

*Section 482.21 Condition of Participation: Quality Assessment and Performance Improvement*

This revised section requires the hospital to develop, implement, and maintain an ongoing effective hospital-wide, data driven, QAPI program. The current requirements provided for the operation of an internal quality assurance program to evaluate the provision of patient care. The revised condition further requires hospitals to examine its methods and practices of providing care, identify opportunities to improve its performance, and then take actions that result in higher quality of care and improved safety for hospital patients. We have not prescribed the structures and methods for implementing this requirement and have focused the condition toward the

expected results of the program. This provides flexibility to the hospital, as it is free to develop a creative program that meets the needs of the hospital and reflects the scope of its services. We believe that developing the data systems necessary to implement a QAPI program and internal policies governing the hospitals approach to the development, implementation, maintenance, and evaluation of the QAPI program will impose minimal burden, depending somewhat on the level of compliance with the existing quality assurance requirements. Flexibility is provided to the hospitals to ensure that each program reflects the scope of its services and operations. We believe this requirement provides a performance expectation of hospital's setting their own goals and using information to continuously strive to improve their

performance over time. Given the variability across the hospitals in size and experience and the flexibility provided by the regulation, we believe the burden associated with these requirements governing the approach to the development, implementation, and evaluation of the QAPI program will reflect that diversity. We want to provide flexibility and do not want to be prescriptive in defining hourly parameters; however, we need to quantify the burden § 482.21 associated with this requirement.

We estimate that the burden associated with updating and in some instances, developing a QAPI program would be an average of 80 hours annually (although this figure may be much lower, since many hospitals have existing internal quality improvement programs).

| Requirement                    | Number of hospitals | Annual hours per hospital | Annual burden hours |
|--------------------------------|---------------------|---------------------------|---------------------|
| QAPI Program Development ..... | 6,069               | 80                        | 485,520             |

*Section 482.21(b) Standard: Program Data*

This regulation would require data collection and necessitates staff training

on data collection. Again, we estimate the burden associated with this requirement would vary, depending on the sophistication of the hospital's

quality assurance programs currently in place.

| Requirement                        | Number of personnel per hospital | Annual hours   | Number of hospitals | Annual burden |
|------------------------------------|----------------------------------|----------------|---------------------|---------------|
| Training .....                     | 10 clinicians .....              | 3 hours .....  | 6,069               | 182,070       |
|                                    | 1 coordinator .....              | 12 hours ..... | 6,069               | 72,828        |
| Data Collection and Analysis ..... | .....                            | 80 hours ..... | 6,069               | 485,520       |
| Subtotal .....                     | .....                            | .....          |                     | 740,418       |

*Section 482.21(c) Standard: Program Activities*

The current QA CoP requires hospitals to document appropriate remedial actions, and address deficiencies found through its QA program. The new QAPI CoP replaces the existing QA CoP by focusing on the continuous improvement of the hospital as an organization requiring hospitals to track incidents, analyze their causes, and share and implement preventive actions and mechanisms of feedback and learning throughout the facility. We realize it is neither practical nor economically feasible to collect data and analyze all areas, processes, and systems of the hospital. Therefore, we are requiring the hospital's governing body to ensure the priorities set by the QAPI

program are reflective of the hospitals services, ensure quality of care, and protect the safety of the patients. The burden associated with these requirements are captured above in sections 482.21 (a) and (b).

*Section 482.21(d) Standard: Performance Improvement Projects*

This new requirement reflects an interdisciplinary, coordinated approach to performance improvement. The proposed new performance improvement projects requirement sets forth the requirement that each hospital must establish a mechanism that further explores the specific needs identified in the organization's assessment. This mechanism of action is a performance improvement project. These projects demonstrate the hospital's ability to:

identify problems; evaluate and track quality indicators, or other aspects of performance; and implement actions or adopt changes that reflect processes of care and hospital operations. The hospital must be able to document and demonstrate to the SA what quality improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects.

We believe, that in order to comply with this QA CoP, hospitals, for the most part, are already documenting their efforts as remedial actions. Nevertheless, we are estimating the QAPI coordinators document the projects being conducted, the reason for the projects, and the measurable progress on these projects.