

through the survey process, an assessment of the hospital's success in using performance measures and objective data to demonstrate improvements have occurred.

Response: We are encouraged by the comments that support the proposed survey focus for the QAPI requirements. Further, we recognize the need for appropriate training of our surveyors. We do not intend for surveyors to judge the measures used by a hospital. Instead, we will train the SAs to assess the hospital's success in its own efforts to improve its performance. The surveyors will ensure that the number of distinct successful improvement activities conducted annually are proportional to the scope and complexity of the hospital services, operations and patient acuity, and that improvement activities demonstrate sustained improvement over time.

Comment: A commenter stated JCAHO should be involved in enforcement, emphasizing the hospital's familiarity with the current JCAHO requirements regarding QAPI.

Response: We disagree. JCAHO is an accreditation organization that sets healthcare standards but it does not have the direct authority to enforce our regulatory requirements. We also note that compliance with our quality standards is assessed either through an accreditation process that we have determined meets or exceeds our requirements or through the survey and certification process conducted by SAs under contractual agreements with us. Ultimately, we are responsible for enforcing our own requirements; and therefore have the following hospital quality oversight responsibilities: (1) Being a prudent purchaser of quality hospital services; (2) establishing minimum standards to ensure the health and safety of our beneficiaries through the CoPs; (3) ensuring that hospitals are in compliance with the CoPs; and (4) promoting quality improvement in hospitals.

Comment: Many commenters expressed concern over the lack of clarity regarding the specific documentation hospitals are required to provide to surveyors to indicate compliance on surveys and the correlation of this information in determining how these regulations improve and protect the quality of care and increase patient satisfaction. Commenters also questioned the hospital's ability to deny access to information collected for quality activities, citing confidentiality and fear of disclosure.

Response: As previously stated, surveyors will not judge the various

measures used by a hospital in its QAPI program. In general, a hospital should maintain materials and documentation that it deems necessary to objectively demonstrate its QAPI goals and outcomes to a surveyor. The surveyor should, at a minimum, expect a hospital to have documentation that describes the program; assessment information (data); the rationale for prioritized improvement projects; and the progress that has been achieved. The SAs and we have the legal authority to review records pertaining to the operation of the provider, including patient medical records (including, medical error reports, and peer review information), when these documents are necessary to determine whether the provider is in compliance with the statutory and regulatory requirements for Medicare and Medicaid participation. Section 1864 of the Act authorizes SAs to determine whether an entity meets hospital qualification under section 1861 of the Act. Included in these qualifications are requirements concerning patient records, hospital administration, and medical and nursing services. The surveyor must have access to the hospital and patient records as necessary to determine compliance for participation in the Medicare program. Also, the facility denial of access to our surveyors or us may prevent us from determining that facility's compliance with program requirements. Therefore, under the statute and regulations, we may need to pursue termination proceedings.

This information is protected by the provision of section 1106 of the Act, 42 CFR 401, as well as, the survey agency's responsibilities for protecting the confidentiality of documents, as set out in sections 3300–3316 and 3318 of the State Operations Manual.

G. Responsibilities of the Hospital's Governing Body

We proposed that the hospital's governing body, medical staff, and administrative officials are responsible for ensuring that the hospital-wide QAPI efforts address identified priorities in the hospital and for implementing and evaluating improvement actions.

Comment: A commenter stated that all of proposed § 482.25(b) should be deleted because it is included in the opening paragraph for the QAPI CoP.

Response: Accountability and leadership are vital to any QAPI program, and the hospital's leadership (for example, administration and governing body) must provide the foundation for its establishment. There must be an explicit organizational goal

that is demonstrated by clear leadership and support. With this, the hospital and its staff would be more likely to consider the quality program as a high priority and initiative. We have expanded the proposed standard entitled "Program Responsibilities" and renamed it "Executive Responsibilities" to more appropriately reflect the scope and intent of this standard. The organization's governing body must have an ongoing commitment to creating safe systems of care. The IOM report, "To Err is Human," states, "Senior level leadership should define program objectives, plans, personnel and budget, and should monitor QAPI activities by requiring reports to the executive committee and board of directors." The executive responsibilities standard clarifies that it is the responsibility of the hospital's governing body to establish a culture of safety and quality and to define the importance of QAPI activities throughout the institution. The culture of a hospital plays a critical role in how well patient safety and quality of care are viewed throughout the institution. The standard also requires the governing body to ensure that the hospital-wide QAPI efforts address priorities for improved quality of care and patient safety and that all improvement actions are evaluated.

Comment: A commenter stated that the governing body should not be held accountable for the performance of independent contractors in the medical staff because the governing body lacks the scientific knowledge to judge physicians.

Response: We are not asking, nor do we expect, the governing body to "judge" physicians or any member of the multidisciplinary team. The governing body is responsible for assuring that there is an ongoing, effective, internal QAPI program and that this program methodically identifies and addresses priorities in the hospital and initiates efforts to evaluate and address improvement actions. The analysis of these projects and events identified by the quality initiative is an integral part of the program. It is not a separate function performed by the governing body. We expect hospitals to learn from these efforts and initiate plans and actions to improve patient care outcomes, safety, and satisfaction.

H. Autopsies

We proposed that hospitals must attempt to secure autopsies in all cases of unusual deaths and in the interest of medical, legal, and educational endeavors. The mechanism for documenting permission to perform an