| 06/15/23 Facilities & Licensing Quarterly Webinar Q&A | |
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| Is quality evaluating Risk? Are we to be involved in the investigations for an adverse event? | No, QAPI has nothing to do with evaluating Risk Management (RM). An example of an adverse event that would be in risk management and in QAPI could be a patient fall which resulted in a broken hip. A QAPI goal might be to have zero falls with injury in the next two quarters. Whereas RM is investigating the fall to determine whether the staff followed policy/procedure or met the standard of care for patients at risk for falls. |
| When does this come out in the SOM W? The Current posted SOM does not include the C-1300s. | At this time, CMS has not provided a timeline for when the QAPI requirements and the interpretive guidance will be in Appendix W for CAHs. The eCFR has the current QAPI requirements for CAHS found at § 485.641, ***C-1300*** – ***C-1330.*** |
| Have small rural PPS hospitals already been required to meet these QAPI measures for a couple years?<br><br>We are a PPS hospital and we were surveyed on our QAPI program already back in 2019. | Yes, 2019 Hospital QAPI requirements on 09/30/19 are the same as the Hospital QAPI requirements on 06/29/23.<br><br>**§ 482.21 Condition of participation: Quality assessment and performance improvement program.**<br><br>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.<br><br>(a) ***Standard: Program scope.***<br><br>(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 |

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| | health outcomes and identify and reduce medical errors.<br><br>(2) The hospital must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital service and operations.<br><br>(b) ***Standard: Program data.***<br><br>(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.<br><br>(2) The hospital must use the data collected to—<br><br>(i) Monitor the effectiveness and safety of services and quality of care; and<br><br>(ii) Identify opportunities for improvement and changes that will lead to improvement.<br><br>(ii) Identify opportunities for improvement and changes that will lead to improvement.<br><br>(3) The frequency and detail of data collection must be specified by the hospital's governing body.<br><br>(c) ***Standard: Program activities.***<br><br>(1) The hospital must set priorities for its performance improvement activities that—<br><br>(i) Focus on high-risk, high-volume, or problem-prone areas;<br><br>(ii) Consider the incidence, prevalence, and severity of problems in those areas; and |

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| | (iii) Affect health outcomes, patient safety, and quality of care.<br><br>(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.<br><br>(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.<br><br>(d) ***Standard: Performance improvement projects.*** As part of its quality assessment and performance improvement program, the hospital must conduct performance improvement projects.<br><br>(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.<br><br>(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.<br><br>(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.<br><br>(4) A hospital is not required to participate in a QIO cooperative project, but its own |

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| | projects are required to be of comparable effort.<br><br>(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:<br><br>(1) That an ongoing program for quality improvement and patient safety, including the reduction of medical errors, is defined, implemented, and maintained.<br><br>(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.<br><br>(3) That clear expectations for safety are established.<br><br>(4) That adequate resources are allocated for measuring, assessing, improving, and sustaining the hospital's performance and reducing risk to patients.<br><br>(5) That the determination of the number of distinct improvement projects is conducted annually.<br><br>(f) ***Standard: Unified and integrated QAPI program for multi-hospital systems.*** If a hospital is part of a hospital system consisting of multiple separately certified hospitals using a system<br><br>governing body that is legally responsible for the conduct of two or more hospitals, the system governing body can elect to have a unified and integrated QAPI program for all of its member hospitals after determining that such a decision is in accordance with all applicable State and local laws. The system |

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| | governing body is responsible and accountable for ensuring that each of its separately certified hospitals meets all of the requirements of this section. Each separately certified hospital subject to the system governing body must demonstrate that:<br><br>(1) The unified and integrated QAPI program is established in a manner that takes into account each member hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital; and<br><br>(2) The unified and integrated QAPI program establishes and implements policies and procedures to ensure that the needs and concerns of each of its separately certified hospitals, regardless of practice or location, are given due consideration, and that the unified and integrated QAPI program has mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed.<br><br>[68 FR 3454, Jan. 24, 2003, as amended at 84 FR 51818, Sept. 30, 2019] |
| Under C-1313 since the standard states the CAH's governing body or responsible person is ultimately responsible could it be interpreted that if the CEO is the responsible person that alleviates the board's responsibility for QAPI? That is one issue we hear. | ***C-1313***<br>**(c) Standard: Governance and leadership.**<br><br>The CAH's governing body or responsible individual is ultimately responsible for the CAH's QAPI program and is responsible and accountable for ensuring that the QAPI program meets the requirements of paragraph (b) of this section.<br><br>***C-0962***<br><br>**§485.627(a) Standard**: Governing Body or Responsible Individual<br><br>The CAH has a governing body or an individual that assumes full legal responsibility for determining, implementing and monitoring policies governing the CAH'S total operation and for ensuring that those policies are administered so as to provide quality health care in a safe environment. |

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| | **Interpretive Guidelines**<br>The CAH must have only one governing body (or responsible individual) and this governing body (or responsible individual) is responsible for the conduct of the CAH as institution. **In the absence of an organized governing body, there must be written documentation that identifies the individual or individuals that are responsible for the conduct of the CAH operations.** |
| This all sounds very much like what Risk Management does with the references to adverse events etc. How is this different from RM? | ***C-1300***<br><br>**§ 485.641** (a) ***Definitions.*** For the purposes of this section— *Adverse event* means an untoward, undesirable, and usually unanticipated event that causes death or serious injury or the risk thereof.<br><br>***C-1311***<br><br>**§ 485.641** (b) ***Standard: QAPI Program Design and scope.*** The CAH's QAPI program must: (5) Address outcome indicators related to improved health outcomes and the prevention and reduction of medical errors, adverse events, CAH-acquired conditions, and transitions of care, including readmissions.<br><br>No, QAPI has nothing to do with evaluating Risk Management (RM). An example of an adverse event that would be in risk management and in QAPI could be a patient fall which resulted in a broken hip. A QAPI goal (outcome indicator) might be to have zero falls with injury in the next two quarters. Whereas RM is investigating the fall to determine whether the staff followed policy/procedure or met the standard of care for patients at risk for falls. |
| Do you suggest CAHs review and possibly use the CMS PPS hospital QAPI interpretative guidance and survey procedures as a way to generally help prepare for a survey? | Yes, for right now until the interpretive guidance for CAH QAPI Regs comes out in Appendix W, it would be very helpful to utilize the Hospital QAPI Interpretive Guidance in Appendix A to prepare for a survey. |