Practical Considerations Arising from the Patient Safety and Quality Improvement Act of 2005

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I. Introduction

By virtually unanimous approval,[1] Congress passed the Patient Safety & Quality Improvement Act of 2005 (the "Act"). The primary purpose of the Act is to improve patient safety. To meet this objective, the Act establishes, at the Federal level, a more uniform and secure procedure for protecting peer review activities conducted by medical providers. Historically, there has been inconsistency among the states regarding the peer review privilege and whether certain peer review documents should be discoverable and/or admissible evidence. The Act resolves that inconsistency by preempting state laws addressing the peer review privilege. There is, however, one significant caveat. In order for peer review work product to be deemed privileged and confidential it must meet certain requisites. This chapter will explore the ways in which a provider can meet the necessary requisites, the general functions of the Act, and the ways in which a patient (or his or her attorney) may challenge the Act. Since the Act was passed in 2005, it is relatively new and not yet subject to judicial review and comment. Therefore, the following can only provide commentary about the potential direction the Courts may take in interpreting the Act and protecting work product and peer review activities.

II. The Act in a Nutshell

The Act, which has been described as being "enacted in response to growing concern about patient safety in the United States," was signed into law on January 29, 2005. Its goal is to improve patient safety by encouraging voluntary and confidential reporting of events adversely affecting patients.[2] In essence, the Act seeks to improve patient safety through the protection of activities during the peer review process and acts of self-critical analysis.

The Act is intended to preempt all Federal, state and local law and establish a uniform application of the privilege. It also intends to provide privilege and confidentiality for patient safety work product and patient safety evaluation systems when such are properly conducted by certified patient safety organizations. As a practical matter, when complying with the Act's certification requisites, properly conducting a program designed to improve patient care, and providing requisite reports, the Act creates mechanisms by which peer review analyses of medical mistakes are privileged and confidential and providers will not be required to disclose such analysis (including in response to discovery requests during the course of litigation).

III. The Peer Review Privilege

States have applied, or for that matter have failed to apply, the peer review privilege in different ways. Some states have found the privilege to be absolute, while other states find no such privilege. Yet other states apply

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[1] The Act passed the United States Senate on July 21, 2005 by unanimous consent. On July 27, 2005, the Bill passed the House of Representatives by a roll call vote with 428 ayes, 3 nays, and 2 present and not voting. Thereafter, the Act was signed into law by President George W. Bush on July 29, 2005.

[2] The Patient Safety and Quality Improvement Act of 2005. Overview, June 2006. Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/qual/psoact.htm.

the privilege only in limited circumstances, which may not include circumstances involving the prosecution of medical malpractice claims. The following is a sampling of the different ways that states have looked at the privilege. The range of applications of the privilege is significant because it illuminates the potential benefit gained, under the Act, by providing uniform protection for peer review work product.

Several states have not recognized a peer review privilege. Kentucky, for example, traditionally has not recognized a peer review privilege in medical malpractice cases. In the case, *In the Estate of McFall v. Peace, Inc. et al.*,[3] the Plaintiff's decedent committed suicide while under moderate suicide precautions at Our Lady of Peace Hospital (OLOP). According to routine protocol, a Quality Assurance Review (QAR) form was filled out by OLOP's nursing coordinator in response to decedent's case. OLOP failed to produce this QAR form during the discovery process. The defense argued that the QAR was protected by the peer review privilege set forth in Kentucky Review Privilege Statute, KRS 311.377. The Supreme Court of Kentucky ruled that the QAR form was not protected as peer review material because "the peer review privilege of KRS 311.377 has no application to medical malpractice suits."[4]

In a case that also addresses the interplay between the application of state and Federal law, West Virginia did not recognize the peer review privilege prior to the enactment of this Act. In *Tucker v. United States*,[5] the Plaintiff alleged negligence by defendant, Dr. John H. Pellegrini, while performing a hysterectomy. Plaintiff sued under the Federal Tort Claims Act (FTCA). A claim was also brought against Raleigh General Hospital for granting and continuing privileges to Dr. Pellegrini. The plaintiff moved to compel the production of several documents, all of which related to the information Raleigh General Hospital had when it chose to offer Dr. Pellegrini staff privileges. Thus, the court was required to determine whether state law, West Virginia Code §30-3c-3, would preclude the production of documents.

The *Tucker* court determined that, while Congress explicitly indicated in the FTCA that state law ought to be used to determine the liability of the United States, Congress' intentions were "inconsistent with the legislative history of [FRE] Rule 501."[6] It stated:

> In non-diversity jurisdiction civil cases, Federal privilege will generally apply. In those situations where a Federal court adopts or incorporates state law to fill interstices or gaps in Federal statutory phrases, the court generally will apply Federal privilege law. When a Federal court chooses to absorb state law, it is applying the state law as a matter of Federal common law. Thus, state law does not supply the rule of decision, even though Federal court may apply a rule derived from state decisions, and state privilege law would not apply.[7]

Consequently, the *Tucker* court did not conclude that recognition of a Federal peer review privilege would promote sufficiently important interests to outweigh the need for probative evidence. Instead, the court indicated that it is more in the interest of Congress to weigh the public interests being served by medical peer review privilege in Federal cases.

Both Indiana and Pennsylvania recognize the privilege, but did not use it in cases of diversity jurisdiction in Federal court. For instance, in an Indiana case, *Lewis v. County of Henry et al.*,[8] the plaintiff sought to compel discovery from the defendant, including information concerning "administrative hearings, quality improve-

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[3] 15 S.W.3d 724, 726; 2000 KY. LEXIS 14 (2000).

[4] *Id. See also* Sisters of Charity Health Systems, Inc. v. Raikes, Ky., 984 S.W.2d 464, 470 (1999).

[5] 143 F. Supp. 2d 619 (S.D. W. Va. 2001).

[6] *Id.* at 621.

[7] *Id.* at 623.

[8] 2006 U.S. Dist. LEXIS 47405 (2006).

ment programs, meeting minutes, policy compliance, and other internal documentation…"[9] The defendants argued that the Indiana Medical Peer Review Privilege, codified by statute[10] protected the information from discovery as confidential and privileged. This statute allows all proceedings of, and communications to, a peer review committee to be confidential and privileged. It precludes committee members from publicly disclosing communications to, records of, or determinations of, a peer review committee.[11] The court stated, "Whenever a principle claim in federal court arises under federal law, with pendent jurisdiction over a state claim, Federal common law of privileges apply."[12] While Federal courts may consider the laws of the state in which the cases arise, the court noted, it must only do so where there is "no substantial cost to Federal substantive and procedural policy."[13] Therefore, the Court applied federal common law and determined the documents were not protected, contrary to the Indiana statute.

In the Pennsylvania case of *Davila v. Patel, et al.*,[14] the plaintiff brought a medical malpractice action against a hospital and doctors. In a motion to compel production of reports from a non-party, the government (as the third-party defendant) requested radiology review reports. The defense argued that the documents and reports were privileged under the Peer Review Protection Act of Pennsylvania.[15] The government countered that Federal law, rather than state law, governed any privilege claims. Since there was no peer review privilege recognized by Federal law, the government was entitled to have access to the radiology review reports gathered as a result of inspections that were performed by an entity charged with review.

The court looked to the Federal Rules of Evidence, Rule 501 for guidance. Rule 501 provided that:

> Except as otherwise required by the U.S. Constitution or by an Act of Congress or in rules prescribed by the Supreme Court pursuant to statutory authority, the privilege of a witness shall be governed by the principles of common law, as interpreted by the courts… in civil actions and proceedings, respective to an element of a claim or defense whereby state law provides the rule, then the privilege should be determined by state law.[16]

By virtue of legislative history, the court stated, "Congress intended that Federal privilege law apply in cases involving the Federal Tort Claims Act.[17]

Conversely, New Mexico is a state that recognized the peer review privilege before the Act. It also recognized and based its decision on the underlying policies behind the Act. In *Weekoty v. United States*,[18] the plaintiff filed a medical malpractice lawsuit against the United States government. The plaintiff (being the decedent's estate) also filed a motion to compel production of documents relating to a morbidity and mortality review. The United States argued that the documents were protected under the self-critical analysis privilege because the "morbidity and mortality review was conducted for the sole purpose of peer review deliberations."[19]

The *Weekoty* court indicated that, generally, the nature and scope of the self critical analysis privilege was undefined. Yet, the self critical analysis privilege had been previously discussed in the context of morbidity and

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[9] *Id.* at 3.

[10] Indiana Peer Review Statute. Ind. Code §34-30-15-1.

[11] *Id.* at 5.

[12] *Id.* at 4.

[13] *Id.* at 6.

[14] 415 F. Supp. 2d 528, 529; 2005 U.S. Dist. LEXIS 23049 (2005).

[15] Pa. Stat. Ann. Tit. 63, §425.1 *et seq.*

[16] Fed. R. Evid. 501; *id.* at 529.

[17] *Id. See* Tucker v. United States, 143 F. Supp. 2d 619, 623–23 (S.D. W. Va. 2001).

[18] 30 F. Supp. 2d 1343; 1998 U.S. Dist. LEXIS 20148 (1998).

[19] *Id.* at 1343.

mortality reviews.[20] Interpreting Rule 501 of the Federal Rules of Evidence, the *Weekoty* court determined that the Supreme Court cautioned that an evidentiary privilege should not be recognized or applied unless it "promotes sufficiently important interests to outweigh the need for probative evidence."[21] This test provides certain flexibility to Federal courts by allowing them to develop privilege rules on a case by case basis.[22]

Further, the *Weekoty* court determined that the peer review in question was not part of the patient's medical treatment; rather, it was "intended as a frank and candid discussion in which… the physicians evaluate the quality and appropriateness of the techniques and procedures used in a patient's care…"[23] The court reasoned that if review sessions were open to discovery and publicity, physicians would lack candidness, which would undermine the overall goal of improving medical care.[24] The court stated:

> As doctors have a responsibility for life and death decisions, the most up to date information and techniques must be available to them. There is an overwhelming public interest in having… review meetings… held on a confidential basis so that the flow of ideas and advice can continue unimpeded.[25]

However, and by way of limitation, it was determined that the self critical analysis privilege did not apply to reports prepared in anticipation of litigation.[26]

New Jersey is yet another state recognizing the policies underlying the Act. In the case of *In the Estate of Debbie Reyes v. Meadowlands Hospital Medical Center, et al.*,[27] the plaintiff-administrator brought a suit for medical malpractice and wrongful death. The defendant moved for an order to protect certain documents gathered through a self-critical analysis procedure. The court determined that case law supported the defendant's argument, looking to *McClain v. College Hospital*,[28] for guidance. In *McClain*, Justice O'Hern articulated:

> We hold that the standard is a showing of a particularized need that outweighs the public interest in confidentiality of the investigative proceedings, taking into account (1) the extent to which the information may be available from other sources; (2) the degree of harm that the litigant will suffer from its unavailability; and (3) the possible prejudice to the agency's investigation.[29]

Furthermore, the court indicated that the current state of the law, specifically N.J.A.C. 8:43G-27.5, supported medical peer review programs.[30]

Finally, New York, while also addressing the interplay between state and Federal laws, had chosen not to recognize the privilege. In *Syposs v. United States, et al.*,[31] the court, essentially called for what has been accomplished by passage of the Act, and noted the need for a more specific privilege to be statutorily created. In *Syposs*, plaintiffs moved to enforce subpoenas seeking peer review records. The defense relied on New York Education Law §6527[32] and New York Public Health Law §2805-m,[33] which exempted records pertaining to the per-

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[20] *Id.* at 1345.
[21] *Id. See also* Jaffee v. Redmond, 518 U.S. 1 (1996).
[22] *See* Trammel v. United States, 445 U.S. 40, 51 (1980).
[23] *Weekoty* at 1344.
[24] *Id.* at 1346.
[25] *Id.* at 1346.
[26] *Id.* at 1344.
[27] 355 N.J. Super. 226; 809 A. 2d 875 (2001).
[28] 99 N.J. 346, 351; 492 A. 2d 991 (1985).
[29] *Id.* at 879.*See* McClain v. College Hospital, 99 N.J. at 351.
[30] *Id.* at 233.
[31] 63 F. Supp. 2d 301; 1999 U.S. Dist. LEXIS 13778 (1999).
[32] New York Education Law §6527 subd. 3 (McKinney 1985).
[33] New York Public Health Law §2805-m (McKinney 1985).

formance of a medical or quality assurance review in state court proceedings. The court reasoned that, where Congress had the opportunity to create a privilege pursuant to statute, but failed to do so (unlike what has now been done), the courts should be especially hesitant in recognizing federal privileges. Thus, a balancing test was applied, weighing the "public's need for the full development of relevant facts in federal litigation against countervailing demand for confidentiality in order to achieve the objectives underlying the privilege at issue."[34] The court, using language that tracks the foundational rationale for the Act, reasoned:

> Physicians and hospitals have an overriding professional obligation and economic incentive to improve the quality of medical care they provide thereby potentially reducing malpractice insurance rates and improving profitability regardless of the availability of strict confidentiality. Whatever degree of confidentiality may also be needed to obtain participation in effective peer reviews can be provided by the courts without imposing inflexible obstacles to their fundamental role of seeking truth and doing justice."[35]

Holding that there was an no objective evidence supporting the view that strict confidentiality of peer review is a prerequisite to achieving the public's interest in maintaining quality health care, the court sustained the order compelling the records.[36] Conversely, the Act (if subject to strict compliance) would result in the opposite outcome.

IV. The Act—The Whos and the Whats

Appendix 1 provides the full text of the Act. It is important to appreciate the definitional structure of the Act, as the definitions for providers, patient safety organizations, and patient safety work product need be given primacy when complying with the statutory scheme. The Act was established to provide for confidentiality over and privileges as will pertain to work product as specifically defined in the Act. For example, the term "work product" is not the traditional legal term of art (*i.e.*, work generated by counsel in anticipation of litigation). Under the Act, work product is defined as the work of the patient safety organization whose focus is on improving the quality of care.

First, it is important to recognize to whom the Act applies. The scheme provides that it is intended to grant privilege and confidentiality to providers, specifically pertaining to *medical* providers. It can pertain to either institutions[37] or individuals.[38] The definitions are, and are intended to be, broad. There are, however, certain groups and facilities missing from the list of "providers," including: physical therapy facilities (although the individual physical or occupational therapist is included), vocational therapists, chiropractors and massage therapists. For individuals not specifically named as a provider, refuge may be available under the catchall cover of "other individual healthcare practitioners," which is part of the definition of a provider. There is no equivalent catchall provision in the definition to include any institutional healthcare service not otherwise specifically listed within the statutory scheme.

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[34] *Id.*

[35] *Id.* at 308.

[36] *Id.*

[37] Hospitals, nursing facilities, comprehensive outpatient rehabilitation facility, home health agency, hospice program, renal dialysis facility, ambulatory surgical center, pharmacy, physician or health care practitioner's office, long term care facility, behavior health residential treatment facility, clinical laboratory or health center.

[38] Physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, psychologist, certified social worker, registered dietician or nutrition professional, physical or occupational therapist, pharmacist, or other individual health care practitioner.

A Patient Safety Organization (PSO) may be established for, or on behalf of, such providers. An appropriate PSO is required in order to realize the benefit of the Act. In order to have an appropriate organization, the PSO must be listed by the Secretary of Health and Human Services and the collected data (*i.e.*, work product) must be reported. Work product is defined as data, reports, records, memoranda, analyses, and statements, which are put together and/or developed by the providers specifically for the purpose of reporting to a patient safety organization and are in fact reported to the specific safety organization. Alternatively, particular information would include information developed by the organization for the conduct of patient safety activities, with the intended result being improved patient safety, health care quality, or health care outcomes.

V. And, Therefore…

The privilege and confidentiality provisions form the heart of the Act. When collecting the work product, the PSO must make a great effort to assure patient confidentiality and privilege. Thus, once providers operate through PSOs and comply with the definitional parameters of the Act, the patient safety work product shall be deemed privileged and confidential. Such work product shall not be subject to any Federal, state or local civil, criminal or administrative subpoena or order, nor will it be subject to discovery in any action at any level or in any kind of proceeding. Furthermore, the work product shall not be admitted into evidence in any civil, criminal, administrative or disciplinary proceeding. Compliance with the scheme in developing information for the purpose of improving patient safety not only protects the results of the development of such information, but it also makes the work product "confidential."

Conversely, failure to properly comply with the scheme will not afford such protection. This has been demonstrated by the single case that has addressed the issue. In this case, the Patient Safety and Quality Improvement Act was not successfully used as a means to avoid responding to discovery. In *Massi v. Walgreen Co.*, 2006 U.S. Dist. LEXIS 77893, Plaintiff alleged that a pharmacist wrongfully filled his prescription with a more potent drug. During the pendency of this matter, Plaintiff filed a motion to compel written discovery. Specifically, with respect to a request for production of documents, Plaintiff challenged Defendant's assertion of the peer review privilege pursuant to the Patient Safety and Quality Improvement Act of 2005, 119 Stat. 424. The specific discovery request sought the production of "all documents, which were kept during the ordinary course of business, which were given to or reviewed in any way by any 'peer review board,' 'pharmacy review board,' or any similar entity, with regards to the misfilled prescription described in the Complaint."

The Court found the Patient Safety and Quality Improvement Act provided that certain "patient safety work product" was privileged and not subject to discovery in a civil proceeding. 42 U.S.C. §299b-22(a), 119 Stat. 424. However, "Patient safety work product" does not include (1) a patient's own medical records or (2) information that is collected, maintained or developed separately from a patient evaluation system. 42 U.S.C. §299b-21(7)(B). Therefore, the Court did not find the Patient Safety and Quality Improvement Act to be applicable in this case because there was no showing made that the information sought was assembled or developed for the purpose of reporting same to a "patient safety organization," as that term is defined by the statute. Accordingly, the Court did not find the requested documents to be privileged.[39]

[39] In the only other case to discuss the Act, Payton v. State of New York, 2008 NY Slip Op 52485U, the Patient Safety and Quality Improvement Act of 2005 was used as a comparative tool in an argument that a report was privileged. Previously, the Court granted Claimant's motion for an order directing Defendant to produce this report. In response to the Order, Defendant submitted the affidavit of Kathleen Ferrara, R.N., Risk Manager in the Department of Risk Management at Stony Brook Hospital, which concluded the report was privileged and confidential, as it was generated as a

VI. Development of Patient Safety Organization

In the Shakespearean play *Hamlet*, Hamlet directs Ophelia to "get thee to a nunnery." The directive born of the Act is to "get thee to a Patient Safety Organization." While this directive lacks the poetic eloquence of Shakespeare (for more reasons that just the lack of iambic pentameter), it sharpens the necessary focus of medical providers. The Act allows medical providers to develop mechanisms by which the peer review analyses of issues of morbidity and mortality may be done in confidence, with the ultimate purpose of improving the quality of patient care, without creating the proverbial "Exhibit A" in a plaintiff's case-in-chief.

In order to obtain certification as a PSO, an initial certification to the Secretary must be submitted, identifying the standard policies and procedures followed when performing patient activities. The certification must also state that the mission and primary activity of the entity will be to conduct activities that are to improve patient safety and the quality of health care. The entity must also establish that it has a qualified staff, bona fide contracts with more than one provider for the purpose of receiving and reviewing patient safety work product, and complies with other administrative requisites.

VII. And All This Means…

Following the requisites of the Act is similar to the concept of playing baseball. In baseball, a player must touch every base in order to score a run. If a player misses a base, no matter how far and how fast he runs, he will most probably be called out. Similarly, if a medical provider wishes to score the proverbial "home-run" of obtaining privileges to and confidentiality for work product that would otherwise be discoverable, the medical provider must "touch all the bases" through statutory compliance.

The key is strict compliance with the statutory scheme. The statutory scheme, and its preemptive effect, should obviate any disparity between state and local laws. The statutory scheme provides that analyses conducted within the purview of the Act, are confidential and privileged. It is necessary to guarantee that there is more than one practitioner involved in the organization for which data is collected. The data must be collected

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result of the hospital's quality assurance program which initiated the Patient Safety Net (PSN), a privileged-confidential intake for retrospective review/quality assurance process to carry out quality assurance, quality improvement and patient safety activities.

The Claimant thereafter requested the Court to review the PSN report *in camera* to determine if the report was privileged. Defendant opposed the motion on the basis that the report "was an integral part of the retrospective review and quality assurance process" and was a confidential and privileged report. The State also submitted the affirmation of William H. Greene, M.D., the Senior Associate Medical Director for Quality Management and Chair of the Medical Staff Quality Assurance Committee since 1995 and the Chief Quality Officer since 2007 at Stony Brook Hospital. Dr. Greene stated in pertinent part: "The PSN is a quality assurance tool necessary to carry out the Quality Assurance, Patient Safety & Quality Improvement Initiatives of [Stony Brook Hospital]. It is a quality assurance report which falls outside the scope of discovery since it relates to the performance of a quality assurance function and/or participation in a medical and dental malpractice prevention program by the hospital which is protected by state privilege and confidentiality laws pursuant to Public Health Law §2805-j, k, l, m and Education Law §6527(3). Similar quality assurance protections are envisioned under the Federal Patient Safety and Quality Improvement Act of 2005."

The Court found that Defendant, because it was the party that sought to invoke the privilege, had the burden to demonstrate that the document sought was prepared in accordance with the relevant statutes that confer the privilege. In this case, the Court found that Defendant, by means of Dr. Greene's Affirmation and Nurse Ferrara's Affidavit, merely asserted in conclusory fashion that the privilege applied to the requested document without making any showing as to why the privilege attached. Thus, Defendant was to provide the document to the Court for an *in camera* inspection, together with its privilege log, if one existed, within forty-five (45) days of the date the Order was filed.

with the primary purpose being to improve patient care. The downfall in attempting to apply the Act to existing peer review programs occurs where the program is not modified to reflect the requisites of the Act. For example, if a peer group committee is established to deal with issues of medical malpractice and evaluating claims, such activity will not be privileged and confidential per the Act. Moreover, even if the actions of a peer group committee are intended to improve patient care within a hospital, or a medical facility, but are not reported to the Secretary as required by the Act, then such activities will not be protected.

Consequently, there are several main objectives to consider when generating work product. First, the review must be engaged in by a patient safety organization; and second, it must pertain to patient safety activities intending to improve patient safety and the quality of healthcare delivered. Efforts outside of these objectives will not afford confidentiality and privilege to the resulting work product. Furthermore, to protect peer review action, there must be appropriate patient safety work product, as defined by (7)(A) of the Act. The patient safety work product must be developed and reported to the PSO; without the reporting, there is no protection.

Providers must come together, organize, obtain certification, maintain certification, properly define their mission, properly document their work, and report (report, report again, and continue reporting) in order to maintain the protection afforded by the Act and assure that their peer review work will be deemed privileged and confidential. Therefore, to be considered "proper," an organization must be listed by the Secretary, certified, and maintain certification. While several steps are necessary to insure compliance, commitment to such detail is essential in maintaining privileged and confidential documents.

There are some hazards of which one must be conscious. For instance, only multiple providers may develop and maintain a PSO; thus, single providers may not have a certified PSO. An ambiguity in the Act is whether a medical facility, made up of numerous individual providers, meets the criteria of the Act. When the language of the Act speaks of multiple providers, and defines providers as institutions, there appears to be an implicit suggestion that multiple institutions combine to form a PSO. This may not be necessary, as individual providers within a given facility may combine to list, certify and maintain certification of their organization. As a result of the Act's ambiguity, this presents an open question left to the courts and/or legislative action.

The Act provides the mechanisms necessary to qualify for and maintain protection over work product. It allows in camera review by the court to determine whether the information which is asserted as being privileged and confidential is, in fact, in compliance with the Act. There are also exceptions to confidentiality and privileges: such as for the purposes of preventing or disclosing criminal conduct, for the purpose of medical liability concerns, and for the purpose of keeping confidential that which is subject to peer review. Sufficient fidelity is integral because of the possibility that there may be a finding that the reports were not intended for patient care improvement purposes, it was not properly reported, and/or the organization was not properly certified.

Failing to touch all the bases will, without question, create pitfalls. Non-compliance with the Act will cause risk of work product exposure in medical malpractice actions. To that end, fidelity to the definitional and procedural requisites of the statute is essential and necessary. To date, there has yet to be a single published (or, for that matter, unpublished) decision, either by a state or Federal court, interpreting, addressing, or dealing with the use, application or constitutionality of the Act. Thus, to best interpret the Act, it is necessary to analyze how similar statutory schemes have been reviewed by the courts and by those opposing (and in some cases supporting) the use of such statutes.

VIII. If a Jurisdiction Does Not Honor the Peer Review Privilege

For those jurisdictions that do not have, never had, or rarely apply the peer review privilege, the Act provides

a mechanism to protect peer review work product. The necessary argument to present, when attempting to keep all reports confidential, is that the Act preempts any and all state or local law pertaining to such work product.

The Act expressly preempts all Federal, state and local laws regarding the confidentiality and protection of peer review documents. In order to fully understand how Federal preemption occurs in this context, it is necessary to briefly review the general mechanics of express Federal preemption.

Under the Supremacy Clause of the Federal Constitution, Congress has the power to preempt state law. U.S. Const. art. VI, cl.2. Preemption occurs when compliance with both state and Federal law is deemed impossible.[40] Regardless of an express provision for preemption, the state law must yield to a congressional act in at least two circumstances: 1) state law is preempted when Congress intends Federal law to "occupy the field;" and 2) state law is naturally preempted where there is any conflict with a Federal statute.[41]

Express preemption is compelled where Congressional command is explicitly stated in the statute's language. Conversely, implied preemption means the preemption is implicitly contained in the structure and purpose of the statute.[42] In any preemption case, the court must ultimately determine whether state regulation is consistent with the structure and purpose of the statute as a whole.[43]

When a court considers issues that arise under the Supremacy Clause, it starts with the assumption that the historic police powers of the states are not superseded by Federal law unless preemption is the clear and manifest purpose of Congress.[44] When a Federal act overrides state law, "the entire scheme of the statute must be considered, and that which needs must be implied is no less force than that which is expressed."[45] Therefore, the following standard must be applied: if the purpose of the Federal act is frustrated by the state law, and thus cannot be accomplished, then state law must yield to the Federal law.[46]

The use of the language "Notwithstanding any other provision of Federal, state, or local law…", when addressing both "Privilege," at Sec. 922 (a), and "Confidentiality," at Sec. 922 (b), defines the express intent of Congress to preempt any and all other law that would define if patient safety/peer review work product is privileged and confidential. Independently, the legislative history of the Act, the relevant portions being attached as Appendix 3, provides for the "belt and suspenders" argument that the intent, be it express or implied, was for the Act to preempt all other law on the issue of the application of privilege and confidentiality to properly conducted peer review activities.

IX. Challenges to the Statute

As a practical matter, an attorney prosecuting a claim for medical malpractice may take one of two approaches to obtain peer review material in those circumstances in which providers have properly complied with the statutory requisites of the Act. The first is to challenge whether the provider has properly met all the criteria of the statute. The second is to challenge the constitutionality of the statute; that is, to say, when all else fails, "kill the messenger."

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[40] Crosby v. National Foreign Trade Council, 530 U.S. 363, 372; 120 S. Ct. 2288 (2000).

[41] *Crosby*, at 372.

[42] Gade v. National Solid Wastes Management Ass'n, 505 U.S. 88, 98; 112 S. Ct. 2374 (1992).

[43] *Id.*

[44] Nat'l Ass'n of State Util. Consumer Advocates v. FCC, 457 F.3d 1238. *See also* Crosby v. National Foreign Trade Council, 530 U.S. at 372.

[45] *Id.*

[46] *Id.*

The "statutory messenger" is killed when an adversary successfully challenges the constitutionality of the statute. Statutes that preempt all state and local law, including those providing for express preemption, have faced a recurring pattern of constitutional challenges. Historically, such challenges and attacks include: 1) that the local regulations are not Federally preempted because they are a valid exercise of the state's police powers (*i.e.*, a 10th Amendment challenge);[47] 2) that the Federal statute is in violation of the contract clause (*i.e.*, 14th Amendment);[48] 3) that the Federal statute is in violation of the commerce clause (*i.e.*, Article 1);[49] 4) that there is a violation of due process or equal protection;[50] and 5) that the statute is vague or that the state law provides relief that the Federal statute does not, thereby failing to preempt state law.[51]

Generally, there is a presumption against Federal preemption of state law. There is, moreover, an additional and related judicial assumption that the historic police powers of the states are not to be superseded by Federal law unless it was the clear and manifest purpose of Congress. Accordingly, if the subject matter of the state law is one within the states' traditional powers, the party arguing for federal preemption must show that preemption was the clear and manifest purpose of Congress.

Therefore, potential challenges to this Act may be based upon such Constitutional attacks. It will be difficult to argue, and prevail, with any other state-law based challenges. This is mainly due to Congressional intent, as well as the Act's express preemption of state law. When a Court finally reviews this Act, it will be within the Court's discretion to decide the constitutionality of this Act and to consider if its application is too expansive to fit within the Constitution's framework.

X. Conclusion

Congress believes that developing and sharing information regarding medical mistakes will improve the quality of patient care by reducing the potential that such mistakes will again occur. Congress has acted on that belief by passing the Patient Safety and Quality Improvement Act of 2005. Medical providers can share in the effort, an effort that is at the heart of each provider's patient-care goal, to improve patient safety and the quality of care. To participate, and to do so in a way that will allow such peer review action, and acts of self-critical analysis, to be done in a way that promotes candor, yet maintains privileges and confidences, requires strict compliance with the provisions of the Act. Failure to do so will likely result in failing to obtain the preemptive effect of the Act's protection from disclosure and discovery of peer review activities. Such failure would defeat the intent of the Act and, simultaneously, create mechanisms that may allow such work product to be subject to discovery during the course of litigation.

From a defense practice standpoint for attorneys, high priority should be given to assisting health care provider clients to achieve compliance with the Act's requirements. First and foremost, heath care practitioners and institutions will need assistance in establishing qualified PSOs and reporting formats. Historical claims of privilege for "incident" documentation based on participation in an internal quality monitoring board may no longer be equated with a guaranty of privilege and/or confidentiality.

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[47] Canadian Nat'l Ry. Co. v. City of Rockwood, 2005 U.S. Dist. LEXIS 4013.

[48] Malone v. White Motor Corp., 435 U.S. 497 (1978).

[49] CSX Transp. v. City of Plymouth, 283 F.3d 812 (2002).

[50] Harrell v. Fla. Constr. Specialists/AARCA/Agent for FWCGIA, 834 So. 2d 352 (2003)

[51] Hughes v. State, 31 Fla. L. Weekly D. 1872 (2006) and Farmer v. United Brotherhood of Carpenters & Joiners, 430 U.S. 290 (1977).

Appendix 1

PUBLIC LAW 109–41—JULY 29, 2005

PATIENT SAFETY AND QUALITY IMPROVEMENT ACT OF 2005

Public Law 109–41
109th Congress

An Act

July 29, 2005
[S. 544]

To amend title IX of the Public Health Service Act to provide for the improvement of patient safety and to reduce the incidence of events that adversely effect patient safety.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Patient Safety and Quality Improvement Act of 2005.

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Patient Safety and Quality Improvement Act of 2005".

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

SEC. 2. AMENDMENTS TO PUBLIC HEALTH SERVICE ACT.

(a) IN GENERAL.—Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.) is amended—

42 USC 299b–1.

(1) in section 912(c), by inserting ", in accordance with part C," after "The Director shall";

(2) by redesignating part C as part D;

42 USC 299c—299c–7.

(3) by redesignating sections 921 through 928, as sections 931 through 938, respectively;

42 USC 299c–7.

(4) in section 938(1) (as so redesignated), by striking "921" and inserting "931"; and

(5) by inserting after part B the following:

"PART C—PATIENT SAFETY IMPROVEMENT

42 USC 299b–21.

"SEC. 921. DEFINITIONS.

"In this part:

"(1) HIPAA CONFIDENTIALITY REGULATIONS.—The term 'HIPAA confidentiality regulations' means regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033).

"(2) IDENTIFIABLE PATIENT SAFETY WORK PRODUCT.—The term 'identifiable patient safety work product' means patient safety work product that—

"(A) is presented in a form and manner that allows the identification of any provider that is a subject of the work product, or any providers that participate in activities that are a subject of the work product;

"(B) constitutes individually identifiable health information as that term is defined in the HIPAA confidentiality regulations; or

"(C) is presented in a form and manner that allows the identification of an individual who reported information in the manner specified in section 922(e).

"(3) NONIDENTIFIABLE PATIENT SAFETY WORK PRODUCT.—The term 'nonidentifiable patient safety work product' means patient safety work product that is not identifiable patient safety work product (as defined in paragraph (2)).

"(4) PATIENT SAFETY ORGANIZATION.—The term 'patient safety organization' means a private or public entity or component thereof that is listed by the Secretary pursuant to section 924(d).

"(5) PATIENT SAFETY ACTIVITIES.—The term 'patient safety activities' means the following activities:

"(A) Efforts to improve patient safety and the quality of health care delivery.

"(B) The collection and analysis of patient safety work product.

"(C) The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices.

"(D) The utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk.

"(E) The maintenance of procedures to preserve confidentiality with respect to patient safety work product.

"(F) The provision of appropriate security measures with respect to patient safety work product.

"(G) The utilization of qualified staff.

"(H) 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.

"(6) PATIENT SAFETY EVALUATION SYSTEM.—The term 'patient safety evaluation system' means the collection, management, or analysis of information for reporting to or by a patient safety organization.

"(7) PATIENT SAFETY WORK PRODUCT.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), the term 'patient safety work product' means any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements—

"(i) which—

"(I) are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization; or

"(II) are developed by a patient safety organization for the conduct of patient safety activities;

and which could result in improved patient safety, health care quality, or health care outcomes; or

"(ii) which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.

"(B) CLARIFICATION.—

"(i) Information described in subparagraph (A) does not include a patient's medical record, billing and discharge information, or any other original patient or provider record.

"(ii) Information described in subparagraph (A) does not include information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system. Such separate information or a copy thereof reported to a patient safety organization shall not by reason of its reporting be considered patient safety work product.

"(iii) Nothing in this part shall be construed to limit—

"(I) the discovery of or admissibility of information described in this subparagraph in a criminal, civil, or administrative proceeding;

"(II) the reporting of information described in this subparagraph to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes; or

"(III) a provider's recordkeeping obligation with respect to information described in this subparagraph under Federal, State, or local law.

"(8) PROVIDER.—The term 'provider' means—

"(A) an individual or entity licensed or otherwise authorized under State law to provide health care services, including—

"(i) a hospital, nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, renal dialysis facility, ambulatory surgical center, pharmacy, physician or health care practitioner's office, long term care facility, behavior health residential treatment facility, clinical laboratory, or health center; or

"(ii) a physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, psychologist, certified social worker, registered dietitian or nutrition professional, physical or occupational therapist, pharmacist, or other individual health care practitioner; or

"(B) any other individual or entity specified in regulations promulgated by the Secretary.

"SEC. 922. PRIVILEGE AND CONFIDENTIALITY PROTECTIONS. 42 USC 299b–22.

"(a) PRIVILEGE.—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.

"(b) CONFIDENTIALITY OF PATIENT SAFETY WORK PRODUCT.—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.

"(c) EXCEPTIONS.—Except as provided in subsection (g)(3)—

"(1) EXCEPTIONS FROM PRIVILEGE AND CONFIDENTIALITY.—Subsections (a) and (b) shall not apply to (and shall not be construed to prohibit) one or more of the following disclosures:

"(A) Disclosure of relevant patient safety work product for use in a criminal proceeding, but only after a court makes an in camera determination that such patient safety work product contains evidence of a criminal act and that such patient safety work product is material to the proceeding and not reasonably available from any other source.

"(B) Disclosure of patient safety work product to the extent required to carry out subsection (f)(4)(A).

"(C) Disclosure of identifiable patient safety work product if authorized by each provider identified in such work product.

"(2) EXCEPTIONS FROM CONFIDENTIALITY.—Subsection (b) shall not apply to (and shall not be construed to prohibit) one or more of the following disclosures:

"(A) Disclosure of patient safety work product to carry out patient safety activities.

"(B) Disclosure of nonidentifiable patient safety work product.

"(C) Disclosure of patient safety work product to grantees, contractors, or other entities carrying out research, evaluation, or demonstration projects authorized, funded, certified, or otherwise sanctioned by rule or other means by the Secretary, for the purpose of conducting research to the extent that disclosure of protected health information would be allowed for such purpose under the HIPAA confidentiality regulations.

"(D) Disclosure by a provider to the Food and Drug Administration with respect to a product or activity regulated by the Food and Drug Administration.

"(E) Voluntary disclosure of patient safety work product by a provider to an accrediting body that accredits that provider.

"(F) Disclosures that the Secretary may determine, by rule or other means, are necessary for business operations and are consistent with the goals of this part.

"(G) Disclosure of patient safety work product to law enforcement authorities relating to the commission of a crime (or to an event reasonably believed to be a crime) if the person making the disclosure believes, reasonably under the circumstances, that the patient safety work product that is disclosed is necessary for criminal law enforcement purposes.

"(H) With respect to a person other than a patient safety organization, the disclosure of patient safety work product that does not include materials that—

"(i) assess the quality of care of an identifiable provider; or

"(ii) describe or pertain to one or more actions or failures to act by an identifiable provider.

"(3) EXCEPTION FROM PRIVILEGE.—Subsection (a) shall not apply to (and shall not be construed to prohibit) voluntary disclosure of nonidentifiable patient safety work product.

"(d) CONTINUED PROTECTION OF INFORMATION AFTER DISCLOSURE.—

"(1) IN GENERAL.—Patient safety work product that is disclosed under subsection (c) shall continue to be privileged and confidential as provided for in subsections (a) and (b), and such disclosure shall not be treated as a waiver of privilege or confidentiality, and the privileged and confidential nature of such work product shall also apply to such work product in the possession or control of a person to whom such work product was disclosed.

"(2) EXCEPTION.—Notwithstanding paragraph (1), and subject to paragraph (3)—

"(A) if patient safety work product is disclosed in a criminal proceeding, the confidentiality protections provided for in subsection (b) shall no longer apply to the work product so disclosed; and

"(B) if patient safety work product is disclosed as provided for in subsection (c)(2)(B) (relating to disclosure of nonidentifiable patient safety work product), the privilege and confidentiality protections provided for in subsections (a) and (b) shall no longer apply to such work product.

"(3) CONSTRUCTION.—Paragraph (2) shall not be construed as terminating or limiting the privilege or confidentiality protections provided for in subsection (a) or (b) with respect to patient safety work product other than the specific patient safety work product disclosed as provided for in subsection (c).

"(4) LIMITATIONS ON ACTIONS.—

"(A) PATIENT SAFETY ORGANIZATIONS.—

"(i) IN GENERAL.—A patient safety organization shall not be compelled to disclose information collected or developed under this part whether or not such

information is patient safety work product unless such information is identified, is not patient safety work product, and is not reasonably available from another source.

"(ii) NONAPPLICATION.—The limitation contained in clause (i) shall not apply in an action against a patient safety organization or with respect to disclosures pursuant to subsection (c)(1).

"(B) PROVIDERS.—An accrediting body shall not take an accrediting action against a provider based on the good faith participation of the provider in the collection, development, reporting, or maintenance of patient safety work product in accordance with this part. An accrediting body may not require a provider to reveal its communications with any patient safety organization established in accordance with this part.

"(e) REPORTER PROTECTION.—

"(1) IN GENERAL.—A provider may not take an adverse employment action, as described in paragraph (2), against an individual based upon the fact that the individual in good faith reported information—

"(A) to the provider with the intention of having the information reported to a patient safety organization; or

"(B) directly to a patient safety organization.

"(2) ADVERSE EMPLOYMENT ACTION.—For purposes of this subsection, an 'adverse employment action' includes—

"(A) loss of employment, the failure to promote an individual, or the failure to provide any other employment-related benefit for which the individual would otherwise be eligible; or

"(B) an adverse evaluation or decision made in relation to accreditation, certification, credentialing, or licensing of the individual.

"(f) ENFORCEMENT.—

"(1) CIVIL MONETARY PENALTY.—Subject to paragraphs (2) and (3), a person who discloses identifiable patient safety work product in knowing or reckless violation of subsection (b) shall be subject to a civil monetary penalty of not more than $10,000 for each act constituting such violation.

"(2) PROCEDURE.—The provisions of section 1128A of the Social Security Act, other than subsections (a) and (b) and the first sentence of subsection (c)(1), shall apply to civil money penalties under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A of the Social Security Act.

"(3) RELATION TO HIPAA.—Penalties shall not be imposed both under this subsection and under the regulations issued pursuant to section 264(c)(1) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d-2 note) for a single act or omission.

"(4) EQUITABLE RELIEF.—

"(A) IN GENERAL.—Without limiting remedies available to other parties, a civil action may be brought by any aggrieved individual to enjoin any act or practice that violates subsection (e) and to obtain other appropriate equitable relief (including reinstatement, back pay, and restoration of benefits) to redress such violation.

"(B) AGAINST STATE EMPLOYEES.—An entity that is a State or an agency of a State government may not assert the privilege described in subsection (a) unless before the time of the assertion, the entity or, in the case of and with respect to an agency, the State has consented to be subject to an action described in subparagraph (A), and that consent has remained in effect.

"(g) RULE OF CONSTRUCTION.—Nothing in this section shall be construed—

"(1) to limit the application of other Federal, State, or local laws that provide greater privilege or confidentiality protections than the privilege and confidentiality protections provided for in this section;

"(2) to limit, alter, or affect the requirements of Federal, State, or local law pertaining to information that is not privileged or confidential under this section;

"(3) except as provided in subsection (i), to alter or affect the implementation of any provision of the HIPAA confidentiality regulations or section 1176 of the Social Security Act (or regulations promulgated under such section);

"(4) to limit the authority of any provider, patient safety organization, or other entity to enter into a contract requiring greater confidentiality or delegating authority to make a disclosure or use in accordance with this section;

"(5) as preempting or otherwise affecting any State law requiring a provider to report information that is not patient safety work product; or

"(6) to limit, alter, or affect any requirement for reporting to the Food and Drug Administration information regarding the safety of a product or activity regulated by the Food and Drug Administration.

"(h) CLARIFICATION.—Nothing in this part prohibits any person from conducting additional analysis for any purpose regardless of whether such additional analysis involves issues identical to or similar to those for which information was reported to or assessed by a patient safety organization or a patient safety evaluation system.

"(i) CLARIFICATION OF APPLICATION OF HIPAA CONFIDENTIALITY REGULATIONS TO PATIENT SAFETY ORGANIZATIONS.—For purposes of applying the HIPAA confidentiality regulations—

"(1) patient safety organizations shall be treated as business associates; and

"(2) patient safety activities of such organizations in relation to a provider are deemed to be health care operations (as defined in such regulations) of the provider.

"(j) REPORTS ON STRATEGIES TO IMPROVE PATIENT SAFETY.—

"(1) DRAFT REPORT.—Not later than the date that is 18 months after any network of patient safety databases is operational, the Secretary, in consultation with the Director, shall prepare a draft report on effective strategies for reducing medical errors and increasing patient safety. The draft report shall include any measure determined appropriate by the Secretary to encourage the appropriate use of such strategies, including use in any federally funded programs. The Secretary shall make the draft report available for public comment and submit the draft report to the Institute of Medicine for review.

Public information.

"(2) FINAL REPORT.—Not later than 1 year after the date described in paragraph (1), the Secretary shall submit a final report to the Congress.

"SEC. 923. NETWORK OF PATIENT SAFETY DATABASES. 42 USC 299b–23.

"(a) IN GENERAL.—The Secretary shall facilitate the creation of, and maintain, a network of patient safety databases that provides an interactive evidence-based management resource for providers, patient safety organizations, and other entities. The network of databases shall have the capacity to accept, aggregate across the network, and analyze nonidentifiable patient safety work product voluntarily reported by patient safety organizations, providers, or other entities. The Secretary shall assess the feasibility of providing for a single point of access to the network for qualified researchers for information aggregated across the network and, if feasible, provide for implementation.

"(b) DATA STANDARDS.—The Secretary may determine common formats for the reporting to and among the network of patient safety databases maintained under subsection (a) of nonidentifiable patient safety work product, including necessary work product elements, common and consistent definitions, and a standardized computer interface for the processing of such work product. To the extent practicable, such standards shall be consistent with the administrative simplification provisions of part C of title XI of the Social Security Act.

"(c) USE OF INFORMATION.—Information reported to and among the network of patient safety databases under subsection (a) shall be used to analyze national and regional statistics, including trends and patterns of health care errors. The information resulting from such analyses shall be made available to the public and included in the annual quality reports prepared under section 913(b)(2). Public information.

"SEC. 924. PATIENT SAFETY ORGANIZATION CERTIFICATION AND LISTING. 42 USC 299b–24.

"(a) CERTIFICATION.—

"(1) INITIAL CERTIFICATION.—An entity that seeks to be a patient safety organization shall submit an initial certification to the Secretary that the entity—

"(A) has policies and procedures in place to perform each of the patient safety activities described in section 921(5); and

"(B) upon being listed under subsection (d), will comply with the criteria described in subsection (b).

"(2) SUBSEQUENT CERTIFICATIONS.—An entity that is a patient safety organization shall submit every 3 years after the date of its initial listing under subsection (d) a subsequent certification to the Secretary that the entity— Deadlines.

"(A) is performing each of the patient safety activities described in section 921(5); and

"(B) is complying with the criteria described in subsection (b).

"(b) CRITERIA.—

"(1) IN GENERAL.—The following are criteria for the initial and subsequent certification of an entity as a patient safety organization:

"(A) The mission and primary activity of the entity are to conduct activities that are to improve patient safety and the quality of health care delivery.

"(B) The entity has appropriately qualified staff (whether directly or through contract), including licensed or certified medical professionals.

"(C) The entity, within each 24-month period that begins after the date of the initial listing under subsection (d), has bona fide contracts, each of a reasonable period of time, with more than 1 provider for the purpose of receiving and reviewing patient safety work product.

"(D) The entity is not, and is not a component of, a health insurance issuer (as defined in section 2791(b)(2)).

"(E) The entity shall fully disclose—

"(i) any financial, reporting, or contractual relationship between the entity and any provider that contracts with the entity; and

"(ii) if applicable, the fact that the entity is not managed, controlled, and operated independently from any provider that contracts with the entity.

"(F) To the extent practical and appropriate, the entity collects patient safety work product from providers in a standardized manner that permits valid comparisons of similar cases among similar providers.

"(G) The utilization of patient safety work product for the purpose of providing direct feedback and assistance to providers to effectively minimize patient risk.

"(2) ADDITIONAL CRITERIA FOR COMPONENT ORGANIZATIONS.—If an entity that seeks to be a patient safety organization is a component of another organization, the following are additional criteria for the initial and subsequent certification of the entity as a patient safety organization:

"(A) The entity maintains patient safety work product separately from the rest of the organization, and establishes appropriate security measures to maintain the confidentiality of the patient safety work product.

"(B) The entity does not make an unauthorized disclosure under this part of patient safety work product to the rest of the organization in breach of confidentiality.

"(C) The mission of the entity does not create a conflict of interest with the rest of the organization.

"(c) REVIEW OF CERTIFICATION.—

"(1) IN GENERAL.—

"(A) INITIAL CERTIFICATION.—Upon the submission by an entity of an initial certification under subsection (a)(1), the Secretary shall determine if the certification meets the requirements of subparagraphs (A) and (B) of such subsection.

"(B) SUBSEQUENT CERTIFICATION.—Upon the submission by an entity of a subsequent certification under subsection (a)(2), the Secretary shall review the certification with respect to requirements of subparagraphs (A) and (B) of such subsection.

"(2) NOTICE OF ACCEPTANCE OR NON-ACCEPTANCE.—If the Secretary determines that—

"(A) an entity's initial certification meets requirements referred to in paragraph (1)(A), the Secretary shall notify the entity of the acceptance of such certification; or

"(B) an entity's initial certification does not meet such requirements, the Secretary shall notify the entity that such certification is not accepted and the reasons therefor.

"(3) DISCLOSURES REGARDING RELATIONSHIP TO PROVIDERS.—The Secretary shall consider any disclosures under subsection (b)(1)(E) by an entity and shall make public findings on whether the entity can fairly and accurately perform the patient safety activities of a patient safety organization. The Secretary shall take those findings into consideration in determining whether to accept the entity's initial certification and any subsequent certification submitted under subsection (a) and, based on those findings, may deny, condition, or revoke acceptance of the entity's certification.

"(d) LISTING.—The Secretary shall compile and maintain a listing of entities with respect to which there is an acceptance of a certification pursuant to subsection (c)(2)(A) that has not been revoked under subsection (e) or voluntarily relinquished.

"(e) REVOCATION OF ACCEPTANCE OF CERTIFICATION.—

"(1) IN GENERAL.—If, after notice of deficiency, an opportunity for a hearing, and a reasonable opportunity for correction, the Secretary determines that a patient safety organization does not meet the certification requirements under subsection (a)(2), including subparagraphs (A) and (B) of such subsection, the Secretary shall revoke the Secretary's acceptance of the certification of such organization.

"(2) SUPPLYING CONFIRMATION OF NOTIFICATION TO PROVIDERS.—Within 15 days of a revocation under paragraph (1), a patient safety organization shall submit to the Secretary a confirmation that the organization has taken all reasonable actions to notify each provider whose patient safety work product is collected or analyzed by the organization of such revocation. Deadline.

"(3) PUBLICATION OF DECISION.—If the Secretary revokes the certification of an organization under paragraph (1), the Secretary shall—

"(A) remove the organization from the listing maintained under subsection (d); and

"(B) publish notice of the revocation in the Federal Register. Federal Register, publication.

"(f) STATUS OF DATA AFTER REMOVAL FROM LISTING.—

"(1) NEW DATA.—With respect to the privilege and confidentiality protections described in section 922, data submitted to an entity within 30 days after the entity is removed from the listing under subsection (e)(3)(A) shall have the same status as data submitted while the entity was still listed.

"(2) PROTECTION TO CONTINUE TO APPLY.—If the privilege and confidentiality protections described in section 922 applied to patient safety work product while an entity was listed, or to data described in paragraph (1), such protections shall continue to apply to such work product or data after the entity is removed from the listing under subsection (e)(3)(A).

"(g) DISPOSITION OF WORK PRODUCT AND DATA.—If the Secretary removes a patient safety organization from the listing as provided for in subsection (e)(3)(A), with respect to the patient safety work product or data described in subsection (f)(1) that the patient safety organization received from another entity, such former patient safety organization shall—

"(1) with the approval of the other entity and a patient safety organization, transfer such work product or data to such patient safety organization;

"(2) return such work product or data to the entity that submitted the work product or data; or

"(3) if returning such work product or data to such entity is not practicable, destroy such work product or data.

42 USC 299b–25. **"SEC. 925. TECHNICAL ASSISTANCE.**

"The Secretary, acting through the Director, may provide technical assistance to patient safety organizations, including convening annual meetings for patient safety organizations to discuss methodology, communication, data collection, or privacy concerns.

42 USC 299b–26. **"SEC. 926. SEVERABILITY.**

"If any provision of this part is held to be unconstitutional, the remainder of this part shall not be affected.".

42 USC 299c–6. (b) AUTHORIZATION OF APPROPRIATIONS.—Section 937 of the Public Health Service Act (as redesignated by subsection (a)) is amended by adding at the end the following:

"(e) PATIENT SAFETY AND QUALITY IMPROVEMENT.—For the purpose of carrying out part C, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2006 through 2010.".

(c) GAO STUDY ON IMPLEMENTATION.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study on the effectiveness of part C of title IX of the Public Health Service Act (as added by subsection (a)) in accomplishing the purposes of such part.

(2) REPORT.—Not later than February 1, 2010, the Comptroller General shall submit a report on the study conducted under paragraph (1). Such report shall include such recommendations for changes in such part as the Comptroller General deems appropriate.

Approved July 29, 2005.

LEGISLATIVE HISTORY—S. 544 (H.R. 3205):

HOUSE REPORTS: No. 109–197 accompanying H.R. 3205 (Comm. on Energy and Commerce).

CONGRESSIONAL RECORD, Vol. 151 (2005):
July 21, considered and passed Senate.
July 27, considered and passed House.

WEEKLY COMPILATION OF PRESIDENTIAL DOCUMENTS, Vol. 41 (2005):
July 29, Presidential remarks.

○

Appendix 2

The Patient Safety and Quality Improvement Act of 2005

The Patient Safety and Quality Improvement Act of 2005 (Public Law 109-41), signed into law on July 29, 2005, was enacted in response to growing concern about patient safety in the United States and the Institute of Medicine's 1999 report, *To Err is Human: Building a Safer Health System*. The goal of the Act is to improve patient safety by encouraging voluntary and confidential reporting of events that adversely affect patients.

The Patient Safety and Quality Improvement Act signifies the Federal Government's commitment to fostering a culture of patient safety. It creates Patient Safety Organizations (PSOs) to collect, aggregate, and analyze confidential information reported by health care providers. Currently, patient safety improvement efforts are hampered by the fear of discovery of peer deliberations, resulting in under-reporting of events and an inability to aggregate sufficient patient safety event data for analysis. By analyzing patient safety event information, PSOs will be able to identify patterns of failures and propose measures to eliminate patient safety risks and hazards.

Many providers fear that patient safety event reports could be used against them in medical malpractice cases or in disciplinary proceedings. The Act addresses these fears by providing Federal legal privilege and confidentiality protections to information that is assembled and reported by providers to a PSO or developed by a PSO ("patient safety work product") for the conduct of patient safety activities. The Act also significantly limits the use of this information in criminal, civil, and administrative proceedings. The Act includes provisions for monetary penalties for violations of confidentiality or privilege protections.

Additionally, the Act specifies the role of PSOs and defines "patient safety work product" and "patient safety evaluation systems," which focus on how patient safety event information is collected, developed, analyzed, and maintained. In addition, the Act has specific requirements for PSOs, such as:

- PSOs are required to work with more than one provider.
- Eligible organizations include public or private entities, profit or not-for-profit entities, provider entities, such as hospital chains, and other entities that establish special components.
- Ineligible organizations include insurance companies or their affiliates.

Finally, the Act calls for the establishment of a Network of Patient Safety Databases (NPSD) to provide an interactive, evidence-based management resource for providers, PSOs, and other entities. It will be used to analyze national and regional statistics, including trends and patterns of patient safety events. The NPSD will employ common formats (definitions, data elements, and so on) and will promote interoperability among reporting systems. The Department of Health and Human Services will provide technical assistance to PSOs.

Appendix 3 **Please note:** Only relevant portions are included here.

Calendar No. 387

108TH CONGRESS *1st Session* | SENATE | REPORT 108–196

PATIENT SAFETY AND QUALITY IMPROVEMENT ACT OF 2003

NOVEMBER 17, 2003.—Ordered to be printed

Mr. GREGG, from the Committee on Health, Education, Labor, and Pensions, submitted the following

R E P O R T

together with

ADDITIONAL VIEWS

[To accompany S. 720]

The Committee on Health, Education, Labor, and Pensions, to which was referred the bill (S. 720) to amend title IX of the Public Health Service Act to provide for the improvement of patient safety and to reduce the incidence of events that adversely effect patient safety, having considered the same, reports favorably thereon with an amendment in the nature of a substitute and recommends that the bill (as amended) do pass.

CONTENTS

29–010

I. Purpose and Need for Legislation

As many as 98,000 Americans die each year from preventable medical errors, according to the Institute of Medicine in its 1999 report To Err Is Human: Building a Safer Health System. This IOM report recognizes that health care professionals are human, humans are prone to error and most human errors are triggered by system failures. The report emphasizes the need to make system improvements and advises that health care information reporting systems must develop and implement processes through which medical error information can be identified, analyzed and utilized to prevent further medical errors. In addition, the report highlights that society's long-standing reliance on the threat of malpractice litigation discourages health care professionals and organizations from disclosing, sharing, and discussing information about medical errors. As a result, medical errors too often do not get identified and the same systems-oriented errors recur. The availability of civil remedies for patients who have been injured by negligence is important to redress patients' injuries. To reduce errors and improve patient safety the IOM recommended, among other things, that "Congress should pass legislation to extend peer review protections to data related to patient safety and quality improvement that are collected and analyzed by health care organizations for internal use or shared with others solely for purposes of improving safety and quality." The IOM acknowledged that a critical component of a comprehensive strategy to improve patient safety is to create an environment that encourages organizations to identify errors, evaluate causes and design systems to prevent future errors from occurring.

Reporting and analyzing errors is one component of the comprehensive strategy recommended by the IOM to reduce errors and improve patient safety and health care quality. In To Err is Human and subsequent reports, the IOM recommends a tiered approach to improve the quality of care: federal protections for a voluntary error reporting system (which is the focus of this bill); a narrowly focused mandatory reporting system to collect standardized information by State governments about adverse events that result in death or serious harm (about 20 States have implemented mandatory reporting statutes for certain serious events); increased investment in information technology; establishing a national focus to create leadership and enhance the knowledge base about safety; raising standards and expectations for improvements in safety; and creating safety systems inside health care organizations through the implementation of safe practices at the delivery level. Enactment of S. 720 is a significant step in an ongoing effort to improve the quality of care provided to all Americans. The committee notes that HHS has undertaken a number of programs to address medical errors and improve quality.

The committee has held five hearings concerning medical error and patient safety since the release of To Err is Human in 1999. In the course of this examination, the committee found that efforts to improve patient safety could best be strengthened by creating a learning environment characterized by supportive, voluntary data gathering systems. Testimony received during the committee's examination of this issue complements the body of research calling

for the creation of a "safe harbor" for the reporting of medical error information; that is, a means of reporting and analyzing information insulated from the risk of incurring additional liability and that absent a new reporting system would not otherwise exist.

This committee finds that S. 720, the "Patient Safety and Quality Improvement Act of 2003" will promote a learning environment that is needed to move beyond the existing culture of blame and punishment that suppresses information about health care errors to a "culture of safety" that focuses on information sharing, improved patient safety and quality and the prevention of future medical errors. The committee believes that it is important to shift the current focus from culpability to a new paradigm of error reduction and quality improvement. A new system and process—separate from but parallel to complementary laws and regulations designed to ensure accountability—is required to encourage the reporting of errors and to create an environment in which errors become opportunities for learning and improvement. This system and process would be separate from, and parallel to, complementary State, Federal, and local laws and regulations designed to ensure accountability; these State, Federal, and local reporting systems are independent of the system contemplated by this bill. The Department of Veterans Affairs and the Federal Aviation Administration, among others, have demonstrated that establishing a confidential error reporting system encourages reporting and results in substantial advances in safety. The Veterans' Health Administration has not only instituted a program for voluntary error reporting, but has also instituted a comprehensive program to improve the quality of care provided at VHA facilities. Integral to this program is the pervasive use of information technology in clinical practice. Physicians at VHA facilities can access patient records electronically and can enter orders for tests or procedures via an integrated computer system that provides alerts if an intended order is contraindicated for a particular patient. Moreover, the VHA electronic record system can issue reminders for specific procedures or screening tests to be performed, so that needed preventive care is not inadvertently omitted. It is far from certain that voluntary reporting alone would have been sufficient to cause the dramatic improvement in health care quality seen at VHA facilities in recent years.

An indispensable element of the reporting system used by the FAA is the collection and analysis of errors reports at a central site. If problems that could endanger passenger safety are found in any aspect of the federal aviation system, FAA issues directives to rectify those problems. Compliance with directives from the FAA is mandatory. The Aviation Safety Reporting System (ASRS) receives about 30,000 reports annually and has an operating budget of approximately $2 million. While S. 720 adopts a similar voluntary and confidential approach to improving patient safety, the committee believes that collecting potentially a million error reports a year at a central location would be impractical and prohibitively expensive. Not only would the sheer number of reports be overwhelming, but also the necessary expertise that would be necessary to properly analyze reports would be prohibitive. A preferred approach is to allow PSO's to report aggregated, nonidentifiable information to national databases specifically established to collect and disseminate information on improving patient safety.

The committee finds that the entire health care delivery system can benefit from a systems analysis of near misses and errors that have resulted in adverse events for systems improvement and corrective actions.

The purpose of this legislation is to encourage a "culture of safety" and quality in the U.S. health care system by providing for broad confidentiality and legal protections of information collected and reported voluntarily for the purposes of improving the quality of medical care and patient safety. These protections will facilitate an environment in which health care professionals and organizations report and evaluate health care errors and share their experiences with others in order to prevent similar occurrences. This legislation is needed to address what may be as many as 98,000 preventable deaths per year associated with medical errors and the estimated $29 billion in national costs associated with such preventable errors.

This bill accomplishes these purposes by establishing and defining a specific class of information known as "patient safety data" and according this new class of data legal protections designed to promote its collection, reporting and analysis. Patient safety data is not subject to a Federal, State, or local civil, criminal, or administrative subpoena or subject to discovery in a Federal, State, or local civil, criminal, or administrative proceeding. Further, this bill will not permit patient safety data to be disclosed under the Freedom of Information Act (FOIA); admitted as evidence or disclosed in a Federal, State, or local civil, criminal, or administrative proceeding; or used in a disciplinary proceeding against a provider. The bill also provides broad confidentiality protections, which are necessary to engender the trust and cooperation of the health care providers. Without participation of health care providers the system cannot be effective in collecting information.

During the past decade patient safety has emerged as a major health policy issue. There has been a steadily growing and forceful call for Congress to pass legislation that will facilitate the development of a confidential and nonpunitive system for reporting health care errors so that such errors can be identified and analyzed to improve patient safety by preventing future errors.

Members of this Committee have worked in a bi-partisan fashion to draft Federal legislation that reflects the IOM's recommendation for congressional action to establish a confidential reporting system to encourage a cooperative effort among providers and organizations geared to improving patient safety. This committee has worked diligently and deliberately to ensure that this legislation strikes the appropriate balance between plaintiff rights and creating a new culture in the health care industry that provides incentives to identify and learn from errors.

II. Summary

The general intent of S. 720, "The Patient Safety and Quality Improvement Act of 2003" is to establish a system to encourage voluntary reporting of adverse medical events, medical errors and incidents of "near misses" and to facilitate the development and adoption of interventions and solutions that will improve patient safety and the quality and outcomes of health care. This legislation

amends the Public Health Service Act to establish protections that will foster voluntary reporting.

This legislation will encourage "providers" (e.g., physicians, nurses, hospitals, nursing homes, and other health care providers) to report information on errors, incidents of "near misses" and enhanced health care quality practices to organizations known as Patient Safety Organizations (PSO's). PSO's are organizations that collect and analyze "patient safety data" and provide feedback to providers on strategies to improve patient safety and quality of care, and that have been listed by the Department of Health and Human Services (HHS) as such. HHS maintains a network of databases to provide an interactive evidence-based management resource for providers, PSO's, and the public. Providers, PSO's, and others may voluntarily submit nonidentifiable patient safety data to a database(s) in the network. HHS, PSO's and providers may disseminate information on recommended interventions and best practices to other PSO's, providers and consumers to improve quality of care and enhance patient safety.

The legislation grants an evidentiary privilege for information collected and developed by providers and PSO's through this voluntary reporting system. The privilege encompasses not only the report to the patient safety organization but also all aspects of the analysis of, and subsequent corrective actions related to, adverse events, medical errors, and "near misses" reported as patient safety data. It covers all deliberations, including oral and written communications, and work products that meet the requirements for patient safety data. This legislation also establishes confidentiality protections for this written and oral patient safety data to promote the reporting of medical errors. As a result, health care providers will be able to report and analyze medical errors, without fear that these reports will become public or be used in litigation. This nonpunitive environment will foster the sharing of medical error information that is a significant step in a process to improve the safety, quality, and outcomes of medical care.

It is vital to note that these protections do not extend backward to underlying factual information contained within or referred to in patient safety data reported to a PSO. In other words, the adverse event or the medical error itself is not privileged; it is the analysis of and subsequent corrective actions related to the adverse event or medical errors that are privileged. The underlying information remains unprivileged and available for reporting to authorities under mandatory or voluntary reporting initiatives. In practice, however, information that an adverse event or medical error has occurred is available through other record keeping systems (such as the patient's medical record, nursing notes, billing information, insurance forms). Because such information of adverse events or medical errors is available or can be collected or developed independent of the reporting system contemplated by this legislation, these protections do not preempt current or preclude future Federal, State or local requirements for the reporting or disclosure of information that ensures accountability or furthers informed consumer choice (e.g., hospital-acquired infections, medical errors, adverse or sentinel health care events, and medical outcomes) other than patient safety data. These protections do not provide a basis for providers to refuse to comply with such reporting requirements

simply because they have reported the same or similar information through the reporting system contemplated by this legislation nor do they preclude providers from voluntarily reporting such information pursuant to voluntary reporting initiatives. As long as there is another source of the information reported to the PSO—even if it is the same information as is reported—the protections in this legislation will not operate to prevent its release or disclosure because the information would come from the other sources, not from patient safety data. The legislation does not affect privileges or stronger confidentiality protections available under other law. The rules, for instance, which, in certain circumstances, require the Food and Drug Administration to protect the names of patients, providers, and reporters would, where applicable, continue to be in effect as they are now. This legislation recognizes and preserves the protection of confidential patient information under the Health Insurance Portability and Accountability Act of 1996. It requires HHS to develop or adopt voluntary national standards that promote the integration of health care information technology systems, requires a study to assess the impact of medical technologies on patient safety, and does not preempt other State and Federal peer review laws.

This legislation recognizes that patient safety can best be improved by fostering efforts to identify and fix errors while ensuring that providers remain accountable for malpractice. Such a balance was envisioned in the 1999 Institute of Medicine (IOM) report, To Err is Human: Building a Safer Health System, and has been corroborated as responsive by numerous patient safety experts, the Department of Veterans Affairs, the Agency for Healthcare Research and Quality, and a broad base of medical and health care organizations. However, it is important to note that numerous analyses indicate that voluntary confidential reporting is but one part of a comprehensive program to improve patient care. While an important component of a program to improve health care quality, voluntary reporting alone will not be sufficient to eliminate the serious problem of medical errors that the Nation faces. This conclusion too is supported by numerous patient safety experts, the Department of Veterans Affairs, the Agency for Healthcare Research and Quality, and a broad base of medical and health care organizations. The committee notes that HHS has already undertaken a number of programs to address medical errors and improve quality.

III. History of Legislation and Votes in Committee

On March 26, 2003, Senator Jeffords, for himself and Senators Frist, Breaux and Gregg introduced S. 720 to provide for the improvement of patient safety and to reduce the incidence of events that adversely effect patient safety.

On July 23, 2003, the committee held an executive session to consider S. 720. Senator Gregg for himself and Senator Jeffords offered a substitute amendment, as modified, that was considered as original text by the committee. The committee approved S. 720, as amended by unanimous vote.

IV. Explanation of Bill and Committee Views

1. Legal protections for patient safety data encourage reporting.

This legislation provides broad confidentiality protections and legal privileges for patient safety data. The committee finds that broad protections are essential to encourage reporting. Currently, there are few incentives and many barriers for providers to collect and report information regarding patient safety. The primary barrier relates to concerns that information shared to promote patient safety would expose providers to liability. Unless this information can be freely shared, errors will continue to be hidden and errors will be repeated. A more open, nonpunitive learning environment is needed to encourage health care professionals and organizations to identify, analyze, and report errors without facing the threat of litigation and, at the same time, without compromising plaintiffs' legal rights or affecting existing and future public reporting initiatives with respect to the underlying data.

This bill provides confidentiality and legal protections for patient safety data, which are defined as information collected or developed and reported to a patient safety organization within a reasonable period of time. The committee recognizes that the reasonableness of the time to report is contingent upon many factors, including the complexity of the facts and circumstances surrounding the analysis of a medical error. Nonetheless, the committee intends that a reasonable period of time be a period of 2 months or less from the collection or development of the patient safety data. This amount of time will allow providers to investigate and report pertinent information to the patient safety organization. The information qualifies as patient safety data during that period if it is collected or developed for reporting and is reported to the patient safety organization within the required time frame. The definition of patient safety data also includes "any deliberative work or process or oral communications with respect to any patient safety data* * * ." (Section 921(A)(ii)) Patient safety data would not be collected or developed in a vacuum, and accordingly the bill includes reports, records, memoranda analyses, oral and written statements and thought processes (or mental impressions) in the definition of patient safety data. For example, if an error occurs, a health care professional must first, at a minimum, evaluate what occurred so that relevant information is recorded in a manner that promotes analysis. Typically, relevant information would be reported on a "data set" or standard form (or computer form) used for reporting such information to a patient safety organization. It is likely that a standard form would be required by a patient safety organization so that only relevant information is collected. Mere inclusion in such a form is not sufficient to establish privilege under the definition of patient safety data. For example, data on hospital-acquired infections may be required to be reported to a State agency and later released to the public. If such data happens to be reported on a standard form for reporting to a PSO, it would not thereby be exempted from the requirement to be reported to the State agency if that State requires such reporting through a parallel but different process. However, analysis or discussion of the data that constituted patient safety data would be exempted.

In addition to protecting the actual information that is submitted to the patient safety organization, it is essential to extend confidentiality and legal protections to any "deliberative work or process" and "oral or written communications" utilized in generating a re-

port to a patient safety organization. This bill includes such communications within the definition of patient safety data to allow for more accurate information to be transmitted to a patient safety organization. As the Institute of Medicine (IOM) stated in its 1999 report, To Err is Human, "The strongest legal protections would cover the entire chain of custody of the information from its initial generation to its ultimate use."

Patient safety data does not include information that is collected or developed and exists separately. For example, data and information that is contained in medical records, hospital claim or billing forms and facts of an adverse event (including oral and written statements not relating to the collection or development of patient safety data) cannot be shielded by being attached to patient safety data and sent to a patient safety organization. This means that medical information—including medical error information—that is currently available under a reporting requirement or initiative or that is available to a patient will continue to be available under this legislation.

This bill follows a similar approach for the analysis and reporting of adverse events, medical errors, and "near misses." As the IOM stated in To Err is Human, "protecting data in a reporting system * * * does not mean that the plaintiff in a lawsuit could not try to obtain such information through other avenues if it is important in securing redress for harm; it just means that the plaintiff would not be assisted by the presence of a reporting system designed specifically for other purposes beneficial to society." Importantly, the bill does not alter existing rights or remedies available to injured patients. Laws that provide greater confidentiality or privilege protections are also not affected by this legislation.

2. This legislation will not preempt Federal, State, or local law governing accountability for a health care professional's negligence, malfeasance, or criminal acts, or that requires the collection and reporting of underlying data on health care provider quality of care, other than patient safety data.

In creating a nonpunitive and voluntary system for the reporting and analyses of events that have led or could lead to patient harm, the committee recognizes the importance of separate systems of laws, regulations, accreditation and licensing requirements that have been (or may in the future be) established for the purpose of maintaining accountability in the health care system. This legislation provides legal protections for specified patient safety data. It is separate from and independent of mandatory or voluntary reporting systems that have been or may be established under Federal, State or local law or regulation. Reporting an error or other incident under this new system will not limit or affect the reporting

of information that is now or will in the future be required to be made under existing Federal, State, or local law to non-patient safety organizations. Information that must be reported under Federal, State or local reporting requirements (such as New York's incident reporting statute 10 NYCRR § 405.8)—even when those laws or regulations require the reporting of the same or similar information regarding the type of events also reported through the system contemplated by this legislation—is not within the definition of patient safety data because it is not "collected or developed * * * for reporting to a patient safety organization * * *" (section 921(2)(A)(i)(I)). Conversely, information covered under state reporting laws fall outside the definition of patient safety data because such information is "collected or developed separately from and that exists separately from patient safety data * * *" (section 921(2)(B)).

State peer review statutes encourage health care professionals to evaluate care provided by the members of the medical staff and to take appropriate action. Moreover, medical staff bylaws typically provide for an immediate summary suspension of health care professionals in serious situations or other disciplinary action against health care professionals even when peer review activities are underway. Patient deaths are reportable to a medical examiner, who generally has the discretion to conduct an investigation of deaths. Impaired healthcare workers are reported to a designated professional regulatory agency or rehabilitation program pursuant to State licensing laws. Federal, State, and local agencies may investigate and prosecute individuals under their respective authorities. Many States have laws that require a healthcare worker to report to the authorities cases of suspected neglect or abuse, typically applicable to children and senior citizens. Further, the state and federal civil court systems are available to patients who are injured, or their survivors if the patient dies, due to negligence.

In addition, a number of employer organizations have instituted (or are planning to institute) voluntary reporting initiatives for providers that participate in their networks. The operation of these legal requirements, or these voluntary initiatives, is not preempted by this legislation but may not afford the protections provided by this bill. This legislation conveys legal protection only on those communications that are sent to the PSO, or that the PSO prepares to send to a provider (and related communications and mate-

rials)—not to the underlying information contained within those communications that is obtainable from other records or sources.

This legislation will not allow providers and patient safety organizations to hide information about a crime by reporting and analyzing the case using this system. The confidentiality and legal protections in this bill would in no way limit or affect the availability of any information or evidence that does not meet the statutory definition of patient safety data and is currently available under existing Federal, State, or local law (section 922(j)(2)). Furthermore, this bill specifically allows an exception to the confidentiality and legal protections for patient safety data in a criminal proceeding when a court makes an in camera determination that the data includes evidence of an intentional act to harm a patient (section 922(c)(1)). This bill specifically states that nothing in the bill would prohibit a provider from reporting a crime to law enforcement authorities (section 922(j)(5)).

3. Patient Safety Organizations analyze patient safety data and provide recommendations, best practices and systems improvements to improve patient safety and quality of care.

This legislation requires that information be reported to or developed by a Patient Safety Organization (PSO) to qualify as patient safety data. The primary purpose of a patient safety organization is to continually work to improve the quality and safety of care provided to patients. The breadth of data available to PSO's, that are expected to enter into contracts with multiple providers, will facilitate the identification and analysis of patterns of organization and behavior that can lead to errors. This broader, systemic perspective will provide an important complement to the quality and safety improvement initiatives of many health care providers and facilitate the type of "shared learning" envisioned by the IOM report. PSO's should provide guidance and direct feedback to the provider's analysis of adverse events, medical errors, and "near misses" (or a provider may contract with a PSO to undertake the initial analysis as well), undertake broader statistical pattern analyses drawing upon data from two or more providers, and assist health care professionals and organizations in identifying and/or undertaking quality improvement initiatives to minimize patient risk. A PSO may be a component of a larger organization, as long as the component meets the criteria set forth in the bill.

V. Regulatory Impact Statement

The committee has determined that there will be minimal increases in the regulatory burden imposed by this bill. The bill does not mandate any new reporting system but provides protection for data submitted to patient safety organizations (PSO) to prevent medical errors from occurring and improve quality of care for patients. Each PSO will certify to HHS that it performs the functions stated in S. 720 and must recertify every 3 years. The Secretary, on his own initiative, or on complaint, could examine the PSO to determine whether the PSO is in fact performing the required functions. HHS will also maintain a network of databases and provide technical assistance to PSO's to assist them with the certification process and with improving patient safety. Accordingly, the committee has determined that there will be minimal regulatory burden imposed with respect to the certification process.

VIII. Section-by-Section Analysis

The bill amends title IX of the Public Health Service Act to provide for the improvement of patient safety and to reduce the incidence of events that adversely effect patient safety.

Sec. 1. Short title

Section 1 entitles the Act the "Patient Safety and Quality Improvement Act of 2003."

Sec. 2. Findings and purpose

Establishes a series of findings, which point to the critical need for confidentiality and legal protections with respect to information

reported for the purposes of quality improvement and patient safety. Specifies that the primary purpose of the bill is to encourage a culture of safety and quality in the health care system by providing for the legal protection of information reported voluntarily for the purposes of quality improvement and patient safety, and ensure accountability by raising standards and expectations for continuous quality improvements in patient safety.

Sec. 3. Amendments to Public Health Service Act

Amends title IX of the Public Health Service Act (42 U.S.C. 299 et seq.) by redesignating part C as part D, redesignating section 921 through 928 as section 931 through 938, and inserting the following sections under new Part C:

Section 921. Definitions.

Section 921(1): Defines the term "non-identifiable" as information presented in a form and manner that prevents identification of a provider, a patient or a reporter of patient safety data.

Section 921(2): Defines "Patient Safety Data" as any data, reports, records, memoranda, analyses (such as root cause analyses), or statements that could result in improved patient safety, quality, or outcomes that are collected or developed by a "provider" for reporting to a PSO and are reported within a reasonable period of time, requested by a PSO, reported to a provider by a PSO, or collected from a provider or PSO or developed by PSO. The definition includes any deliberative work or process or oral communication with respect to patient safety data. Patient safety data does not include information that is collected or developed and exists separately from Patient Safety Data (such as, medical records and copies of "separate" information).

Section 922. Privilege and Confidentiality Protections.

Section 922(a): Patient Safety Data is privileged and shall not be: subject to a federal, state, or local civil, criminal, or administrative subpoena; subject to discovery in a federal, state, or local civil, criminal, or administrative proceeding; disclosed pursuant to the Freedom of Information Act (FOIA); admitted as evidence or dis-

closed in a federal, state, or local civil, criminal, or administrative proceeding; or utilized in a disciplinary proceeding against a provider.

Section 922(b): Patient safety data shall be confidential and shall not be disclosed, except as set forth in paragraphs (c) and (d).

Section 922(c): The following disclosures and uses are allowed: disclosure of relevant patient safety data by a provider or PSO for use in a criminal proceeding only after a court makes an in camera determination that such data contains evidence of an intentional act to directly harm a patient; voluntary disclosure by provider or PSO to the FDA or a person subject to the FDA's jurisdiction regarding a FDA-regulated product or activity; voluntary disclosures by provider to CDC for public health surveillance, investigation, or other public activities; and voluntary disclosure by provider or PSO of non-identifiable data.

Section 922(d): The following disclosures are also allowed: disclosure by a provider or PSO to carry out the activities of the PSO; use or disclosure by a provider or PSO in connection with providing treatment, improving patient safety, health care quality or administrative efficiency, or other customary activity of the provider or in obtaining payment; disclosure among PSOs; disclosure by provider or PSO to grantees or contractors carrying out patient safety research, evaluation, or demonstration projects authorized by the Director; and disclosure by a provider to an accrediting body that accredits that provider.

Section 922(e): Patient safety data used or disclosed in accordance with section 922(d) shall continue to be privileged and confidential in accordance with sections 922(a) and (b) and shall not be disclosed by an entity that possessed such information before such use or disclosure, or by an entity to which the information was disclosed, unless such additional disclosure is permitted under section 922(d).

Section 922(f): Except as provided in section 922(c), no action may be brought or process served against a patient safety organization to compel disclosure of information collected or developed under this part whether or not such information is patient safety data. An accrediting body may not require a provider to reveal its communications with a PSO.

Section 922(j): This legislation does not: limit other privileges and confidentiality protections available under federal, state, or local laws that provide greater protection; limit, alter, or affect the requirements of federal, state, or local law pertaining to patient-related data that is not privileged or confidential under this Title; affect the health information privacy provisions under HIPAA; limit the authority of any provider, PSO, or other person to enter into a contract requiring greater confidentiality protections than provided in this Title or delegating authority to make a disclosure or use in accordance with the Title; or prohibit a provider from reporting a crime to law enforcement authorities.

IX. ADDITIONAL VIEWS OF SENATORS KENNEDY, DODD AND CLINTON

The signatories of these "Additional Views" fully support the goal of establishing a voluntary national patient safety reporting program with a legal privilege to adhere to any information newly created for that program. Such a program would be the first step in a comprehensive effort to reduce errors and enhance the quality of health care. The signatories believe, however, that enhanced use of information technology should be an integral part of any effort to improve health care quality and reduce errors.

Improved use of information technology (IT) is an integral part of reducing medical errors and improving patient care. Over one million serious medication errors are made in American hospitals every year, resulting in over 7,000 deaths. The economic costs of medication errors are also staggering. Each serious medication error adds $2,000 to the cost of a hospital stay. The total cost of medication errors is over $2 billion annually.

Dramatic decreases in medication errors are seen consistently when computerized systems are installed and used. To cite but a few examples, use of a computerized prescription order entry system was shown to reduce hospital length of stay by 0.89 days per patient and to reduce costs by 12.7%, according to a study by Tierney and colleagues published in the Journal of the American Medical Association.

In a study of a computerized prescription order entry system for patients with infectious disease, Evans and colleagues found that use of the system reduced by 76% prescriptions of drugs to which patients were allergic, reduced excess drug dosages by 78% and reduced adverse reactions by 86%. The same study showed that the system reduced the cost per patient of drugs prescribed by over 75% and reduced hospital costs per patient by 41%.

Computerized records also allow doctors to look at a patient's entire medical records at once—making proper care coordination a real possibility. According to the Institute of Medicine, "Health information is dispersed in a collection of paper records that are poorly organized and often illegible, and frequently cannot be retrieved in a timely fashion, making it nearly impossible to manage many forms of chronic illness that require frequent monitoring and ongoing patient support." IT systems can transform this sorry state of affairs and help patients get the type of coordinated care they need. The Institute of Medicine, in its recent report Leadership by Example, concluded that, "the Federal government should take steps immediately to encourage and facilitate the development of information technology infrastructure that is critical to health care quality and safety enhancement."

SEC. 922. PRIVILEGE AND CONFIDENTIALITY PROTECTIONS.

(a) PRIVILEGE.—Notwithstanding any other provision of Federal, State, or local law, patient safety data shall be privileged and, subject to the provisions of subsection (c), shall not be—

(1) subject to a Federal, State, or local civil, criminal, or administrative subpoena;

(2) subject to discovery in connection with a Federal, State, or local civil, criminal, or administrative proceeding;

(3) disclosed 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 or otherwise disclosed in any Federal, State, or local civil, criminal, or administrative proceeding; or

(5) utilized in a disciplinary proceeding against a provider.

(b) CONFIDENTIALITY.—Notwithstanding any other provision of Federal, State, or local law, and subject to the provisions of subsections (c) and (d), patient safety data shall be confidential and shall not be disclosed.

(c) EXCEPTIONS TO PRIVILEGE AND CONFIDENTIALITY.—Nothing in this section shall be construed to prohibit one or more of the following uses or disclosures:

(1) Disclosure by a provider or patient safety organization of relevant patient safety data for use in a criminal proceeding only after a court makes an in camera determination that such patient safety data contains evidence of an intentional act to directly harm the patient.

(2) Voluntary disclosure by a provider or patient safety organization of information to the Food and Drug Administration, or to a person that is subject to the jurisdiction of the Food and Drug Administration, with respect to a Food and Drug Administration-regulated product or activity for which that entity has responsibility, for the purposes of activities related to the quality, safety, or effectiveness of a Food and Drug Administration-regulated product or activity or a Food and Drug Administration proceeding.

(3) Voluntary disclosure of non-identifiable patient safety data by a provider or a provider patient safety organization.

(4) Voluntary disclosure by a provider of patient safety data to the Centers for Disease Control and Prevention for public health surveillance, investigation, or other public health activities.

(d) PROTECTED DISCLOSURE AND USE OF INFORMATION.—Nothing in this section shall be construed to prohibit one or more of the following uses or disclosures:

(1) Disclosure by a provider or patient safety organization of information to which subsections (a) or (b) applies to carry out activities described in paragraph (2) or (3) of section 921.

(2) Use or disclosure by a provider or patient safety organization of patient safety data in connection with providing treatment, improving patient safety, health care quality or administrative efficiency, or any other customary activity of the provider or in obtaining payment.

(3) Disclosure of patient safety data among patient safety organizations.

(4) Disclosure of patient safety data by a provider or patient safety organization to grantees or contractors carrying out patient safety research, evaluation, or demonstration projects authorized by the Director.

(5) Disclosure of patient safety data by a provider to an accrediting body that accredits that provider.

(e) CONTINUED PROTECTION OF INFORMATION.—Patient safety data used or disclosed in accordance with subsection (d) shall continue to be privileged and confidential in accordance with subsections (a) and (b) and shall not be disclosed—

(1) by an entity that possessed such information before such use or disclosure; or

(2) by an entity to which the information was disclosed;

unless such additional disclosure is permitted under subsection (d).

(f) LIMITATION ON ACTIONS.—

(1) PATIENT SAFETY ORGANIZATIONS.—Except as provided in subsection (c), no action may be brought or process served against a patient safety organization to compel disclosure of information collected or developed under this part whether or not such information is patient safety data.

(2) PROVIDERS.—An accrediting body shall not take an accrediting action against a provider based on the good faith participation of the provider in the collection, development, reporting, or maintenance of patient safety data in accordance with this part. An accrediting body may not require a provider to reveal its communications with any patient safety organization established in accordance with this part.

(g) DISCLOSURE OR USE OF INFORMATION.—

(1) IN GENERAL.—Except with respect to the specific patient safety data that is used or disclosed, the disclosure or use of any patient safety data in accordance with subsection (c) or (d) shall not be treated as a waiver of any privilege or protection established under this part.

(2) INADVERTENT DISCLOSURE OR USE.—The inadvertent disclosure or use of patient safety data shall not waive any privilege or protection established under this part with respect to such data.

(h) REPORTER PROTECTION.—

(1) IN GENERAL.—A provider may not take an adverse employment action, as described in paragraph (2), against an individual based upon the fact that the individual in good faith reported information—

(A) to the provider with the intention of having the information reported to a patient safety organization; or

(B) directly to a patient safety organization.

(2) ADVERSE EMPLOYMENT ACTION.—For purposes of this subsection, an "adverse employment action" includes—

(A) loss of employment, the failure to promote an individual, or the failure to provide any other employment-related benefit for which the individual would otherwise be eligible; or

(B) an adverse evaluation or decision made in relation to accreditation, certification, credentialing, or licensing of the individual.

(i) ENFORCEMENT.—

(1) PROHIBITION.—Except as provided in subsections (c) and (d) and as otherwise provided for in this section, it shall be unlawful for any person to negligently or intentionally disclose any patient safety data described in subsection (a) and any such person shall, upon adjudication, be assessed in accordance with section 934(d).

(2) RELATION TO HIPAA.—The penalty provided for under paragraph (1) shall not apply if the defendant would otherwise be subject to a penalty under the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note) or under section 1176 of the Social Security Act (42 U.S.C. 1320d–5) for the same disclosure.

(3) EQUITABLE RELIEF.—Without limiting remedies available to other parties, a civil action may be brought by any aggrieved individual to enjoin any act or practice that violates subsection (h) and to obtain other appropriate equitable relief (including reinstatement, back pay, and restoration of benefits) to redress such violation.

(4) ACTIONS AGAINST STATE EMPLOYEES.—Notwithstanding subsection (a), with respect to a State employer, the privilege described in such subsection shall not apply to such employer unless the employer consents, in advance, to be subject to a civil action under paragraph (3).

(j) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to—

(1) limit other privileges that are available under Federal, State, or local laws that provide greater confidentiality protections or privileges than the privilege and confidentiality protections provided for in this section;

(2) limit, alter, or affect the requirements of Federal, State, or local law pertaining to patient-related data that is not privileged or confidential under this section;

(3) alter or affect the implementation of any provision of section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033), section 1176 of the Social Security Act (42 U.S.C. 1320d–5), or any regulation promulgated under such sections;

(4) limit the authority of any provider, patient safety organization, or other person to enter into a contract requiring greater confidentiality or delegating authority to make a disclosure or use in accordance with subsection (c) or (d); and

(5) prohibit a provider from reporting crime to law enforcement authorities.

SEC. 923. PATIENT SAFETY NETWORK OF DATABASES.

(a) IN GENERAL.—The Secretary shall maintain a patient safety network of databases that provides an interactive evidence-based management resource for providers, patient safety organizations, and other persons. The network of databases shall have the capacity to accept, aggregate, and analyze nonidentifiable patient safety data voluntarily reported by patient safety organizations, providers, or other persons.

(b) NETWORK OF DATABASE STANDARDS.—The Secretary may determine common formats for the reporting to the patient safety network of databases maintained under subsection (a) of nonidentifiable patient safety data, including necessary data elements, common and consistent definitions, and a standardized computer interface for the processing of such data. To the extent practicable, such standards shall be consistent with the administrative simplification provisions of Part C of title XI of the Social Security Act.

PART [C] *D*—GENERAL PROVISIONS

SEC. [921] *931.* ADVISORY COUNCIL FOR HEALTHCARE RESEARCH AND QUALITY.

(a) ESTABLISHMENT.—* * *

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SEC. [922] *932.* PEER REVIEW WITH RESPECT TO GRANTS AND CONTRACTS.

(a) REQUIREMENT OF REVIEW.—

(1) IN GENERAL.—* * *

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SEC. [923] *933.* CERTAIN PROVISIONS WITH RESPECT TO DEVELOPMENT, COLLECTION, AND DISSEMINATION OF DATA.

(a) STANDARDS WITH RESPECT TO UTILITY OF DATA.—

(1) IN GENERAL.—* * *

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SEC. [924] *934.* DISSEMINATION OF INFORMATION.

(a) IN GENERAL.—The Director shall—

(1) * * *

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(d) PENALTY.—Any person who violates subsection (c) shall be subject to a civil monetary penalty of not more than $10,000 for each such violation involved. [Such penalty shall be imposed and collected in the same manner as civil money penalties under sub-

section (a) of section 1128A of the Social Security Act are imposed and collected.] *Penalties provided for under this section shall be imposed and collected by the Secretary using the administrative and procedural processes used to impose and collect civil money penalties under section 1128A of the Social Security Act (other than subsections (a) and (b), the second sentence of subsection (f), and subsections (i), (m), and (n)), unless the Secretary determines that a modification of procedures would be more suitable or reasonable to carry out this subsection and provides for such modification by regulation.*

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