Patient Safety Organizations: The Way of the Future

Legal Considerations for Providers Considering PSO Participation

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The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) authorized the creation of Patient Safety Organizations (PSOs) to encourage voluntary reporting of adverse events and aggregating of information to reduce medical errors and improve the quality of patient care in the United States.

By way of background, the Patient Safety Act resulted in part from the November 1999 report by the Institute of Medicine of the National Academies entitled “To Err is Human: Building a Safer System.” The report concluded that there is a fundamental problem in today’s health care industry related to patient safety. In response to this report and the growing concern about patient safety, Congress passed the Patient Safety Act in 2005, but the Final Rule permitting certification of PSOs did not become effective until January 19, 2009. It has created a tremendous opportunity for healthcare providers to either participate in a PSO, or to create their own PSO, and it has established a framework by which hospitals, doctors, and other health care providers may conduct a wide range of patient care activities on a privileged and confidential basis. This federal protection is important, particularly to providers operating in multiple states where state-based protections may be limited, or in some cases non-existent. Currently there are approximately 77 certified PSOs of varying size and specialty operating nationwide.

Participation in a PSO is voluntary but that may change with time. For example, Section 1311(h) of the Patient Protection and Affordable Care Act (ACA) requires hospitals with more than 50 beds to meet certain patient safety standards by January 1, 2015 in order to contract with insurers that sell Qualified Health Plans (QHPs) in Exchanges (QHP Issuers). Included in these standards is a requirement for a comprehensive hospital discharge program and use of a Patient Safety Evaluation System (PSES), which means the collection, management, or analysis of information for reporting to or by a Patient Safety Organization (PSO). The Final Rule implementing Section 1311(h)(1) of the Affordable Care Act was just released in February 2014. It delays the January 1, 2015 compliance deadline and gives hospitals of 51 or more beds at least two additional years to join/form a PSO (anticipated date of January 1, 2017) in order to contract with QHP Issuers. This delay was in part to allow further development of PSOs. Under the Final Rule, hospitals may contract with QHP Issuers if by January 1, 2015 they either (1) are Medicare-certified, or (2) have a Medicaid-only CMS Certification Number (CCN). The Final Rule announced a second phase of implementation, anticipated to begin on January 1, 2017.

Two Options for Providers to Consider

If a provider may benefit from PSO participation, the organization should initially perform a mapping process whereby it determines which patient safety processes are currently utilized. In reality, if the organization is a hospital, it most likely already has many of the requisite pieces in place; including, for example, an existing quality assurance structure, organizational charts, process flow charts, certain related policies and procedures, training elements/initiatives, outcomes data, risk alerts, root cause analyses, and clinical performance measures. Look at the activities already underway relating to quality, patient safety and risk management, and how they might function in a PSO environment.

One critical determination for providers is whether to create their own PSO or join another existing one. Creating your own PSO, usually as a component of an existing provider or health care system takes some time, effort and infrastructure development, but it can afford greater latitude in sharing patient safety information. Some providers like the idea of participating in a component PSO so that their information is more closely held, rather than sharing it with unaffiliated providers in an independent or commercial PSO. For others, especially single or smaller health care providers, joining an existing or commercial PSO may be the better option.

Participation in a PSO offers an unprecedented level of federal protection, privilege and confidentiality for work product related to patient safety. But, the Act is quite complex and still relatively new. As a result, there is not yet a well-established body of case law interpreting the Act and the extent of the protections which appear to be very broad. With time, there will undoubtedly be more case law and more familiarity with the Patient Safety Act by the courts, which should create a more solid framework of protection. One other consideration providers will need to keep in mind is that once information is labeled as protected patient safety information and the provider reports it to the PSO, with but a few exceptions, it remains privileged, protected and confidential. Thus, if the provider later wishes to use that information for another purpose, for example, to defend itself in a malpractice case, it cannot do so since the information has been submitted to a PSO.

Overall, the benefits of PSO participation are considerable and outweigh potential drawbacks. For the first time, providers are able to analyze patient safety information in a more protected environment, confidentially share that information with others, and ultimately provide benefit to the healthcare providers as well as the patients they are serving. With time, we anticipate more and more providers will be participating in PSOs or creating their own component PSO to meet important quality objectives and compliance requirements.

For more information, see
http://www.advisory.com/Research/Health-Care-Law-Roundtable/Members/White-Papers/2014/General-Counsel-Agenda-Q1-2014

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