

Requirement	Number of personnel per hospital	Annual hours per hospital	Number of hospitals	Annual hours
PIP Documentation .....	Coordinator .....	32 hours .....	6,069	194,208
Subtotal .....	.....	.....		194,208

*Section 482.21(e) Standard: Executive Responsibilities*

The participating hospitals must have in writing by-laws governing the medical staff and the governing body. This incorporation of executive responsibilities pertaining to QAPI would be a one-time development by an administrative team consisting of medical staff or an appointed committee of 5 physicians and one clerical personnel. We are not associating burden with this requirement, as by-laws should be updated regularly as a normal function of the hospital. This requirement is necessary to patient health and safety because the by-laws provide the framework within which all patient care services are furnished. The initial development of the by-laws will take approximately 2.5 hours. Not more than 2 hospitals a year become certified under Medicare and Medicaid. Therefore, since this requirement impacts less than 10 hospitals on an annual basis this requirement is exempt from the PRA.

We have submitted a copy of this final rule to OMB for its review of the information collection requirements in § 482.21.

If you have any comments on any of the information collection and record keeping requirements, please mail the original and three copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Information Services, Standards and Security Group Division of CMS Enterprise, Standards Room N2-14-26, 7500 Security Blvd., Baltimore, Maryland 21244-1850, *Attention:* John Burke CMS-3050-F; and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, *Attention:* Brenda Aguilar, CMS Desk Officer CMS-3050-F.

**List of Subjects in 42 CFR Part 482**

Grant programs-health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

For the reasons stated in the preamble of this final rule, 42 CFR chapter IV is amended as set forth below:

**PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS**

1. The authority citation for part 482 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

**Subpart C—Basic Hospital Functions**

2. In §482.21 the heading and text are revised to read as follows:

**§ 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.

(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 and identify and reduce medical errors.

(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.

(b) *Standard: Program data.* (1) The program must incorporate quality indicator data including patient care data, and other relevant data, for example, information submitted to, or received from, the hospital's Quality Improvement Organization.

(2) The hospital must use the data collected to—

(i) Monitor the effectiveness and safety of services and quality of care; and

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

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

(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.

(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.

(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.

(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.

(e) *Standard: Executive responsibilities.* The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for