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Healthcare Advisory

Patient Safety and Quality Improvement Act

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Since 1999, the healthcare industry has evolved to require reporting of medical errors or unanticipated outcomes to the state governments, to accreditation agencies, to managed care companies and employer coalitions.

Are you concerned about the press, the general public or plaintiffs' attorneys gaining access to sentinel event, medical staff peer review and hospital or physician office operations data? In the event that this is a concern for you as a provider, it is important to maximize the benefit of legal protections that prevent improper disclosure. Currently, there are several protections currently provided by state law, quality assurance privilege, peer review privilege and attorney-client privilege. However, the potential of the information being obtained by plaintiff's attorneys or rating agencies is still a very real concern. In order to support the need to protect this sensitive information and promote reporting of medical errors to improve quality care, the federal government took very affirmative and quick action in July 2005.

The Patient Safety & Quality Improvement Act was passed and enacted. Its goal is to

. . . help create a "culture of safety" by providing peer review protections for information reported on health care errors for the purposes of quality improvement and patient safety.

The "culture of safety" is created by providing a new protection for information obtained and used for patient safety activities. This Act specifically creates privilege and confidentiality protections for "patient safety work product". "Patient safety work product" means any data, reports, records, memoranda, analyses, including root cause analyses, or written or oral statements which:

(i) are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization; or

(ii) are developed by a patient safety organization for the conduct of patient safety activities and which could result in improved patient safety health care quality or healthcare outcomes; or

(iii) Which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.

Patient Safety activities occur daily in a hospital setting through the Medical Staff peer review process, the Sentinel Event Process, root cause analyses, and general quality assurance review. Likewise, physician offices that conduct peer review and medical auditing for quality care may also maintain patient safety work product data. However, in order to obtain the patient safety work product protections the information must be assembled, developed or reported to a patient safety organization.

Patient Safety Organizations could be a private or public entity. At this time, the Department of Health and Human Services ("DHHS") has been tasked to create and publish criteria in order to certify patient safety organizations. Once the criteria are established, the individual organizations can file for certification. Certification will depend upon the criteria set forth by DHHS and the policies and procedures of the entity. Once the entity is certified as a patient safety organization, the information utilized for patient safety and quality improvement activities may be protected by the federal privilege and would not be discoverable for use in civil, administrative, and with certain exceptions, criminal proceedings.

Although the current process for certification has not been published, facilities that are interested in becoming a Patient Safety Organization can begin to evaluate its policies and procedures regarding peer review and quality assurance activities. The policies and procedures should be adapted to comply with the patient safety activities as defined by the regulation and to promote the patient safety and quality improvement activities as set forth by the Patient Safety and Quality Improvement Act. Therefore, begin by taking an inventory of the current policies and procedures related to quality assurance or peer review of the Hospital or physician's office. In addition, review the bylaws for the medical staff to determine if the documents specifically reference patient safety activities.

Individual physician offices may also be considered Patient Safety Organizations, particularly physician offices that have individual peers evaluating the other peer's quality and performance. It is important to determine whether or not the physician office currently has policies and procedures to outline the peer review process in order to obtain not only the state privilege, but in the future, the federal privilege. Accordingly, while the certification criteria have not been established by DHHS, the criteria will be established, and in order to be ready to file for certification, it is important to begin the process now.