CLIENT ALERT

New Patient Safety and Quality Improvement Act of 2005 Enacted

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In late July, Congress passed and President Bush signed into law the Patient Safety and Quality Improvement Act of 2005. The law creates a new voluntary reporting system for medical errors responding to five years of increased focus on the human and financial costs of medical errors. The outline below provides background on the medical errors issue, summarizes the new legislation and notes key points on the Act's impact and uncertainties.

Background

- *To Err is Human* , Institute of Medicine, 1999
    - Definition: *An error is defined as the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning).*
    - Medical errors are the 8th leading cause of death.
    - 44,000-98,000 Americans die each year in hospitals as a result of medical errors.
    - Total costs (including (lost income, lost household production, disability, health care costs) are estimated to be between $17-$29 billion.
    - Recommendation 5.1: A nationwide mandatory reporting system should be established that provides for the collection of standardized information by state governments about adverse events that result in death or serious harm. Standardized reporting format; linked to systems of accountability; public disclosure.
    - Recommendation 5.2: The development of voluntary reporting efforts should be encouraged **.** Not necessary for it to be nationwide.

- "Minimizing Medical Errors: Legal Issues in the Debate on Improving Patient Safety." Public Interest Colloquium, American Health Lawyers Association. Feb. 28-March 1, 2003.
    - The problem of medical errors is national in scope, and national (though not necessarily federal) leadership is needed to address the issue. National leadership should include visibility of reporting to the public and real analysis that can actually influence future healthcare outcomes.
    - Existing mandatory reporting systems do not work well. Incidents reported voluntarily need to be shielded from discovery in litigation and from retaliation.
    - There is a need for change away from the current culture of "shame and blame" in reporting adverse medical events to focusing on the benefits of collection and analysis of data generated through such reporting.

The Legislation

Summary: The Patient Safety and Quality Improvement Act of 2005 establishes a confidential reporting structure in which physicians, hospitals, and other health care professional and entities can voluntarily report information on errors to Patient

Safety Organizations (PSOs). PSOs, in turn, would analyze the data to develop patient safety improvements strategies. The law stipulates that submitted patient safety information will be confidential and legally protected, and provides penalties for unlawful disclosures. It also preserves confidentiality of patient information under the Health Insurance Portability and Accountability Act of 1996. It does not shield information available outside of a patient safety evaluation system, such as medical and billing records.

- Provides the following:
  - Providers, including physicians, could voluntarily report confidential and legally privileged "Patient Safety Work Product" (PSWP) to a certified PSO (public or private) as part of a "Patient Safety Evaluation System."
  - PSWP is information that **may** result in improved patient safety, health care quality, or health care outcomes and is either gathered by a provider for PSO reporting and actually reported, or developed by a PSO for patient safety activities. Information does not identify specific patients, health care providers or individuals who report errors.
  - PSOs would analyze PSWP, provide feedback to providers, and may report non-identifiable PSWP to a database (which may be linked to a network of databases facilitated by HHS).
  - PSWP is privileged and shall not be:
    - Subject to subpoena
    - Subject to discovery
    - Subject to disclosure under Freedom of Information Act or any other similar law.
    - Admitted as evidence
    - Admitted in a professional disciplinary proceeding of a professional disciplinary body.
  - PSWP may be disclosed if:
    - In a criminal proceeding after in camera review
    - If authorized by each of the providers identified therein
    - In a proceeding against an employer for retaliating against an employee who reported PSWP
  - Information or evidence available from original records (e.g., medical records), and information that is not PSWP and can be collected under other laws (e.g., state reporting requirements), would not be limited or affected.
  - Stronger state protections are not preempted.
  - An adverse action cannot be taken for good faith reporting of PSWP to a PSO. An accrediting body cannot take an accrediting action against a provider based on the provider's good faith participation in reporting PSWP.
  - HHS required to facilitate a network of databases to provide interactive evidence-based management resources for providers, PSOs, and others. Information in the network will be used to analyze national and regional statistics and make recommendations on ways to reduce errors. Such analyses will be made available to the public.
- CBO estimates this operation will cost $58 million over the next five years.

The Impact and Uncertainties

- Voluntary reporting does not guarantee the usefulness of the system. Providers may remain hesitant to share their mistakes openly, as the scope of protections afforded PSWP is still uncertain.

- There may be genuine confusion over what it means to have PSWP gathered for PSO reporting. PSWP does not included original patient or provider records, or information that is collected, maintained, or developed separately, or exists separately. Questions remains as to how providers are meant to distinguish between information characterized as "separate" and PSWP.
- 22 states have reporting systems, with all but one being mandatory. The different federal and state reporting procedures may result in confusing procedures and inaccurate data.
- A high degree of culpability for penalties upon disclosure (knowingly or recklessly violating the confidentiality or privilege provisions) may result in few such penalties being assessed.
- It may be reasonable for health care systems, and even some individual hospitals, to establish a PSO for their own confidential and privileged safety program, taking into account the differences of their states' reporting laws and the wherewithal of data analysis and utilization.

Resources

- Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-41 (2005).
- *To Err is Human*, Institute of Medicine, 1999. Accessed at http://www.nap.edu/openbook/0309068371/html.
- "Congress Approves Bill to Create National Medical Error Reporting System." Daily Health Policy Report, Kaiser Family Foundation. July 28, 2005.
- Summary of S.544. American Medical Association. http://www.ama-assn.org
- Gilbert M. Gaul, Plan Would Compile, Analyze Medical Errors, *Washington Post,* July 29, 2005, at A06.
- Patient Safety Network, Agency for Healthcare Research and Quality. http://psnet.ahrq.gov
- "Minimizing Medical Errors: Legal Issues in the Debate on Improving Patient Safety." Public Interest Colloquium, American Health Lawyers Association. Feb. 28-March 1, 2003. http://www.healthlawyers.org

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