

**THE PATIENT SAFETY AND QUALITY
IMPROVEMENT**

ACT OF 2005

**A Practical Analysis of the
Federal Patient Safety Reporting Provisions and What
They Mean to Health Care Providers**

A monograph prepared and edited by

Marcia Malouin
Maribeth Dickerson
Gregory Drutchas
for the friends and clients of



KITCH DRUTCHAS WAGNER VALITUTTI & SHERBROOK
One Woodward Avenue, Suite 2400
Detroit, Michigan 48226
(313) 965-7900

© 2005

**THE PATIENT SAFETY AND QUALITY
IMPROVEMENT**

ACT OF 2005

A Practical Analysis of the Federal Patient
Safety Reporting Provisions and What They
Mean to Health Care Providers

A monograph prepared and edited by

Marcia Malouin
Maribeth Dickerson
Gregory Drutchas

for the friends and clients of

KITCH DRUTCHAS WAGNER VALITUTTI & SHERBROOK
One Woodward Avenue, Suite 2400
Detroit, Michigan 48226
(313) 965-7900

© 2005 Kitch Drutchas Wagner Valitutti & Sherbrook

TABLE OF CONTENTS

<i>I.</i>	<i>INTRODUCTION</i>	1
<i>II.</i>	<i>STRUCTURE OF THE SYSTEM</i>	2
1.	What is the purpose of the Patient Safety Quality Improvement Act?.....	2
2.	What is a patient safety organization?.....	2
3.	Who is considered a provider that can report information under the Act?.....	2
4.	Can a provider establish its own patient safety organization?.....	2
5.	What does the patient safety organization certification process consist of?.....	2
6.	What will these patient safety organizations do with information that providers report to them?.....	3
7.	What provider information is protected by the federal confidentiality provisions?.....	3
8.	Does the information retain confidentiality after it is reported to a patient safety organization?.....	3
9.	What are the confidentiality protections established in the Act?.....	4
10.	What are the parameters under which the confidential information may be disclosed?.....	4
11.	Does disclosure of the information waive the safety work product privilege and confidentiality protection?.....	5

TABLE OF CONTENTS (Continued)

12.	Can any of this put our accreditation status at risk?.....	6
13.	Do the HIPPA Privacy Regulations allow a provider to disclose protected health information to a patient safety organization?	6
14.	What happens if the Department of Health and Human Services decertifies the patient safety organization that has your information?.....	6
15.	Are there penalties associated with not following the new law?.....	6
16.	Why would a provider report?.....	7
17.	May a provider discipline an employee who reports a patient safety incident?.....	7
18.	What does this Act mean for me as a provider?.....	7
<i>III.</i>	<i>CONCLUSION</i>	8

INTRODUCTION

The November 29, 1999, Institute of Medicine report, *To Err is Human: Building A Safer Health System*, called for the creation of a national patient safety center to address medical errors within the health care system. An important thesis of the document was that an effective error reporting system is an essential element of any improvements in eventually avoiding errors. While some statements in the report were controversial and debated, the overall premise and recommendations in the report were well accepted and regarded among providers as a statement of industry goals. As a result, Congress enacted the Patient Safety and Quality Improvement Act of 2005, which was signed by the President on July 29, 2005, 42 USC 921 *et. seq.*

The Act establishes a voluntary reporting system for mistakes and near misses, with federal confidentiality provisions to protect the information so providers are not hampered from disclosing mistakes by the fear of litigation.

This summary is designed to help providers understand the application of the confidentiality provisions and thus, make an informed decision about voluntarily reporting medical errors.

STRUCTURE OF THE SYSTEM

1. What is the purpose of the Patient Safety Quality Improvement Act?

The stated purpose of the Act is to improve patient safety by encouraging health care providers to voluntarily report medical errors to patient safety organizations for review and analysis.

2. What is a patient safety organization?

A patient safety organization is a private or public entity that is formed primarily to conduct patient safety and quality improvement activities and is certified as a patient safety organization by the Secretary of the Department of Health and Human Services. The entity may not be a health insurance issuer or a component of a health insurance issuer.

3. Who is considered a provider that can report information under the Act?

Any individual or entity licensed or otherwise authorized by state law to provide health care services. Providers are classified in the categories of entities and individual practitioners, as well as any future designations made by the Secretary of HHS. Examples given of provider entities include not only hospitals but nursing homes, home health agencies, pharmacies, and clinical laboratories. Examples of individual providers include physicians and their assistants, nurses, social workers, and dieticians.

4. Can a provider establish its own patient safety organization?

The Act does not specifically prohibit a provider from establishing a patient safety organization. However, each patient safety organization must contract with more than one provider to receive and review patient safety information. The patient safety organization must also disclose to the Department of Health and Human Services any financial, reporting or contractual relationship with any provider that it contracts with and whether it is managed, controlled, or operated by any provider that it contracts with. The Department of Health and Human Services will then decide if the patient safety organization can perform patient safety activities fairly and accurately before certifying the patient safety organization.

5. What does the patient safety organization certification process consist of?

The Act authorizes funds to be appropriated to implement the Act for fiscal years 2006 through 2010. At present, procedures and specific criteria for certification have not yet been published. This process will, most likely, occur through publication in the Federal Register when HHS is ready to begin certifying patient safety organizations. Until then, there is no place to report and, therefore, the privilege and confidentiality provisions do not attach.

6. What will these patient safety organizations do with information that providers report to them?

The patient safety organizations will maintain databases on reported incidents, analyze the collected information for trends in health care and areas of needed improvement, develop and disseminate recommendations, protocols, and best practices, and provide feedback and assistance to providers to minimize patient risk.

7. What provider information is protected by the federal confidentiality provisions?

The law protects the confidentiality of any information (i.e., data, reports, records, memoranda, analyses or written or oral statements) that is collected or developed by the provider for reporting and is reported to the patient safety organization. Confidentiality also attaches to any information that identifies the fact that the provider collected or analyzed patient safety information or reported to a patient safety organization.

The confidentiality of information that is collected, maintained, or developed separately, or that exists separately, from that which is actually collected, managed, or analyzed for reporting to a patient safety organization is not protected by the Act. Thus, the confidentiality of a patient's medical record, billing and discharge information or any other original patient or provider record is not protected by the Act.

8. Does the information retain confidentiality after it is reported to patient safety organization?

Yes. The confidentiality protections continue to apply to the information after it is received by the patient safety organization. Confidentiality also applies to the information that is developed by the patient safety organization for the conduct of patient safety activities, and to the feedback the patient safety organization gives to the provider.

9. What are the confidentiality protections established in the Act?

The Act provides that, regardless of any other federal, state or local law, a patient safety work product privilege attaches such that the confidential information shall:

- not be subject to a federal, state, or local civil, criminal, or administrative subpoena or order;
- not be subject to discovery in connection with a federal, state, or local civil, criminal, or administrative proceeding;
- not be subject to disclosure under the federal Freedom of Information Act or any other similar federal, state, or local law;
- not be admissible as evidence in any federal, state, or local governmental civil or criminal proceedings or administrative adjudicatory or rulemaking proceedings, including those against a provider;
- not be admissible in a state professional disciplinary proceeding.

In addition to the patient safety work product privilege, the Act establishes confidentiality protections to the information prohibiting its disclosure outside of narrowly established parameters for disclosure.

10. What are the parameters under which the confidential information may be disclosed?

Disclosure is allowed:

- for use in criminal proceedings, but only after the court makes an *in camera* determination (private review without others present)

that the information contains evidence of a criminal act and the information is material to the proceeding and not reasonably available from another source;

- to the extent required to carry out a civil action against the provider brought by an individual who was disciplined for reporting a safety incident (a whistleblower);
- if authorized by each provider identified in the information;
- to carry out patient safety activities;
- if the information is presented in a form and manner that does not allow the identification of any provider, patient, or individual who reported the information;
- To grantees, contractors, or other entities carrying out sanctioned research, evaluation, or demonstration projects;
- To the Food and Drug Administration about a product or activity regulated by that agency;
- By the provider to the provider's accrediting body;
- If necessary for business operations if the Secretary of Health and Human Services first determines that the disclosure is consistent with the goals of the Act;
- To law enforcement authorities of information relating to the commission of a crime;
- If the information does not include materials that assess the quality of care of an identifiable provider or that describe or pertain to an act or failure to act by an identifiable provider.

11. Does disclosure of the information waive the safety work product privilege and confidentiality protection?

Not ordinarily. With few exceptions, disclosure of the information is not treated as a waiver of privilege or confidentiality, and the privileged and confidential nature of the information continues to apply when the information

is in the possession or control of a person to whom it was disclosed. If disclosed in a criminal proceeding, however, the confidentiality protections no longer apply to the information disclosed. Moreover, the safety work product privilege and confidentiality protections do not apply to information disclosed in a form and manner that does not allow the identification of any provider, patient, or individual who reported the information.

12. Can any of this put our accreditation status at risk?

Accrediting organizations are prohibited from taking accrediting action against providers based on the provider's good faith participation in a patient safety evaluation system. Although providers may voluntarily report safety information to their accrediting bodies, accrediting bodies are also prohibited from requiring a provider to reveal its communications with any patient safety organization. Moreover, if a patient safety organization is a component of the accrediting body, it must maintain the patient safety information separately from the rest of the organization, must establish appropriate security measures to maintain the information's confidentiality, and may not make unauthorized disclosure of the information to the rest of the organization.

13. Do the HIPPA Privacy Regulations allow a provider to disclose protected health information to a patient safety organization?

Yes. Patient safety organizations are treated as business associates, and the patient safety activities of a patient safety organization in relation to a provider are deemed to be health care operations of the provider. Therefore, a provider will need to enter into a HIPAA business associate agreement with any patient safety organization before reporting information to the patient safety organization.

14. What happens if the Department of Health and Human Services decertifies the patient safety organization that has your information?

The patient safety organization must either transfer the information to another patient safety organization approved by the provider or return the information to the provider, or if return is impracticable, destroy the information.

15. Are there penalties associated with not following the new law?

Reporting is voluntary and providers will not be penalized for not reporting an incident.

However, civil penalties up to \$10,000 can be assessed against any person who knowingly or recklessly discloses patient safety work product in a manner prohibited by the law.

16. Why would a provider report?

Since reporting is not mandatory, for moral-ethical and educational purposes. Participation in the patient safety evaluation system and receipt of feedback from patient safety organizations help providers to increase their knowledge of error trends that can be used to eliminate errors over time. Reporting in an organized and coordinated institutional manner may also forestall the risk that employees may report on their own in a manner which leaves an organization unprotected.

In this respect, recognize in order for work product and confidentiality protections to apply to the provider's information, the information must be assembled or developed for the specific purpose of reporting to a safety organization and must be reported to the patient safety organization. Doing it any other way puts the information at risk for legal discovery.

17. May a provider discipline an employee who reports a patient safety incident?

The Act prohibits a provider from taking an adverse employment action against an individual for making a good faith report of an incident to the provider or directly to a patient safety organization. The Act insulates the individual from discipline for the act of reporting, not for the conduct creating the patient care incident itself.

18. What does this Act mean for me as a provider?

Since reporting may be in a provider's best interest and this permissive law may be replaced at some later point by a mandatory one, providers need to establish a patient safety evaluation system for collecting, analyzing, or managing the information that will be reported to a patient safety organization.

Most providers already have systems in place that are being used to collect safety and quality improvement information. However, information currently maintained in separate performance, risk management, and peer review systems will not be covered by the Act's confidentiality provisions if the information is not collected for reporting and reported to a patient safety organization. So a special effort and process is needed.

CONCLUSION

The details of the certification process for patient safety organizations and the logistics of the Act are still forthcoming. The process should be funded beginning in 2006 for HHS to establish procedures and criteria for patient safety organizations and providers to structure reporting processes that ensure the privilege and confidentiality provisions attach to their patient safety information.

Please call Marcia Malouin with any questions concerning the Patient Safety Quality Improvement Act at (517) 381-4426.