Operations Manual (SOM) Hospital Appendix A for the QAPI CoP
- The QAPI CoP requires a hospital to "maintain and demonstrate evidence of its QAPI program for review by CMS, as well as the governing body oversight of the program in **an effort to deliver safe, quality patient care and prevent adverse events and patient harm**." (42 CFR 482.21)

## Background:

QAPI CoP deficiencies are the third most frequently cited of the 24 CoPs for Medicare-certified hospitals. A hospital with a well-designed and well-maintained QAPI program, fully engaged in hospital-wide continuous assessment and improvement efforts can significantly enhance its ability to provide high quality and safe care to its patients, and thereby reduce the incidence of medical errors and adverse events throughout the hospital.

In its ongoing effort to promote and advance a proactive culture of safety in our nation's hospitals, CMS has developed this updated interpretive guidance to provide surveyors with a consistent approach for assessing whether a hospital's QAPI program fully complies with the CoP requirements to improve performance, patient safety, and overall quality of care. The focus of the QAPI CoP assessment for surveyors is to determine whether a hospital has an effective, ongoing system in place for identifying problematic events, policies, or practices, and is taking actions to remedy its identified problem areas, with follow-up to determine if they were effective in improving performance and quality.

The updated hospital QAPI program interpretive guidance provides an essential tool for surveyors to use so that they may more consistently focus their evaluation of a hospital's

compliance with the CoP requirements on a hospital's efforts not only to improve its performance and quality, but also on its ability to sustain such efforts over time.
In addition to its focus on the importance of a sustainable QAPI program to promote patient safety and reduce harm, the updated QAPI CoP interpretive guidance emphasizes the integral role hospital leadership plays in advancing a sustained program for improvement throughout the hospital. A component of the successful execution of a hospital QAPI program requires engagement by the hospital's governing body. Leadership oversight in the development and ongoing planning of a hospital's QAPI activities is an essential component. This includes ensuring that clear expectations for safety are established and communicated hospital-wide.

**Discussion:**

**Update to SOM Appendix A for Hospitals**
CMS is releasing an update of Appendix A of the SOM, providing interpretive guidelines for the QAPI CoP at 42 CFR 482.21. The goal of the interpretive guidance is to provide surveyors with the tools to consistently assess a hospital's ability to develop, implement, and maintain an effective, ongoing, hospital-wide, and data-driven quality assessment and performance improvement program, which also includes tracking and monitoring of adverse events and medical errors. We must point out that while the updated interpretive guidance is clearly designed as an essential guide for surveyors as they evaluate hospitals for their compliance with the QAPI CoP requirements, it is not intended for use by surveyors exclusively. CMS urges hospitals to also make full use of the guidance, information, and resource materials contained throughout Appendix A of the SOM, but most especially the material related to QAPI since the QAPI requirements and a hospital's QAPI program itself are central to establishing, advancing, and sustaining a culture of safety and quality care throughout the hospital and for the patients it serves.

**QAPI Requirements**
Medicare-certified hospitals are required to have a QAPI program that provides a process by which a hospital can fully examine the quality of care it delivers and then implement specific improvement activities and projects on an ongoing basis for all of the services provided by the hospital, while considering the scope and complexity of those services and the patient populations it serves. This process is expected to study and make improvements to existing processes and service delivery methods while, at the same time, remaining proactive in seeking innovative approaches to improving patient outcomes and preventing medical errors. Through continuous collection and analysis of quality indicators and data, corrective actions are expected to be appropriate to remedy and change processes, operations, and services in ways that will ultimately improve patient care and outcomes on a sustainable basis.

The prioritization of performance improvement activities should focus on high-risk, high-volume, or problem-prone areas and their effects on health outcomes, patient safety, and quality of care. Prevention of hospital adverse events through reporting and tracking of these events would be included in these activities. Data gathered for quality indicators should be used to determine if the services provided by the hospital are effective and sustainable.

Surveyors will evaluate the hospital's success in its efforts to improve performance and the quality of patient care. The focus of the QAPI assessment is to determine whether a hospital has an effective, ongoing system in place for identifying problematic events, policies, or practices,

and is taking sustainable actions to remedy these problems, including following up on these remedial actions to determine if they were effective in improving performance and quality.

The hospital governing body is responsible for the oversight of the QAPI program through its periodic review of the program, including, the development of a plan to implement and maintain the QAPI program, the review of the progress of QAPI projects, the determination of annual QAPI projects, and the evaluation of the effectiveness of improvement actions that the hospital has implemented. This group of leaders is also responsible for ensuring that clear expectations for safety are established and communicated hospital-wide, as well as allocating adequate resources to carry out the functions of the QAPI program requirements.

Establishing clear expectations for safety should, at a minimum, include, informing all staff of their specific roles and responsibilities in QAPI. Clear expectations for safety must also be set and communicated to those providing services under arrangements or contracts and should be documented in the contracts.

As a component of their assessment of compliance with the QAPI CoP, surveyors will evaluate the involvement of the hospital's leadership in the oversight and execution of the hospital-wide QAPI program. This evaluation may include a review of how QAPI priorities are established, how data is collected, and how data is used to monitor quality and safety. Hospitals will be expected to provide evidence of how the governing body initiated performance improvements projects because of adverse events. Lastly, there will be a review of the governing body processes related to the QAPI program as well as the governing body's effectiveness in communicating the goals of the QAPI program and the governing's body's clear expectations for a culture of safety that is hospital-wide in its scope, including all locations of the hospital (onsite and off-site inpatient and outpatient services and departments) and all services provided directly by the hospital as well as those services provided under arrangement or contract. This means that the services at all locations of the hospital must be taken into consideration when developing, defining, implementing, and maintaining the QAPI program.

Surveyors will continue to use a systematic process of review, utilizing evidence provided by the hospital through documentation, interviews, and observations of the hospital-wide QAPI program. This will include all locations, services, and departments of the hospital, whether on-campus or off-campus, (i.e., other inpatient campuses, inpatient units located on another hospital's campus/buildings, off-campus EDs, etc.) covered under the hospital's Medicare provider agreement. While it is not expected that all departments and services be continuously engaged in large-scale or resource-intensive QAPI projects, it is still expected that the hospital will have evidence of the continuous monitoring of the quality and safety of all services provided and that it takes actions as necessary to improve the quality and safety of those services.

CMS remains committed to the goal of protecting the health and safety of all patients receiving care in hospitals. The assessment of a hospital's ability to provide a comprehensive QAPI program is an important component of this goal. A hospital that appropriately and actively collects, tracks, and analyzes quality and safety data and indicators, initiates improvements based on its analyses, and then monitors the sustainability of its quality initiatives in order to ultimately deliver safe and high-quality patient care, while also working to improve patient outcomes and reduce patient harm, shows a commitment to this goal through such efforts to meet the requirements for compliance with the QAPI program CoP.

**Contact:**
For questions or concerns relating to this memorandum, please contact QSOG_Hospital@cms.hhs.gov.

**Effective Date:**
Immediately. Please communicate to all appropriate staff within 30 days.

/s/

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Attachment(s)- SOM Appendix A Hospital QAPI Interpretive Guidance

# CMS Hospital Appendix A
# QAPI Guidance Updates

## A-0263
**(Rev. 37 Issued: 10-17-08; Effective/Implementation Date: 10-17-08)**

## §482.21 Condition of Participation: Quality Assessment and Performance Improvement Program

**The hospital must develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program. The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.**

***Interpretive Guidelines §482.21***

*A hospital is required to have a quality assessment and performance improvement (QAPI) program that provides a mechanism to systematically examine the quality of care delivered and implement specific improvement projects on an ongoing basis for all of the services provided by the hospital. The hospital should also consider the complexity of those services when determining quality parameters of those services. Hospitals are expected to continuously study and improve their processes and service delivery and take a proactive approach to improve their performance and focus on improving patient outcomes and the prevention of medical errors.*

*CMS does not prescribe a particular QAPI program that all hospitals must use. Rather, each hospital is provided with the flexibility to develop its own program based on its unique needs, priorities, clinical programs, as well as its own considerations for the health equity needs of its patient population. Each hospital should have processes in place to continually identify opportunities for quality and safety improvements and to implement changes that lead to improved outcomes that are sustained over time.*

*The hospital is expected to provide evidence of continuous data collection, data analysis (with identified areas for improvement), and implementation of changes, including the ongoing monitoring of those changes to determine their effectiveness. In addition, there should be evidence that the governing body is engaged in the oversight of the QAPI program for all services provided by the hospital, including those provided under contract or arrangement.*

*The hospital-wide program should include all locations and services and departments of the hospital, whether on-campus or off-campus (i.e., other inpatient campuses, inpatient units located on another hospital's campus/buildings, off-campus EDs, etc.), covered under the hospital's Medicare provider agreement. While it is not expected that all departments and services be continuously engaged in large scale or resource-intensive QAPI projects, all departments and services (including those provided under arrangement or contract) should provide evidence that there is continuous monitoring of the quality and*

*safety of the services provided and take corrective actions as necessary to ensure patient safety and to improve the quality of care provided.*

*For services under contract, in accordance with 42 CFR 482.12(e), the hospital's governing body must ensure that contractors provide services in a manner that allows the hospital to comply with all applicable Conditions of Participation and standards for the contracted services. Furthermore, the hospital must be able to demonstrate how it includes services provided under an arrangement or contract in its QAPI program. This may be done by providing evidence of the evaluation of contracted services and, when appropriate, conducting performance improvement activities or projects related to services under arrangement or contract.*

***Survey Process***

*Surveyors are not expected to judge the performance and quality measures used by a hospital. Instead, surveyors will evaluate the hospital's success in its efforts to improve performance and quality. The focus of the QAPI CoP assessment is to determine whether a hospital has an effective, ongoing system in place for identifying problematic events, policies, or practices, and is taking actions to remedy them and then following up on these remedial actions to determine if they were effective in improving performance and quality. The survey focus will also include whether improvements are sustained over time.*

*There may also be an evaluation of the QAPI program when surveyors identify non-compliance with other regulatory requirements. For example, a surveyor may observe deficiencies in infection control or medication administration practices. Citations should be made under the applicable portions of the infection control, nursing, or pharmacy CoPs. However, surveyors should also investigate the tracking of medical errors and adverse events related to healthcare-associated infections or medication errors, what type of analyses and actions have been taken to reduce future errors, and what follow-up evaluations are underway. If, during the course of the survey, such lapses in care and safety are found to be very serious or widespread, surveyors should investigate the effectiveness of the QAPI program related to the handling of medical errors and adverse events. If there is evidence that the hospital is taking effective actions through its QAPI program to correct such deficiencies, then a citation of QAPI CoP deficiencies generally would not be appropriate, despite the individual lapses surveyors might have observed for other regulatory requirements.*

*Surveyors should avoid using the hospital's own QAPI program data and analyses as evidence of violations of other CoPs unless there is evidence of current non-compliance with the regulatory requirements. However, surveyors may review additional records pertaining to the operation of the hospital, including medical error reports and peer review information when these documents are necessary to determine compliance with statutory and regulatory requirements. With rare exceptions, surveyors must not use the information they have gathered from QAPI program records as the basis for a deficiency citation under other CoPs. There may be cases where it might be appropriate to use QAPI program information as evidence of a deficiency, but these cases would be the exception rather than the rule. For example, a review of the QAPI program documents might show that a hospital identified three incidents of wrong-site surgery over twelve months, and another five near misses, but that no subsequent action was taken to analyze these incidents and implement any changes to its pre-surgical verification procedures. Here, the QAPI documents would suggest there is current noncompliance with the QAPI CoP since the hospital's QAPI program did not take any action to address the problems it had*

*identified. In this circumstance, it would also be appropriate for surveyors to review the medical records for the incidents identified in the QAPI system to assess compliance with the surgical services CoP.*

*Surveyors should be aware of the sensitivity of the documents when reviewing QAPI program materials furnished by a hospital that relate to peer review or other analyses of adverse events. Surveyors must:*

- *Avoid making copies of such information unless absolutely necessary to support a deficiency citation; and*

- *Avoid making notes that could identify particular events-- e.g., do not write: "root cause analysis of an adverse event in August, 20XX related to inadvertent disposal of an organ recovered from a living donor showed that primary causes were Y and Z and that the process for handling a recovered organ should be modified in XX manner. In December 20XX hospital made the following changes to its process…." Instead write: "confirmed that hospital conducted a root cause analysis of an adverse event related to the hospital's transplant program; reviewed analysis, which was systematic, detailed, and resulted in recommendations; confirmed the hospital implemented recommendations and is monitoring for effectiveness." Ensure that the recommendations resulted in improvements to processes, outcomes, etc., resulting in positive patient outcomes.*

*Additionally, surveyors should:*

- *Verify the hospital has a formal QAPI program by asking for a copy of the program documents.*

- *Review program documentation and verify the program is:*

    - *Based on, and reflects, the complexity of the hospital's organization and services*
        - *Is the size and complexity of the hospital reflected in the overall scope of the QAPI program?*
    - *Hospital-wide (including services under contract or arrangement)*
        - *Is there evidence that all hospital departments and services are included in the QAPI program?*
        - *Does the documentation include participation by all contracted services?*
            - *Do written contracts include QAPI requirements and roles and responsibilities of the contractor?*
    - *Data-driven (does the documentation indicate what data is used to make QAPI program decisions?)*
    - *Focused on quality indicators/measures related to improved health outcomes, as well as the prevention and reduction of medical errors (does the program focus on non-clinical measures such as employee satisfaction data as opposed to clinical measures such as infection control incidence rates and/or nationally recognized quality indicators?)*

- *Verify that the hospital enables surveyors to assess its compliance with the QAPI requirements by providing access to staff and program documentation as requested.*

    *If the surveyor requests information that the hospital asserts is protected from review, ask the hospital if it can provide alternative evidence of compliance that is not protected.*
    - *If the hospital produces alternative evidence, it is within the sole discretion of the surveyor to determine whether it provides sufficient evidence with which to assess compliance with the QAPI requirements.*

    - *If the hospital cannot produce alternative evidence or if the alternative evidence is insufficient to determine compliance, a deficiency must be cited.*

## A-0273

***(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)***

## Data Collection & Analysis

## §§482.21(a), 482.21(b)(1), 482.21(b)(2)(i), & 482.21(b)(3)

**§482.21(a) Standard: Program Scope**

**(1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes….**

**(2) The hospital must measure, analyze, and track quality indicators…and other aspects of performance that assess processes of care, hospital service, and operations.**

**§482.21(b) Standard: Program Data.**

**(1) The program must incorporate quality indicator data including patient care data, and other relevant data *such as data submitted to or received from Medicare quality reporting and quality performance programs, including but not limited to data related to hospital readmissions and hospital-acquired conditions.***

**(2) The hospital must use the data collected to--**
**(i) Monitor the effectiveness and safety of services and quality of care; and….**

**(3) The frequency and detail of data collection must be specified by the hospital's governing body.**

***Interpretive Guidance* §§482.21(a), 482.21(b)(1), 482.21(b)(2)(i), & 482.21(b)(3)**

***Quality Indicators and Data Analysis***

*A QAPI program should include the continuous collection and analysis of quality indicators/data and corrective actions as appropriate to remedy processes, operations, and services that will improve patient outcomes. The quality indicator data should include patient care data such as adverse events and other data such as that received from Medicare quality reporting and performance programs. Examples of those measures may include, but not limited to, Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) data, maternal morbidity, sepsis, and safe opioid practices. The data gathered for quality indicators should be used to determine if the services provided by the hospital are effective toward delivering safe, quality care to the patients it serves. There may also be considerations for cultural competence as hospitals develop these measures. The hospital should demonstrate that the quality indicators it has selected, along with the associated data, are used to monitor quality and safety and to also identify opportunities for quality improvement.*

*An analysis of the data should demonstrate that the quality indicators used produce measurable improvement related to the specific quality indicator. For example, a medication error indicator included in the program must demonstrate a decrease in medication errors. The care process of proper hand hygiene (handwashing) must demonstrate increased staff compliance with hand hygiene standards of practice. A central line infection indicator must demonstrate a decrease in the incidence and prevalence of central line infections. Measurable improvement is evidenced by quantifiable data. For example, a hospital may have identified 10 medication errors in one month in its ICU. After analysis of the errors and implementation of medication administration changes, it tracks medication errors over the next 6 months. The 6 months of data show that there was only 1 medication error in the ICU over the entire 6 months. In this example, this is measurable improvement evidenced by data. CMS does not prescribe thresholds for acceptable improvement and expects hospitals to determine these thresholds in accordance with national standards of practice.*

*Additionally, a hospital is allowed to develop its own measures and indicators that are based on the scope and complexity of its their services, and on considerations for the health equity of its specific patient population. Under the QAPI CoP, a hospital is not required to use any specific set of measures or indicators.*

***Governing body responsibility for frequency and detail of data collection***

*The governing body is responsible for specifying the frequency and the detail of the data collection, which may include, but is not limited to, what data will be collected, what the data is intended to measure, in what areas of the hospital the data will be collected, and how frequently the various types of data will be collected. This does not mean that the governing body is expected to have a high degree of technical expertise in the area of quality data collection. However, the governing body must have information that describes the hospital's QAPI data collection program in sufficient detail so that the governing body is able to determine what program data requirements to approve.*

*There must be evidence that the governing body has had an active role in the development and ongoing planning of the frequency and detail of QAPI data collection. Such evidence may be documentation in the governing body meeting minutes that it has reviewed and approved the frequency and detail of the QAPI data collection program.*

***Survey Procedures §482.21(a)***

- *Ask QAPI staff to provide a list of the quality indicators they are currently tracking.*
    - *Verify that this includes the tracking of adverse events.*
    - *Verify that the quality indicator data include patient care data, and other relevant data such as that received from Medicare quality reporting and performance programs, including, but not limited to, data related to hospital readmissions and hospital-acquired conditions.*
    - *Verify that the quality indicators are reflective of the hospital's patient population.*

- *Ask QAPI staff to provide evidence (measurement data) of measurable improvements in the quality indicators it has selected for its program.*
    - *Verify that improvements are ongoing (several data analyses showing improvement over time) and not just one-time events.*
    - *If the evaluation did not show improvements or sustained improvements, is there evidence that the hospital implemented a revised or new solution?*

***Survey Procedures §482.21(b)***

- *Ask to see evidence that the governing body has specified the frequency and detail of QAPI program data collection*
    - *Look at governing body meeting minutes.*
    - *Do QAPI program reviews include this information?*

- *Verify the hospital is using the data being collected to monitor the safety and quality of care.*
    - *Select a sample of data being collected and ask the governing body or other appropriate leadership to explain how the collection of the particular data is used to monitor quality and safety.*

- *Verify the hospital is using the data being collected to identify opportunities for improvement*
    - *Select a sample of data being collected and ask the governing body or other appropriate leadership to give examples of how the specific data has identified opportunities for improvement.*
    - *Ask to see documented evidence of the opportunities the hospital has identified for improvement based on the collection of data*

## A-0283

**(Rev. 105, Issued: 03-21-14, Effective: 03-21-14, Implementation: 03-21-14)**

## Quality Improvement Activities

**§§482.21(b)(2)(ii), 482.21(c)(1) & 482.21(c)(3)**
**§482.21(b)(2) Standard: Program Data**

**The hospital must use the data collected to--…**

**(ii) Identify opportunities for improvement and changes that will lead to improvement.**

***Interpretive Guidance* §§482.21(b)(2)(ii)**

*As a component of the hospital's QAPI program, the hospital should utilize the data collected to identify opportunities of continuous and ongoing improvement as well as mechanisms for change to improve safety and quality of care for the patients it serves.*

**§482.21(c) Standard: Program Activities**

**(1) The hospital must set priorities for its performance improvement activities that--**

**(i) Focus on high-risk, high-volume, or problem-prone areas;**

**(ii) Consider the incidence, prevalence, and severity of problems in those areas; and**

**(iii) Affect health outcomes, patient safety, and quality of care….**

**(3) The hospital must take actions aimed at performance improvement and, after implementing those actions, the hospital must measure its success, and track performance to ensure that improvements are sustained.**

***Interpretive Guidance* §§482.21(c)(1) & 482.21 (c)(3)**

*Hospitals should evaluate their QAPI program data to ensure that they are considering the information below in establishing priority areas where it will undertake specific actions to improve its performance. The prioritization of quality of efforts should address the effect on health outcomes, patient safety, and quality of care. Hospitals should determine these areas based on the complexity of the services they provide.*

- ***High-risk areas*** *- where the opportunity for error is higher than in other areas, for example, where there are complex processes, and/or where the consequences of poor quality or medical errors are more likely to have a serious, adverse impact on patients. Examples may include, but are not limited to, Emergency Departments, Labor and Delivery Units, ICUs, and care areas treating immunocompromised patients.*

- ***High volume areas -*** *where the number of potential patients who could be adversely affected is high due to common elements in their care. These areas may include, but are not limited to, clinical staff hand hygiene, sanitary food preparation, and general medication administration.*

- ***Problem-prone areas*** *- where the hospital's own internal QAPI data shows a history of problems, or where nationally available research or expert consensus has identified areas*

*especially prone to problems. These areas may include, but are not limited to, hospital-acquired infections, central-venous catheter use, patient hand-off communication processes between members of the healthcare team, systems for identifying patients, and medication administration.*

- ***Incidence*** *refers to the rate or frequency at which an event being measured occurs within a specific timeframe.*

- ***Prevalence*** *refers to how widespread something is at a specific point in time in a particular place or population.*

- ***Severity*** *refers to the degree of seriousness or significance of an event or issue in a hospital.*

***Survey Procedures §§482.21(b)(2)(ii), 482.21(c)(1) & 482.21(c)(3)***

- *Ask to see a list of current or recent performance improvement activities.*

- *Ask the governing body or the leadership staff who oversee the QAPI program to provide evidence that its improvement activities are focused on high-risk, high-volume, or problem-prone areas. Does it have any data (either derived from its own QAPI data collection or public data) on incidence, prevalence, or severity to support its choices? Does it have evidence that the activities affect health outcomes through improving quality of care or patient safety?*

- *Ask the governing body or leadership staff who oversee the QAPI program to provide evidence of QAPI activities that were initiated based on data reported through the medical error/adverse event tracking system.*

- *Ask to see evidence that the hospital tracks data for the identified indicators, which may include, but are not limited to blood product transfusion reactions, drug reactions, errors in medication administration, and infection control-related errors and events.*

## A-0286

**(Rev. 105, Issued: 03-21-14, Effective: 03-21-14, Implementation: 03-21-14)**

## Patient Safety, Medical Errors & Adverse Events

## §§482.21(a)(1), 482.21(a)(2), 482.21(c)(2), & 482.21(e)(3)

**§482.21(a) Standard: Program Scope.**

**(1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will … identify and reduce medical errors.**

**(2) The hospital must measure, analyze, and track…adverse patient events….**

**§482.21(c) Standard: Program Activities.**

**(2) Performance improvement activities must track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospital.**

**§482.21(e) Standard: Executive Responsibilities. The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following: …**

**(3) That clear expectations for safety are established.**

***Interpretive Guidance §§482.21(a)(1), 482.21(a)(2), 482.21(c)(2), & 482.21(e)(3)***

***Medical errors and adverse events***

*The reporting mechanism for medical errors and adverse events is at the discretion of the hospital. CMS does not specify the type of reporting mechanism to be used, but expects that the system will permit the hospital to track and analyze medical errors and adverse events in an effective and meaningful manner. As appropriate, hospitals should educate all hospital staff and contract staff on what is considered a medical error and an adverse event, as well as when and how to report these events.*

*CMS has adopted the following definition of an error from the Quality Interagency Coordination Task Force (QuIC) (68 FR 3435, 3436, January 24, 2003):*

*"An **error** is defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Errors can include problems in practice, products, procedures, and systems."*

*There are many types of medical errors, including, but not limited to:*

- *Medication administration errors - wrong medication, wrong dosage, wrong patient, etc.;*
- *Surgical errors - wrong patient, wrong site, retained instrument, etc.;*
- *Equipment failure – defibrillator without working batteries, IV pump that results in inadvertent dosing, alarms not working properly, etc.;*
- *Infection control errors – poor aseptic technique, incorrect processing of sterile instruments and equipment, incorrect isolation practices, lack of standard precautions, etc.;*
- *Blood transfusion-related errors – wrong patient, wrong blood product administered, etc.; and*

- *Diagnostic errors – misdiagnoses leading to incorrect choice of therapy, failure to use an indicated diagnostic test, misinterpretation of test results, failure to act properly on abnormal results.*

*Not every medical error results in harm to a patient; the error may be detected and addressed before a harmful effect can occur (a "**near miss**") or the consequence of the error may be minimal. From a patient safety perspective, a near miss is considered an error and much can be learned from the near miss in terms of system weaknesses that could, in the future, result in actual harm to patients. Therefore, hospitals must track and analyze errors that result in near misses, and focus on their prevention and reduction.*

*While the regulation also specifically calls for measuring, analyzing, and tracking of adverse events, adverse events may or may not be preventable. A preventable adverse event is an injury caused by an error. Section 482.70 defines an adverse event as "an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof."*

***Analysis of Causes of Medical Errors and Adverse Events***

*Hospitals should analyze medical errors and adverse events to determine the cause(s) by using a systemic approach for determining the cause of the error and for implementing appropriate preventive actions.*

***Implementing Improvement/Preventive Strategies***

*After the systemic analysis of the error or adverse event has led to the identification of the cause of the event, hospitals should develop and implement preventive actions to improve the quality and safety associated with the event or the error. Preventive actions include, but are not limited to, changes in policies and procedures, repairing or replacing equipment, staff education and training, etc. Where appropriate, the hospital should make all affected staff aware of the strategies and related actions it has implemented to correct and prevent specific errors and adverse events, and also provide applicable training. Hospitals should be able to provide evidence of the implemented changes, such as documented staff education and training, documentation of new or revised policies, evidence that equipment has been repaired or replaced, etc.*

***Evaluating Changes and Sustaining Improvement***

*The hospital should also have a method to assess whether the strategies and actions it has implemented resulted in improved outcomes and that those improved outcomes are sustained over time. This means the hospital should collect data that enables the hospital to determine whether indicators, related to a specific area targeted for change, actually demonstrated an improvement after implementation of the changes.*

*For example, the hospital should continue to periodically collect data on proper hand hygiene and then analyze the data to determine if the solution has resulted in sustained improvement in handwashing compliance. If the analysis of the periodic collection of handwashing data shows that the solution has not resulted in a sustained improvement over an appropriate period of time, a new or revised*

*strategy/solution must be implemented, with subsequent data collection and monitoring to evaluate the effectiveness of the new solution.*

***Prospective hospitals applying for initial certification in Medicare***

*A facility seeking Medicare program initial certification as a hospital may not have been in operation long enough to demonstrate extensive internal data collection for the identification of opportunities for improvement based on the monitoring data. However, it must be able to show that it has an active data collection and analysis infrastructure in place, and indicate when it expects to have sufficient data to begin analysis. In addition, because hospitals may utilize quality indicators from outside sources to prioritize QAPI program activities, an initial applicant would still be expected to provide evidence of implementing improvement actions based on selected indicators from outside sources.*

***Survey Procedures***

- *Ask to see evidence of the medical error/adverse event reporting system. Ask for a copy of the medical error and adverse event reporting policy. Ask for a demonstration of how to use the system and how the system is able to organize the reported data for meaningful analysis.*
  - *Can the system organize the data by type of error/adverse event?*
  - *Can the system organize the data by dates to show trends over time?*
  - *Can the system organize the data by shift, by unit where the error occurred, etc.?*

- *Ask to see evidence of hospital-wide staff education and training regarding what errors and adverse events must be reported and how to report them. Look at the materials used for education and training.*
  - *Are there training records to show staff received the training?*

- *Interview staff in various units to assess their understanding of identifying and reporting medical errors and adverse events.*

- *Select a sample of several (at least three) adverse events or errors the hospital has tracked and ask to see written evidence it has used a systemic approach (e.g., root cause analysis (RCA)) to analyze the cause of the events and errors), implemented changes based on the identified causes to prevent further events or errors, conducted periodic data collection to verify if the changes resulted in improvements, and analyzed the post-implementation data to assess whether the improvement (if there was an improvement) was sustained over time.*

## A-0297

**(Rev. 105, Issued: 03-21-14, Effective: 03-21-14, Implementation: 03-21-14)**

## Performance Improvement Projects

**§482.21(d) Standard: Performance Improvement Projects.**

**As part of its quality assessment and performance improvement program, the hospital must conduct performance improvement projects.**

**(1) The number and scope of distinct improvement projects conducted annually must be proportional to the scope and complexity of the hospital's services and operations.**

**(2) A hospital may, as one of its projects, develop and implement an information technology system explicitly designed to improve patient safety and quality of care. This project, in its initial stage of development, does not need to demonstrate measurable improvement in indicators related to health outcomes.**

**(3) The hospital must document what quality improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects.**

**(4) A hospital is not required to participate in a QIO cooperative project, but its own projects are required to be of comparable effort.**

***Interpretive Guidelines §482.21(d):***

*Performance improvement **projects** are differentiated from performance improvement **activities** under 482.21(b)(2) in that performance improvement projects require a significant amount of up-front planning, include project objectives, and have a definitive beginning and end date (time-limited). Whereas performance improvement **activities** make up the continuous, ongoing functions of a hospital QAPI program, such as ongoing tracking of medical errors and adverse events, analysis of data, implementation of changes with associated education and training, continuous monitoring of quality and safety in all hospital departments and service areas, etc.*

*CMS does not prescribe the specific types of performance improvement projects to be conducted annually. It is up to each hospital's governing body to determine the number and types of annual projects based on the complexity and scope of the services provided by the hospital. No fixed ratio is required, but it is acceptable for smaller hospitals with a smaller number of distinct services to have fewer projects than a large hospital with many different services.*

*Hospitals may choose to participate in Quality Improvement Organization (QIO) projects to fulfill the annual project requirement, but are not required to do so to be compliant with the QAPI regulation. QIOs are funded by CMS to promote, through cooperative projects, improvements in services provided by Medicare-participating providers. If a hospital does not participate in a QIO project, it is expected to implement its own annual projects that are comparable in effort to a QIO project. The hospital should consider the number of patients affected, the range of services covered, and the projected magnitude of the benefit to individual patients when developing annual projects. (68 FR at 3441)*

*Hospitals should keep records on each performance improvement project completed within the previous six years, as well as a list of projects currently underway. The documentation for each project must, at a minimum, include an explanation of why the project was undertaken. The explanation of the project should indicate what data was collected in the hospital, or what publicly available data and/or recommendations of nationally recognized organizations, leads the hospital to believe that the project activities will result in improvements in patient health outcomes and safety in the hospital. For projects that are in progress, the hospital should be able to explain what activities the project entails and how*

*the impact of the project is being monitored. The hospital should also be able to provide evidence of baseline data it is collecting (or will be collecting, in the case of projects just beginning) that will enable the hospital to assess whether the project achieved measurable outcomes. For projects that are completed, the hospital should be able to demonstrate that the project resulted in measurable progress toward improving the quality of care or patient safety.*

***Survey Procedures***

- *Ask the hospital to provide a list of distinct performance improvement projects the hospital is currently conducting and has conducted within the last three years to verify the hospital is conducting annual QAPI projects.*

- *Ask to see the documentation of why each project was conducted and evidence to support the progress being made on each project.*

    - *Does the documentation include data to support "why" each project was conducted (e.g., medical error and adverse event reports indicated a need for improvement in a particular area)?*
    - *Does the documentation include evidence of ongoing monitoring of the project's progress, such as periodic data collection and analysis?*

- *Ask the Governing Body to explain how the selection (number and scope) of the specific projects is in alignment with the hospital's complexity and the scope of services it provides.*

    - *Consider the size of the facility and the intensity of its services, such as critical care services/units, complex surgeries, transplant services, maternal/child health services, and oncology services, including radiation and chemotherapy, etc.*

## A-0308

**(Rev. 105, Issued: 03-21-14, Effective: 03-21-14, Implementation: 03-21-14) Standard**

**Tag for requirements found only in Condition stem statement**

**§482.21 Condition of Participation: Quality Assessment and Performance Improvement Program**

**… The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement)…. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.**

## A-0309

**(Rev. 105, Issued: 03-21-14, Effective: 03-21-14, Implementation: 03-21-14)**

## Executive Responsibilities

**§482.21(e) Standard: Executive Responsibilities**

**The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following:**

**(1) That an ongoing program for quality improvement and patient safety, including the reduction of medical errors, is defined, implemented, and maintained.**

**(2) That the hospital-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety and that all improvement actions are evaluated….**

**(5) That the determination of the number of distinct improvement projects is conducted annually.**

***Interpretive Guidelines §482.21(e)(1), (2) & (5)***

*The hospital's leadership, meaning the hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials, are all responsible and accountable for the hospital's QAPI program. The medical staff may delegate this leadership responsibility and accountability for the QAPI program to the medical staff executive committee if it has such a committee. "Administrative officials" includes, at a minimum, the hospital's chief executive officer, chief operating officer, and the chief nurse executive (or equivalent), but would also include other executives in the hospital's administration.*

*Because the QAPI program is required to be a hospital-wide program, the governing body, medical staff, and administrative officials are responsible for the QAPI requirements at all locations of the hospital (onsite and off-site inpatient and outpatient services and departments) and with regard to all services provided directly by the hospital as well as those services provided under arrangement or contract. This means that the services at all locations of the hospital must be taken into consideration when developing, defining, implementing, and maintaining the QAPI program.*

*Together these hospital leaders are responsible for ensuring that the requirements identified in this standard, as well as in the other standards of this CoP, are met. Therefore, the hospital should be able to provide evidence that all such individuals are engaged in and fulfilling their QAPI responsibilities. While these leaders are not expected to be directly involved in the day-to-day activities of the hospital's QAPI program, they should be actively engaged in the oversight of the QAPI program through their periodic review of the program, including, but not limited to, the development of a plan to implement and maintain the QAPI program, the review of the progress of QAPI projects, the determination of annual QAPI projects, the evaluation of the effectiveness of improvement actions that the hospital has implemented, etc. Evidence may also include, but is not limited to, the establishment of a QAPI plan, QAPI meeting minutes with attendance rosters, signatures on annual QAPI project reviews and approvals, minutes from annual budget meetings that incorporate planning for QAPI resources, etc.*

*Additionally, this group of leaders is responsible for ensuring that clear expectations for safety are established and communicated hospital-wide. Establishing clear expectations for safety should, at a minimum, include, but not be not limited to, informing all staff of their specific roles and responsibilities in QAPI. Clear expectations for safety must also be set and communicated to those providing services under arrangements or contracts and should be documented in the contracts. It is expected that upon survey, all staff (including contractors) are able to articulate their roles and responsibilities in supporting the hospital's expectations for safety, such as what safety risks or breaches they are expected to report and how they would be expected to report them. Hospitals may communicate safety expectations through education and training, the use of posters that are constant reminders of safety requirements, staff newsletters, etc.*

***Contracted Services or Services Under Arrangement***

*When hospitals choose to provide services under an arrangement or through a contract instead of providing the services directly, it does not mean that the hospital is not responsible for the quality and safety of the services provided by the contractor. Instead, in accordance with 42 CFR 482.12(e)(1), the hospital's governing body must ensure that services performed under contract are provided in a safe and effective manner and, under 482.21, must ensure that services provided under contract or arrangement are included in the QAPI program. Therefore, the hospital must be able to demonstrate how it includes services provided under an arrangement or contract in its QAPI program, Evidence of this inclusion would include, but not be limited to, periodic assessment of contracted services, what resources the contractor has allocated to QAPI activities, how the contractor actively participates in QAPI activities, such as providing the governing body with periodic quality reports/data, attending QAPI planning meetings, and, when appropriate, conducting performance improvement projects. For example, a hospital that provides emergency services (and staffing) for its emergency department (ED) under contract or arrangement must demonstrate that it routinely receives quality data from the ED contractor, reviews the data, and takes necessary action based on the data. It is expected that the hospital must be able to provide evidence that the contracted services are included in the QAPI program in order to demonstrate compliance with the QAPI CoP.*

*Evidence of the executive leadership exercising its required QAPI program oversight would include:*

- *budget or other documents that indicate the resources available to the QAPI program, and*
- *minutes of governing body meetings that show QAPI as a standing agenda item, and more specifically, that the executive leadership makes the required QAPI program decisions related to planning, data collection, and projects, conducts regular reviews of information on the performance of the QAPI program, and makes decisions based on that review for the overall direction and management of the program.*

***Survey Procedures***

- *Ask to see evidence that the governing body, hospital CEO, Medical Staff (or its executive committee), and other administrative officials are providing oversight in the QAPI program*
    - *Are there QAPI meeting minutes that document their attendance?*
    - *Do the Governing Body meeting agendas provide evidence that the QAPI program thas been addressed?*
    - *Do the governing body meeting minutes include evidence of QAPI discussions?*

- *Are there documents such as annual QAPI program reviews that include their signatures?*

- *Ask to see evidence that the governing body, medical staff (or its executive committee), and administrative officials:*

  - *Approve the number of distinct QAPI projects to be conducted annually.*

  - *Review the results of QAPI data collection, analyses, activities, and projects, and make decisions based on such review.*

- *For those services the hospital provides under arrangement or contract, ask to see evidence that the contractor is actively involved in the QAPI program:*

  - *Do the governing body, medical staff, and administrative officials periodically receive and review quality data from the contractor?*

  - *Is the contracted service involved in any current or past hospital QAPI projects?*

  - *Does the contract or agreement include the hospital's expectations regarding the contractor's roles and responsibilities regarding QAPI?*

  - *Does the data from the contractor demonstrate positive outcomes related to the services provided?*

## A-0315

**(Rev. 105, Issued: 03-21-14, Effective: 03-21-14, Implementation: 03-21-14) Providing**

**Adequate Resources**

**§482.21(e) Standard: Executive Responsibilities**

**[§482.21(e) The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following:]**

**(4) That adequate resources are allocated for measuring, assessing, improving, and sustaining the hospital's performance and reducing risk to patients.**

***Interpretive Guidelines §482.21(e)(4)***

*The resources dedicated to the QAPI program should be commensurate with the overall scope and complexity of the services provided by the hospital. The hospital's governing body, in collaboration with its administrative officials and medical staff, should allocate adequate resources to carry out the*

*functions specified by the QAPI program CoP requirements. Adequate resources would mean that the hospital provides sufficient numbers of staff (including consultants, as needed), staff time, information systems, and education and training to support all elements of the QAPI programs' required activities and projects. In addition, adequate means that staff should be qualified to perform the QAPI functions to which they are assigned. Qualified also means staff have experience or training in the functions for which they are responsible. The hospital may choose to use qualified and experienced contractors for the day-to-day technical aspects of the QAPI program, such as data collection and analysis. However, the hospital's governing body retains the responsibility for the ongoing management of the QAPI program, even when a contractor is used for those functions.*

*CMS does not prescribe a particular formula for determining whether the hospital has allocated adequate resources to its QAPI program. However, hospitals should be able to demonstrate inclusion of the QAPI program in its budget process and identify in detail the resources it dedicates to the QAPI program. This includes the resources that a contracted service has allocated to support QAPI functions. Additionally, the hospital must be able to provide evidence of the number of staff it has allocated to focus on the management and oversight of the day-to-day QAPI program functions.*

***Survey Procedures***

- *Ask to see detailed evidence of the resources (staff, staff time, education, information systems, etc.) that are provided to support required QAPI functions.*

- *Ask to see evidence that staff are qualified to engage in their respective QAPI responsibilities.*
    - *Have all staff been educated and trained on how to report errors and adverse events?*
    - *Have staff that are required to conduct data collection and analysis received training or possess experience in these functions?*

- *For those services provided under contract, ask to see evidence that contracted services have been incorporated into the QAPI program and that there is governing body oversight of these services and the QAPI program.*