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The future of medical necessity peer review: The Patient Safety Act

- » Use the National Health Care Privilege under the Patient Safety Act to improve patient safety by sharing “lessons learned.”
- » Build an effective medical necessity surveillance system using the privilege to improve care quality.
- » Create a learning system to prevent the same mistakes from being repeated by other health care professionals.
- » Build an effective communication bridge between the Patient Safety Evaluation System and the compliance/legal team.
- » Learn the role of the compliance group in ensuring that the Patient Safety Evaluation System is compliant.

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Hospitals face significant compliance risk for the submission of claims to federal healthcare programs for services that turn out to be medically unnecessary. To identify patterns associated with fraud, the Centers for Medicare & Medicaid Services (CMS) applies predictive algorithms and other sophisticated analytics to identify billing patterns associated with Medicare fee-for-service claims that could expose high-volume producers of high-risk invasive procedures to government investigations.¹

For example, in July 2015, CMS issued a report regarding its implementation of the Fraud Prevention System, which uses predictive analytics to manage government fraud and False Claims Act investigations. According to this report, CMS identified or prevented \$820 million in inappropriate payments in the program's first three years. Moreover, CMS identified or prevented \$454 million in 2014. In the future, CMS plans to expand its algorithms to identify

even lower thresholds of non-compliance among healthcare providers.²

These compliance risks require that providers, especially high-volume producers, proactively identify and understand any outlier data. Because the findings of any internal review may be sought by the government or potential whistleblowers, it is critical that a provider take the necessary steps to ensure the confidentiality of its review. As more fully discussed below, neither the attorney-client privilege nor state peer review protections are ideal for this type of surveillance review. This article identifies the advantages to health systems and medical groups using Patient Safety Organizations (PSOs) and the Patient Safety and Quality Improvement Act's³ (Patient Safety Act's) nationally uniform privilege in surveillance review. Collectively, a PSO and the Patient Safety Act's privilege can be used to create a confidential learning system that promotes information sharing, physician education, and cost-effective patient outcomes based on medically necessary procedures.



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Driving quality of patient care through the False Claims Act

Medicare requires healthcare providers to assure that health services ordered for government patients are “provided economically and only when, and to the extent, medically necessary.”⁴ Medically necessary care is patient care that is provided in accordance with generally accepted standards of medical practice or that is clinically appropriate. In 1998 the American Medical Association defined medical necessity as:

health care services or products that a prudent physician would provide to a patient for the purpose of preventing, diagnosing or treating an illness, injury, disease or its symptoms in a manner that is: (a) in accordance with generally accepted standards of medical practice; (b) clinically appropriate in terms of type, frequency, extent, site, and duration; and (c) not primarily... for the convenience of the patient, treating physician, or other health care provider.⁵

In the event of a pattern of Medicare claims for unnecessary procedures, the government typically will investigate whether or not the hospital had an effective peer review program or otherwise audited the medical necessity of the procedures for which it billed. In the absence of an effective peer review program, hospitals face potential liability under the False Claims Act, which could result in treble damages (i.e., three times the amount of reimbursement received for the procedures), additional per-claim monetary penalties, and administrative sanctions up to and including exclusion from federal healthcare programs.

Not only is there liability risk from the federal government, private payers can also demand reimbursement for claims paid, and medical malpractice claims and class action lawsuits may be filed to compensate patients

for their injuries related to the unnecessary care provided. To ensure such penalties are avoided, it has now become a best practice for hospitals to implement systematic medical necessity reviews, particularly for high-risk invasive procedures, including but not limited to cardiology, orthopedic, and obstetric procedures.

There are clear drawbacks to using the established peer review process and attorney-client privilege to conduct medical necessity reviews. Preserving the state peer-review protection may limit the dissemination of root cause analyses and, thereby, frustrate the provider’s ability to leverage “lessons learned” from past instances of non-compliance. Failing to prevent future quality problems involving similar instances of past non-compliance is an invitation to a federal investigation, based on the theory that the provider exhibited “deliberate ignorance” to the risks of medically unnecessary procedures. Equally important, medical necessity reviews, which are conducted at the direction of counsel, can be expensive, resource intensive, and, like state peer protections, fail to promote system-wide learning, which prevents the risk or recidivism for a health system consisting of different physicians and different hospitals. As a result, not every review of cases, even those performed by high-volume providers, ought to be conducted under attorney-client privilege. In cases where there are no allegations of wrongdoing against the provider, or when a health system simply wants to ensure that the physicians are providing high-quality care to patients, the surveillance review should be conducted under the Patient Safety Act’s learning system.

Improving medical procedure quality through the Patient Safety Act

The Patient Safety Act was enacted as the cornerstone of the federal effort to reduce preventable injuries and deaths in the United States’ healthcare system. Congress designed the Patient Safety Act to foster a “learning environment”

that would allow all licensed healthcare providers to assess their quality of patient care without fear that their data and analyses will be subject to discovery in medical malpractice actions or cause harm to their professional reputations.⁶ Such protections are critical to creating a learning environment that fosters continual quality improvement and the development of high reliability in the quality of patient care.

The Patient Safety Act provides three separate protections for “patient safety work product,” which means any data, reports, records, memoranda, analyses (such as root-cause analyses), deliberations, or written or oral statements which could result in improved patient safety, healthcare quality, or healthcare outcomes.⁷

First, the information is protected by a privilege. The privilege runs with the quality information and cannot be intentionally or unintentionally waived by any provider. The Patient Safety Act privilege is national in scope and is stronger than any state peer privilege. The privilege protections in the patient safety work product include:

- (a) ...Notwithstanding any other provision of Federal, State, or local law, and subject to subsection (c), patient safety work product shall be privileged and shall not be:
 - (1) subject to a Federal, State, or local civil, criminal, or administrative subpoena or order, including in a Federal, State, or local civil or administrative disciplinary proceeding against a provider;
 - (2) subject to discovery in connection with a Federal, State, or local civil, criminal, or administrative proceeding, including in a Federal, State, or local civil or administrative disciplinary proceeding against a provider;
 - (3) subject to disclosure pursuant to section 552 of Title 5, United States Code (commonly known as the Freedom of Information Act) or any other similar Federal, State, or local law;

- (4) admitted as evidence in any Federal, State, or local governmental civil proceeding, criminal proceeding, administrative rulemaking proceeding, or administrative adjudicatory proceeding, including any such proceeding against a provider; or
- (5) admitted in a professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under State law.⁸

The privilege can be used to share quality information among hospitals and medical groups across state lines. The privilege also protects providers, such as primary care providers, who may not have typically conducted a quality improvement peer review process, because their states do not provide a privilege to conduct such activities.

Second, the statutory confidentiality provisions are similar to the Health Insurance Portability and Accountability Act (HIPAA) and provide privacy rights for providers and patients. According to the Patient Safety Act: “Notwithstanding any other provision of Federal, State, or local law, and subject to subsection (c), patient safety work product shall be confidential and shall not be disclosed.”⁹ It is well recognized that if information could be used to harm the providers’ professional reputation, they would be less willing to participate in the learning system.

Finally, Congress placed a limitation on actions against a PSO. A PSO cannot be compelled to disclose information it collected or developed, whether or not such information is privileged patient safety work product, unless such information is identified, is not patient safety work product, and is not reasonably available from another source.¹⁰ This added protection prevents the mining of the rich database of confidential quality information that is collected and aggregated for the benefit of patients.

The Patient Safety Act provides a system to collect, manage, and analyze information for reporting to or by a PSO. The Patient Safety Evaluation System (PSES) provides a paradigm to evaluate complaints and incident reports that is removed from potential conflict of interest, bias, and institutional financial pressures. An internal PSO removes the need to employ external review agencies that are expensive and may vary in quality or lack standardization.

Even if an external PSO is used for the review, the program can be designed by the provider to yield a standardized quality review and to develop best practices to solve any quality or technical issue that may be identified during the review. The Patient Safety Act requires that the health system educate providers about best practices and implement processes that will foster the continual improvement of the standards of care that are applicable to their practice.

Using a Patient Safety Organization

As an alternative to having external agencies conduct surveillance peer reviews, numerous health systems and medical groups have been forming system-wide PSOs in order to take advantage of the federal protections provided by the Patient Safety Act. The advantages of a PSO include the ability to draw upon internal resources throughout the system to remove bias that can be caused by using medical staff of a hospital, and to share information enterprise-wide to promote system-wide learning and establishment of systemized reliable care.

Because of the compliance risks implicated by medically unnecessary procedures, and because the PSO focuses on quality concerns

or outcomes and not compliance, it is critical that an effective bridge of communication exists between the hospital or medical group's PSES and the Compliance department on one hand, and the medical staff on the other. In addition, it is critical that the PSES process be audited periodically by the Compliance department to ensure that the process is not biased; the policies and procedures are followed; cases are randomly selected and

blinded; reviewers are appropriately trained and, if appropriate, certified to conduct the review; and that quality issues identified that may signal potentially unnecessary care are referred to the medical staff and Compliance

department, as appropriate, for separate, independent follow up and investigation.

PSOs are not intended to hide poor performing doctors through the veil of the Patient Safety Act privilege. The Patient Safety Act was drafted during the discovery of the New Jersey "Angel of Death." A nurse who worked at ten different hospitals in New Jersey and Pennsylvania admitted to killing as many as 45 patients between 1988 and 2003 with overdoses of drugs.¹¹ Congress designed PSOs to collect and aggregate data from many sources and believed that a PSO should be able to identify potential patient safety issues, such as overdoses connected to a single provider. The PSO would inform all of the hospitals or medical groups at which the provider was employed or maintained privileges, to investigate the quality of the patient care related to the quality-of-care issue that was uncovered. Bear in mind that the PSO likely would not have enough information to substantiate that the provider is consistently providing

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substandard care, intentionally causing the injury to patients, or engaging in a pattern of unnecessary medical procedures. The PSO would simply see a relationship that needs to be investigated by the hospital.

The PSO's primary mission is to provide best practices and education to resolve any quality-of-care issues that are uncovered during its analysis, while serving as the "canary in the coal mine" to share information that triggers a separate, independent investigation into the provider's care. The privileged patient safety work product could not be disclosed to the Compliance department, unless there is a reasonable belief that a crime had been committed, such as in the New Jersey Angel of Death case. Nonetheless, the PSES can share feedback from the PSO indicating that the provider appears to need education on the medical necessity of a particular medical procedure. This signal should raise a duty on the part of the hospital to investigate the patient care provided by that physician. If appropriate, the PSO or PSES should develop education, clinical solutions, updated clinical protocols, and lessons learned to prevent future occurrences of the quality issue uncovered during the review. This training should be given to the errant physician, as well as other physicians within that specialty. At this juncture, a separate, independent audit for medical necessity should be conducted at the direction of counsel and with the assistance of the Compliance department.

Conclusion

Congress carefully constructed the Patient Safety Act to balance the need for providers to have confidentiality protections for self-critical analysis, and the need for accountability to federal programs. Importantly, the Patient Safety Act privilege and confidentiality protections are intended to provide a means for healthcare providers to candidly review and discuss how to improve patient care. Therefore, if the initial probe by the PSO or hospital PSES uncovers information that suggests that medically unnecessary procedures were performed, the PSES would alert the hospital compliance group, who would then conduct a separate, independent investigation. It is up to the compliance group to ensure that the PSES is operating properly, that confidentiality of the patient safety work product is maintained, and that communication bridges are working. Lives can be saved by ensuring that incidents are not repeated and that no harm comes to other patients in other healthcare facilities. This transparency is intended to raise the level of care by all providers and make patient care more reliable across the entire health system or medical group. ©

1. CMS Medicare Fraud Prevention Initiative, *see* www.cms.gov
2. *Id.*
3. The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b-21, *et seq.*
4. 42 USC 1320c-5(a)(1).
5. American Medical Association: Policy H-320.953. Available at <http://bit.ly/1MEkF63>
6. H.R. Rep. 109-197, at 9; S. Rep. No. 108-196, at 3.
7. 42 U.S.C. § 299b-21(7).
8. 42 USC 299b-22(a).
9. 42 U.S.C. 299b-22(b)
10. 42 U.S.C. 299b-22(d)(4)(A)(1).
11. CBS 60 Minutes: "Angel of Death: Killer nurse stopped, but not soon enough." April 29, 2013. Available at <http://cbsn.ws/1Ntr7sP>

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