THE INDIANA PEER REVIEW STATUTE

A Comparison with the Patient Safety and Quality Improvement Act

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The U.S. Department of Health and Human Services ("HHS") recently issued the final rule for the Patient Safety and Quality Improvement Act of 2005 ("Patient Safety Act"). The final rule became effective on January 19, 2009. The purpose of this article is to discuss the general workings of Indiana's peer review statute and then outline the Patient Safety Act's purpose, requirements and protections to show the similarities between Indiana's peer review statute and the Patient Safety Act.

First, let us look at Indiana's peer review statute in very general terms. Indiana has adopted, by statute, a peer review privilege. The protections afforded under the Indiana peer review statute appear quite clear. For instance, "[a]ll proceedings of a peer review committee are confidential." I.C. § 34-30-15-1(a). Also, "[a]ll communications to a peer review committee shall be privileged communications." I.C. § 34-30-15-1(b). Essentially, the communications, records and determination of a peer review committee may not be revealed except a governing board of a hospital, professional health care organization, preferred provider organization or a health maintenance organization may disclose the final action taken with regard to a professional health care provider without violating the provisions of the peer review statute. I.C. § 34-30-15-(c) and (d).

The purpose of the peer review privilege is to foster an effective review of medical care. Information and materials submitted or disclosed to the agency by the peer review committee are confidential and privileged from use as evidence in an administrative or judicial proceeding and the information may not be released outside the agency. Persons who attend a peer review committee proceedings are not permitted to disclose any information acquired in connection with or in the course of the proceeding, any opinion, recommendation of the committee or any opinion, recommendation or evaluation of any committee member. I.C. § 34-30-15-2.

It should also be noted under the Indiana peer review statute that information that is otherwise discoverable or admissible from original sources is not immune from discovery or use in any proceeding merely because it was presented during proceedings before a peer review committee. Likewise, a member, employee, agent of a committee or other person appearing before the committee may not be prevented from testifying as to matters within that person's knowledge. I.C. § 34-30-15-3.

In most cases, the communications to, records of and determinations of a peer review committee may only be disclosed to the peer review committee of a hospital, a nonprofit health care organization, a preferred provider organization, a health maintenance organization or a limited service health maintenance organization, or another health facility. There is a handful of other permissible disclosures under the statute.

In the most general terms, Indiana's peer review statute allows for a full and comprehensive review of an event that adversely affects a patient in order to prevent the event from occurring again, and, if applicable, develop procedures to safeguard against the event. The process benefits both the health care providers and the patients.

The policies, reasoning and goals of the Patient Safety Act are similar to the policies, reasoning and goals of the Indiana peer review statute. The Patient Safety Act can be found in 42 U.S.C. § 299b-21 through 299b-26. The Patient Safety Act focuses on creating a voluntary program through which health care providers can share information relating to patient safety events with Patient Safety Organizations ("PSOs"). The aim of the Patient Safety Act is to improve patient safety and the quality of care nationwide.

Much like Indiana's peer review statutes, the Patient Safety Act attaches privileges and confidentiality protections to the information shared by health care providers to the PSOs. The privileges and confidentiality protections are essential to the Patient Safety Act because it encourages providers to share the information without fear of liability. These protections enable all health care providers who so choose to share data within a protected legal environment, both within and across state lines, without the threat that the information will be used against the subject providers. Like Indiana's peer review statute, the Patient Safety Act believes that patient safety will be improved by the sharing of events that adversely affect patients because the information will be analyzed to identify patterns of failures which can then lead to procedures to eliminate the failures that will benefit both patients and healthcare providers.

The Patient Safety Act serves as the statutory authority to create the Patient Safety Organizations. PSOs are the entities that collect, aggregate and analyze confidential information reported by health care providers. An entity must submit a certification form requesting the Secretary of the HHS to list it as a PSO. There are certain requirements that an entity must meet in order to become a PSO. In addition, there are certain entities that are excluded from seeking a listing as a PSO.

There are fifteen requirements that an entity must meet in order to submit a proper certification to the Secretary of the HHS. The majority of the requirements pertain to patient safety activities. Examples of the requirements include:

- efforts to improve patient safety and the quality of health care delivery
- collection and analysis of patient safety work product
- development and dissemination of information to improve patient safety, such as recommendations, protocols or information regarding best practices
- use of patient safety work product for purposes of encouraging a culture of safety and of providing feedback and assistance to minimize patient risk
- maintenance of procedures to preserve confidentiality with respect to patient safety work product

- provision of appropriate security measures with respect to patient safety work product

- use of qualified staff

- activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system.

In addition, the entities seeking PSO status must certify that it will comply with the following seven additional requirements:

- the mission and primary activity of the PSO must be to conduct activities that are to improve patient safety and the quality of health care delivery

- the PSO must have appropriately qualified workforce members, including licensed or certified medical professionals

- the PSO, within the 24 month period that begins on the date of its initial listing as a PSO, and within each sequential 24 month period thereafter, must have 2 bona fide contracts, each with a different provider for the purpose of receiving and reviewing patient safety work product.

- the PSO is not a health insurance issuer and is not a component of a health insurance issuer

- the PSO must make disclosures to the Secretary as provided in the final rule

- to the extent practical and appropriate, the PSO must collect patient safety work product from providers in a standardized manner that permits valid comparisons of similar cases among similar providers

- the PSO must utilize patient safety work product for the purpose of providing direct feedback and assistance to providers to effectively minimize patient risk.

The intentions of the HHS were to minimize barriers to entry for entities seeking listing and create maximum transparency to create a robust marketplace for PSO services. The Secretary of the HHS has the authority to approve or deny PSO listings for the entities submitting a request. The Secretary of the HHS may accept the certification submission and list the entity of the PSO if the Secretary determines that the entity meets the applicable requirements of the Patient Safety Act. The Secretary may also deny the submission for certification or may request information or conduct announced or unannounced reviews of, or site visits to, PSOs to assess or verify the PSOs compliance with the requirements for certification.

Patient safety work product is the information shared by health care providers to PSOs and the information that health care providers want protected. Patient safety work product ("PSWP") means any data, reports records, memoranda analyses (such as root cause analyses) or written or oral statements:

1. which could improve patient safety, health care quality or health care outcomes and is assembled or developed by a provider for reporting to a PSO and is reported to a PSO, or is developed by a PSO for the conduct of patient safety activities; or

2. which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.

By definition it does not include a patient's medical record, billing and discharge information, or any other original patient or provider information, nor does it include information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system.

Disclosures of PSWP to PSOs are privileged and confidential. There are a few exceptions where disclosure of the information will not be protected by privilege or confidentiality. These exceptions include:

1. Disclosure of relevant PSWP for use in a criminal proceeding if such PSWP contains evidence of a criminal act, is material to the proceeding, and is not reasonably available from any other source;

2. Disclosure to the extent required to permit equitable relief under the Public Health Service Act;

3. Disclosure of identifiable PSWP consistent with a valid authorization from each provider identified in such work product; and

4. Disclosure of nonidentifiable PSWP.

Also, there are six disclosures to the PSOs that remain privileged but are not confidential and are permitted disclosures outside of the PSOs:

1. Disclosure of PSWP for patient safety activities by a provider to a PSO or by a PSO to that disclosing provider;

2. Disclosure to persons carrying out research, evaluation or demonstration projects authorized, funded, certified, or otherwise sanctioned by the Secretary;

3. Disclosure concerning an FDA-regulated product or activity to the FDA, an entity required to report to the FDA concerning the quality, safety, or effectiveness of an

FDA-regulated product or activity, or a contractor acting on behalf of FDA or such entity for these purposes;

4. Voluntary disclosure to an accrediting body that accredits that provider;

5. Disclosure for business operations to attorneys, accountants, and other professionals; and

6. Disclosure to an appropriate law enforcement authority relating to an event that either constitutes the commission of a crime, or for which the disclosing person reasonably believes constitutes the commission of a crime.

A person who discloses identifiable patient safety work product in knowing or reckless violation of the confidentiality provisions shall be subject to a civil money penalty for each act constituting such violation. The Secretary may impose a civil money penalty in the amount of not more than $10,000. In determining the amount of any civil money penalty, the Secretary may consider a list of aggravating or mitigating factors, as warranted by the circumstances. The list of the aggravating or mitigating factors can be found in the final rule.

As you can see by reviewing Indiana's peer review statute and the Patient Safety Act, the purpose of each is to improve patient safety and the quality of care to patients whether it is in Indiana or any other place in the United States. Indiana and the HHS believe this purpose is best accomplished by allowing health care providers to fully review a situation without fear that the review and results of the review could be admissible on whether a health care provider is liable for the events that adversely affected a patient. Furthermore, in order to alleviate health care providers' fear of liability, the protections afforded under the Indiana peer review statute and the Patient Safety Act do not allow the disclosure of confidential information (or PSWP). While Indiana's peer review statute and the Patient Safety Act are not identical, the purpose and protection of each have one goal.

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