Medical Apology Laws, Mandatory Reporting, and Adverse Event Reporting Under the PSQIA

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I. <u>Medical Apology Laws:</u>

A. Introduction

Curbing medical malpractice lawsuits remains at the forefront of the national

debate over healthcare reform. Although the number of malpractice lawsuits has

remained relatively steady over the past few years, the total monetary cost, in terms of

payments and insurance premiums, has risen steadily. Recently, a growing number of

states have taken the lead in trying to curb medical malpractice cases by encouraging

dialogue between physicians and patients about medical errors. One of the most popular

and successful efforts by states to reduce medical malpractice costs has been the passage

of so-called "medical apology laws." These laws generally provide that a medical

provider's expression of an "apology" to a patient following a medical error can not be

used as evidence against the provider in a subsequent malpractice lawsuit.

Thirty-five states and the District of Columbia currently have either statutes or

rules of evidence that prevent the use of apologies as evidence of fault in medical

malpractice cases. Twenty-five of these laws were enacted in 2005 or later; only a

handful existed before the year 2000. The express purpose of these statutes is "to reduce

the incidence of claims and lawsuits arising out of . . . unanticipated outcomes [of

medical carel."

B. <u>Variances in State Apology Laws</u>

As of September 2008, thirty-five states and the District of Columbia have

adopted rules of evidence or other statutory restrictions on the use of apologies in medical

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malpractice cases. These statutes differ in ways that are often subtle, but which have dramatic implications for practical applications, including: (1) the type of communication protected; (2) by whom the protected communication may be made; (3) to whom the protected communication may be made; (4) the sentiments protected; and (5) the context in which a communication will be protected. Additionally, a number of states have unique provisions with no analogue in their counterparts around the country, including: time limits on protected apologies; protection for apologies to domestic partners; protection for payment of medical expenses; and prohibition on settlements during patient convalescence.

### 1. Types of Communication Protected

The vast majority of state apology laws protect written statements, oral statements, and conduct (usually formulated as "statements, affirmations, gestures, and conduct"). Two states, North Carolina and South Dakota, protect only a limited class of conduct: that which assists an individual affected by an adverse outcome. One state, Vermont, does not protect written apologies or conduct. Utah does not protect unsworn statements.

#### 2. Who Makes the Communication

Many apology laws impose requirements on who may make an apology within the protections of the law. Twenty-one jurisdictions limit their protections to apologies made by healthcare providers. All but two of these jurisdictions expressly permit the employees and/or agents of a healthcare provider to apologize on the provider's behalf. The other fifteen states impose no such restriction; in those states, apologies are

inadmissible if they fall within the remaining provisions of the statute, regardless of who apologizes.

#### 3. Who Receives the Communication

Nearly every apology law contains a provision defining the class of persons to whom an individual may apologize within the protection of the statute; only seven protect apologies without regard to the recipient's identity. The other twenty-nine apology laws contain provisions that, for the most part, limit the class of individuals to whom one may apologize to the victim of an accident or adverse medical event, the victim's family, the victim's representative, or some combination thereof.

The restrictions on permissible recipients of protected apologies represent the greatest source of practical variance between these statutes. Two statutes protect apologies to the friends of patients. Two protect apologies made to domestic partners of a patient. Virginia's statute does not protect apologies to the patient, as it applies only in wrongful death actions.

While the most common formulation protects apologies to the patient, the patient's family, or the patient's agent or representative, the definition of "family" varies in ways that create practical pitfalls for healthcare practitioners. For example, many apology laws offer no protection to apologies made to adopted relatives. Some of those that include adopted relatives in the definition of family include only adopted siblings, excluding by omission adopted parents, adopted children, and any other adopted relationship. Oklahoma's statute omits stepmothers from the definition of "family" while including stepfathers.

Because of this broad variance in apology laws, healthcare providers who wish to avail themselves of the protection of these laws must take special care when determining to whom an apology should be made.

#### 4. Sentiments Protected

While there are a wide range of formulations of which sentiments are protected by apology laws, only a few of these contain meaningful differences. What distinctions one might draw between statements expressing "sympathy" and those expressing "compassion, commiseration, and condolence" are unlikely to be worthy of practical consideration. The more critical distinctions are those between expressions of sympathy and admissions of fault. Five apology laws protect expressions of mistake, error, and fault. Nineteen of the remaining thirty-one explicitly define as admissible statements acknowledging fault or liability. Three apology laws protect explanations of the circumstances which led to an adverse medical event. Recognizing the extent of the protections afforded by these laws is essential to crafting an apology that fully acknowledges an adverse event but does not exacerbate the healthcare provider's legal exposure.

#### 5. Context of Apology

Most apology laws impose a restriction on the context in which an apology qualifies for protection. Eleven statutes require only that the apology relate to the pain, suffering, injury, or death of an individual as a result of an unanticipated outcome of medical care. Six require that the apology relate to the pain, suffering, injury or death of an individual as a result of an accident, whether medical or otherwise. Several have unique context provisions, such as a requirement that the healthcare provider apologize

within a certain time after discovery of a medical error. This variance in protected contexts makes it important for healthcare providers to determine whether the context is protected under the relevant apology law before issuing an apology.

# C. <u>State Apology Laws:</u>

At the present time, there are roughly 36 states that have enacted some form of apology laws or regulations, including:

STATE	STATUTORY CITATION
Arizona	ARIZ. REV. STAT. ANN. §12-2605 (2005)
California	CAL. EVID. CODE § 1160 (West 2000)
Colorado	Colo. Rev. Stat. Ann. §13-25-135 (West 2003)
Connecticut	CONN. GEN. STAT. ANN. §52-184d (West 2005)
Delaware	Del. Code Ann. tit. 10, § 4318(b) (2008).
District of Columbia	D.C. Code § 16-2841 (2008).
Florida	FLA. STAT. ANN. §90.4026 (West 2001)
Georgia	GA CODE ANN. §24-3-37.1 (West 2005)
Hawaii	HAW. REV. STAT. § 409.5 (2008).
Idaho	IDAHO CODE Ann. § 9-207(1) (2008).
Illinois	110 ILL. COMP. STAT. ANN. 5/8-1901 (West 2005)
Indiana	Ind. Code Ann. §§ 34-43.5-1-3, 34-43.5-1-4 (2008).
Iowa	IOWA CODE § 622.31 (2008).
Louisiana	La. Rev. Stat. Ann. § 13: 3715.5 (2005)
Maine	ME REV. STAT. ANN. TIT. 24, § 2907 (2005)

MD. CODE ANN., CTS. & JUD. PROC. §10-920 (West
2004)
Mass. Gen. Laws ch. 233, §23D (West 1986)
Mo. Ann. Stat. § 538.229 (West 2005)
MONT. CODE ANN. §26-1-814 (2005)
Neb. Rev. Stat. § 27-1201(1) (2008).
N.H. REV. STAT. ANN. § 507-E:4 (2006)
N.C. Gen. Stat. § 8C-1, Rule 413 (2004).
N.D. CENT. CODE § 31-04-12 (2008).
OHIO REV. CODE ANN. §2317.43 (West 2004)
OKLA. STAT. tit. 63, § 1-1708.1H (2005)
OR. REV. STAT. ANN. §677.082 (West 2003)
S.C. CODE ANN. § 19-1-190(D) (2007).
.D. Codified Laws § 19-12-14 (2008).
TENN. R. EVID. 409.1 (2008).
TEX. CIV. PRAC. & REM. CODE ANN. §18.061 (Vernon
1999)
UTAH CODE ANN. § 78B-3-422 (2008).
Vt. Stat. Ann. tit. 12, § 1912(a) (2007).
VA. CODE ANN. §8.01-52.1 (West 2005)
WASH. REV. CODE ANN. § 5.66.010 (West 2002)
W. VA. CODE ANN. § 55-7-11a (West 2005)
Wyo. Stat. Ann. § 1-1-130 (2004)

### II. <u>Mandatory Reporting of Medical Errors and Adverse Events</u>

### A. Federal Regimes for Mandatory Adverse Event Reporting

There currently exist a number of federal regimes for mandatory reporting of adverse events. These federal regimes, which have evolved slowly over the past decade, are highly specialized and much more narrowly focused than state mandatory reporting statutes. Unlike state reporting statutes, the various federal regimes generally apply to a limited set of adverse events, and have relatively specific guidelines for reporting these events. The focused nature of these federal reporting regimes, however, can result in failures of compliance by healthcare providers and compliance officers. This leaves healthcare providers and entities exposed to potential sanctions for failing to timely report adverse events, as well as opening the door to a number of collateral consequences, including whistleblower suits where the accurate reporting of adverse events is a condition of payment of public funds.

### 1. <u>Medical Device Reporting</u>

Congressional regulations require that medical device "manufacturers" and "device user facilities" report deaths or serious injuries<sup>iii</sup> that result from the use of medical devices. Device user facilities are required to report these adverse events within ten business days to the Food and Drug Administration (FDA) Center for Devices and Radiological Health and, if the manufacturer's identity is known, to the manufacturer as well. The manufacturer must, in turn, investigate the event and provide additional information to the FDA within thirty calendar days. Because of the broad definition of manufacturer in this context, it is important for any device user, including hospitals and

other medical facilities, to carefully determine whether it might also be deemed a device manufacturer for reporting purposes.

## 2. <u>Vaccine Adverse Event Reporting System</u>

The Vaccine Adverse Event Reporting System (VAERS) accepts reports from health care providers, manufacturers, and the public regarding adverse events associated with U.S. licensed vaccines. VAERS is administered jointly by the FDA and the Centers for Disease Control (CDC); both entities receive reports via the VAERS. Manufacturers and health care providers are required to report any adverse events through VAERS, with sanctions for failure to report generally limited to license revocation or similar disciplinary action. vi

#### 3. Current Good Tissue Practice regulations

Human cells or tissue, other than blood, intended to in any way be transferred into a human being is regulated by the FDA as a human cell, tissue, and cellular and tissue-based product, or "HCT/P." HCT/P "establishments" (which recover, process, store, label, package, manufacture, or distribute HCT/P), are required to investigate adverse reactions involving any communicable disease associated with HCT/P it distributed and to report any such reactions that are fatal, life-threatening, result in permanent impairment or harm, or require medical or surgical intervention. Health care providers that do not qualify as HCT/P establishments are encouraged to voluntarily report adverse reactions to the FDA and to the HCT/P establishment from which the HCT/P was acquired.

### 4. <u>Blood and Blood Product Manufacturing Errors:</u>

Blood and blood product manufacturers<sup>ix</sup> are required to report any event related to the manufacture (including testing, processing, packing, labeling, or storage) or the holding or distribution of blood or blood products which represents a deviation from good manufacturing practice or standards, or represents an unexpected event that may affect the safety, purity, or potency of the product.<sup>x</sup> These reports must be made to the Center for Biologics Evaluation and Research (CBER), Office of Compliance and Biologics Quality (OCBQ) no more than forty-five calendar days from the date of discovery of information reasonably suggesting a reportable event has occurred.

### 5. Deaths Related to Patient Restraint or Seclusion:

The Centers for Medicare and Medicaid Services ("CMS") requires hospitals, as part of the Medicare Conditions of Participation, to report to their CMS any patient death that occurs while the patient is restrained or in seclusion, within 24 hours after the patient has been removed from restraint or seclusion, and within one week after restraint or seclusion where it is reasonable to assume that the patient's death resulted in part from restraint or seclusion. "Reasonable to assume" includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing or asphyxiation. This reporting to the CMS is to be done via telephone by the close of business on the business day on which the hospital learned of the patient's death.

### B. <u>State Legislation Requiring Mandatory Reporting of Medical Errors</u>

Most mandatory reporting obligations come from various state laws and regulations, as opposed to the narrowly tailored federal reporting regimes. Although a small number of states have had reporting requirements for some time, most have just recently adopted reporting requirements. As of July 2006, at least 33 states had some form of mandatory or voluntary requirement for reporting medical errors. At least 24 states had some type of mandatory reporting requirement. A number of states are currently considering the adoption of mandatory reporting rules. Moreover, given the increasing public attention paid to medical errors, the number of states with reporting requirements is likely to continue to grow.

There is little uniformity amongst these state reporting requirements, and they are subject to statutory and regulatory changes, as well as updates to interpretive guidelines, web-sites and forms. In a number of key aspects the state reporting requirements differ quite dramatically, including: (1) the definition of an "adverse event;" (2) what type of information needs to be reported; (3) when the reporting must be made; (4) the consequences, if any, for failing to report; and (5) what the state does with the adverse event information it receives from healthcare facilities.

Although the differences in the state mandatory reporting statutes far outweigh the similarities, one common element is that nearly all provide some degree of confidentiality over adverse event reports. In general, these confidentiality provisions prevent adverse events reports from being used in subsequent civil lawsuits. A few states go even further by prohibiting the use of adverse event reports in criminal and administrative proceedings. The scope and strength of these confidentiality measures

should be carefully analyzed by all healthcare facilities that are subject to mandatory reporting rules.

### 1. <u>Definition of "Adverse Events"</u>

One of the key ways in which state adverse event reporting statutes differ is in the definition of those events that must be reported. The states adverse event reporting statutes generally fall within three categories: (1) states with specific lists of adverse events; (2) states with broadly defined adverse events; and (3) states with narrowly defined adverse events. Understanding the precise adverse events that trigger a mandatory reporting obligation is a critical component of an effective compliance program for all hospitals and health care providers.

### a. <u>States with Specific Lists of Adverse Events</u>

A number of states, currently require mandatory reporting of a specific list of adverse events, defined either in the reporting statute itself or in related regulations. For example, Connecticut, Illinois and Minnesota, generally require the reporting of a broad list of twenty-seven "Serious Reportable Events," created by the National Quality Forum ("NQF"); which includes:

- Surgery on the wrong body part;
- Surgery on the wrong patient wrong surgical procedure performed;
- Retained foreign object within a patient after a procedure;
- Intraoperative or immediate post-operative death in an ASA Class I patient;
- Patient death or serious disability caused by the use of contaminated drugs or devices provided by the facility;
- Patient death or disability caused by misuse of a device;

- Patient death or serious disability caused by an intravascular air embolism while cared for in a facility;
- Infant discharged to the wrong person;
- Patient death or disability associated with patient elopement;
- Patient suicide or attempted suicide (resulting in serious disability);
- Patient death or serious disability caused by medication error;
- Hemolytic reaction caused by an incompatible blood;
- Maternal death or serious disability during a low-risk pregnancy;
- Patient death or serious disability caused by hypoglycemia;
- Death or serious disability caused by a failure to identify and treat hyperbilirubinemia in neonates;
- Stage 3 or 4 pressure ulcers acquired after admission to the facility;
- Patient death or serious disability due to spinal manipulative therapy;
- Artificial insemination with the wrong donor sperm or egg;
- Patient death or serious disability caused by electric shock while in the facility;
- Incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances;
- Patient death or serious disability caused by a burn incurred while in the facility's care;
- Patient death or serious disability associated with a fall while in the facility;
- Patient death or serious disability associated with the use of restraints or bedrails;
- Any instance of care ordered or provided by someone impersonating a healthcare Provider;

- Abduction of a patient;
- Sexual assault on a patient;
- Death or significant injury of a patient or staff member resulting from a physical assault on the facility's property.

A number of other states have defined lists of specific adverse events that must be reported, although not identical to the NQF's list of Serious Reportable Events. These states include: Colorado; Florida; Georgia; Kansas; Maine; Massachusetts; New York; Rhode Island; South Carolina; South Dakota; Texas; Utah and Washington. The lists of adverse events that must be reported in these states vary significantly from state to state.

#### b. States with Broadly Defined Adverse Events

A number of states, including California, New Jersey; Pennsylvania and Tennessee, have more broadly worded, less precise rules as to what must be reported. In these states, the task for hospitals and health care providers is often more challenging because they are forced to make their own judgment as to whether an event must be reported, as opposed to consulting a narrowly defined list of adverse events.

Pennsylvania, for example, requires that all licensed hospitals, ambulatory surgical facilities, birthing centers and certain abortion facilities report what are defined as "serious events" and "incidents." A "Serious event" is defined as an event, occurrence or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional health care services to the patient. An "Incident" is defined as an event, occurrence or situation involving the clinical care of a patient in a medical facility which could have injured the patient but did not either cause an unanticipated injury or require the delivery of additional health care services to the

patient. By requiring the reporting of both adverse events and near misses, Pennsylvania's mandatory reporting statute is arguably one of the most expansive in the United States. Hospitals and medical facilities subject to this expansive statute face the potential for far greater reporting obligations than those in states that follow a more narrowly defined list of reportable adverse events.

#### c. States with Narrowly Defined Adverse Events

The last group of states with mandatory reporting rules includes those that limit the reporting obligations to either a specific type of facility and/or adverse event. For example, Ohio requires freestanding Radiation Therapy Centers ("RTC's") to identify, document, and report to the Ohio Department of Health, Bureau of Radiation Protection, incidents in which equipment malfunction contributed or may have contributed to patient injury or death. In addition, Ohio RTC's are required to report all instances of treatment of the wrong subject, wrong treatment site, or wrong modality of treatment.

While such statutes are clearly more limited in scope, they nonetheless present unique compliance risks for those health care facilities that are required to follow these more narrowly defined reporting obligations. One obvious concern is that health care facilities may be unaware of their reporting obligations because the reporting statute is narrowly tailored and applies to relatively few facilities. Because these more narrowly tailored reporting statutes can often "fly under the radar scope," health care facilities must continue to pay attention to whether their state has adopted, or is even considering, any type of medical error reporting.

# 2. Type of Information the Must Be Reported

Although the 1999 "Too Err is Human" report called for the standardized reporting of adverse events, efforts to achieve uniformity in the type of information that must be reported have to date been largely unsuccessful. Instead, the rules vary widely from state to state, often making it difficult for providers to know precisely what information they need to collect and report. Additionally, the lack of uniformity has hampered the ability to use adverse events reports to draw broad, definitive conclusions about the quality of healthcare in America, and to develop strategies to prevent future adverse medical events. xiv

Many of the states with mandatory reporting statutes require an immediate notification of the adverse event, followed later on by a more detailed root cause analysis and corrective action plan. Maryland, for example, requires hospitals to report adverse events to the Maryland Department of Health and Mental Hygiene within five days of the hospital's knowledge of the event.<sup>xv</sup> Hospitals also must conduct a Root Cause Analysis for certain events, and file with the Department an Action Plan within 60 days of the event.

A few states, by contrast, require that substantially less information be disclosed about adverse events. Texas, for example, requires hospitals to submit an annual report to the state listing the numbers of specific adverse events that have occurred. Texas facilities are obligated to create a root cause analysis and corrective action plan, but those reports need not be submitted to the state. Instead, the root cause analysis documents must be maintained at the facility and must be made available to the state upon request.

These differences highlight the importance for all healthcare providers to determine precisely what adverse events trigger their reporting obligations, as well the need to determine the type of information they will be required to report. Unfortunately, at the present time only a handful of states have web sites and/or handbooks that provide answers to these and other important questions regarding mandatory reporting obligations. Yellow the focus on medical errors and quality of care continues to increase, more states will devote resources to helping providers understand and fulfill their reporting obligations.

### 3. Consequences for Failing to Report Medical Errors

Complying with mandatory reporting requirements is not simply an academic exercise. Failing to report adverse events as required by federal and state statutes and regulations can have far reaching consequences for healthcare providers and facilities. Moreover, system failure to report can potentially serve as a catalyst for whistleblower suits and investigations by various government agencies.

The most immediate, direct consequence for failing to comply with mandatory reporting requirements is that licensed healthcare providers (and in some cases even unlicensed staff) and facilities can potentially face criminal, civil, administrative and licensing sanctions. In the majority of states with mandatory reporting statutes, the failure to report adverse events as required is punishable by a combination of civil penalties and potential disciplinary action against the facility's operating license. XVIIII In two states, California and Utah, the potential sanctions for failing to report adverse events can result in criminal prosecution. XIX Therefore, the stakes are high for healthcare

facilities that, either intentionally or through oversight, fail to fulfill their federal and state mandatory requirements for reporting adverse events.

The failure to report adverse events can also trigger a number of significant collateral consequences. First, such failures can raise larger questions about a facility's overall quality of care and compliance that can provoke investigations by federal and state regulatory agencies. A number of regulatory agencies are beginning to use more creative means to monitor compliance with reporting requirements, including matching death certificates with reports of adverse events. Second, failing to report adverse events can encourage whistleblower litigation by employees who are concerned that the facility is not adequately addressing potential failures in quality of care. This risk continues to grow as more and more states pass their own false claims statutes in response to incentives provided in the federal Deficit Reduction Act of 2005. Third, systemic failures to report adverse events can serve as compelling evidence in so-called "quality-of-care" false claims cases, which seek recovery based upon the violation of Medicare and Medicaid regulations requiring, as a condition for payment, that hospitals and physicians provide patients with quality medical care.

These potentially devastating direct and indirect consequences demonstrate the essential need for healthcare facilities to comply with federal and state mandatory requirements for reporting medical errors. Although there are many personal, emotional and institutional barriers that can inhibit efforts to report such errors, the risks that can result from failing to report far outweigh these barriers. The obligation to make reports of adverse events has implications for virtually everyone with hospital responsibilities for patient care, governance, finance, legal compliance and risk management. Every hospital

needs to assure that it has systems in place to capture and report adverse events, and every hospital board, CEO, and medical staff leader needs to identify a responsible individual with both the power and the information to determine whether required reporting is occurring. Without such measures in place, hospitals and other healthcare facilities face a significant, and potentially far reaching compliance risk.

#### III. Voluntary Reporting of Adverse Events Under the PSQIA

Congress created a nationwide reporting system through the passage of the Patient Safety and Quality Improvement Act of 2005 ("PSQIA"). The PSQIA does not impose any obligations on healthcare providers to report medical errors or other patient safety information. Instead, it was designed to create another central repository, or national patient safety center, to gather and analyze patient safety information voluntarily reported by healthcare providers. President Bush stated, just prior to signing the PSQIA into law, that: "[w]ith this law, we'll be able to obtain more accurate information about medical treatments. And by providing doctors with information about what treatments work and what treatments cause problems, we will reduce medical errors that injure and cause the deaths of thousands of Americans each year."

Although the PSQIA became effective upon the President's signature in July of 2005, it failed to have any practical effect as it awaited the adoption of regulations from the Department of Health and Human Services ("HHS") on key provisions. In January of 2008, HHS finally issued the long awaited proposed regulations on the PSQIA. Those

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<sup>42</sup> U.S.C. § 299b.

President Bush's statements at the signing of the PSQIA are available for viewing on the internet at http://www.whitehouse.gov/news/releases/2005/07/20050729.html.

regulations, as amended by HHS in November 2008, became final effective January 19, 2009.

#### A. <u>PSQIA: Overview of the Statute</u>

The PSQIA establishes a network of Patient Safety Organizations ("PSOs") to which providers (individuals and entities) can voluntarily report medical errors, adverse events and patient information (known as "patient safety work product"). The aim of the PSQIA's voluntary reporting system is "improving patient safety and the quality of care nationwide." Unlike the recommendations of the IOM in the "To Err is Human" report, the PSQIA does not require healthcare providers to report medical errors or to divulge any patient safety information.

The PSQIA provides that the PSO's are to take these voluntary reports, analyze them, and provide comments and insight to the providers. HHS is further required to establish a network of databases to compile the information submitted by PSO's and to disseminate that information in some form throughout the country. The statute, does not, however, specify what information healthcare providers are to report. Nor does it indicate what "analysis" the PSO's will undertake.

The PSQIA attaches broad privilege and confidentiality protections to patient safety work product to encourage providers to share this information without fear of liability. According to HHS, "[t]hese protections will enable all health care systems, including multi-facility health systems, to share data within a protected legal

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<sup>&</sup>lt;sup>3</sup> 73 Fed. Reg. 70732 (November 21, 2008).

environment, both within and across states, without threat that the information will be used against the subject providers."<sup>4</sup>

## B. <u>PSQIA – Regulations</u>

On February 12, 2008, HHS published a Notice of Proposed Rulemaking proposing to implement the PSQIA. These proposed regulations provided comprehensive rules regarding the substantive and procedures requirements of the PSQIA. The regulations were generally divided into four subparts: Subpart A, setting forth definitions of essential terms; Subpart B, implementing the statutory requirements for the listing of PSOs; Subpart C, setting forth the privilege and confidentiality protections that attach to patient safety work product; and Subpart D, establishing a framework to enable the Secretary of HHS to monitor and ensure compliance. After receiving over 150 comments from a variety of entities, HHS issued the final PSQIA regulations on November 21, 2008.

### 1. PSQIA: Patient Safety Organizations

To qualify as a Patient Safety Organization, an entity must be certified by HHS as having satisfied the following requirements<sup>5</sup>:

- Its mission and primary duty is to conduct activities that designed to improve patient safety and the quality of health care delivery;
- It has appropriately qualified staff (whether directly or through contract),
   including licensed or certified medical professionals, to perform its duties;

<sup>&</sup>lt;u>Id</u>.

<sup>&</sup>lt;sup>5</sup> 42 U.S.C. § 299b-24(b).

- It must have bona-fide contracts<sup>6</sup> with more than one provider for the purpose of receiving and reviewing Patient Safety Work Product;
- It may not be a component of a health insurer;
- If the entity is a component of another organization, it must maintain Patient Safety Work Product separate from the rest of the organization and may not make an unauthorized disclosure<sup>7</sup> of Patient Safety Work Product to the rest of the organization; and
- To the extent practical and appropriate, the entity collects patient safety
  work product in a standardized manner that permits valid comparisons of
  similar cases among similar providers.

The final PSQIA regulations describe in detail the substantive and procedural requirements for becoming certified as a PSO. According to the final regulations, an entity wishing to become a PSO must certify, in writing, compliance with the fifteen requirements, which are comprised of eight "patient safety activities" and seven PSO structural criteria. If an entity certifies compliance with these fifteen requirements, meets the statutory requirements of a PSO, and submits certification of compliance with other enumerated eligibility criteria, then HHS may approve the PSO for a period of three years. After the initial three years, the PSO may apply for additional renewable three year periods as an approved PSO.

According to the final PSQIA regulations, the term "bona fide contract" means a written contract between a provider and a PSO that is executed in good faith or a written agreement between a Federal, State, local, or Tribal provider and a Federal, State, local, or Tribal PSO. 73 Fed. Reg. 70734 (Nov. 21, 2008).

According to the final regulations, the term "disclosure" means the release, transfer, provision of access to, or divulging in any manner of patient safety work product by a person holding patient safety work product to another person. 73 Fed. Reg. 70736 (Nov. 21, 2008).

# 2. PSQIA: Patient Safety Work Product

Patient Safety Work Product is broadly defined by the PSQIA as any information, written or oral, that may result in improved patient safety, health care quality, or health care outcomes. Patient Safety Work Product must either be: (1) gathered by a provider to be reported to a Patient Safety Organization and is actually reported; or (2) developed by a Patient Safety Organization for patient safety activities.<sup>8</sup>

Although the statutory language is exceedingly broad, the following are specifically excluded from the definition of Patient Safety Work Product<sup>9</sup>:

- (1) Individual patient medical records;
- (2) Billing and discharge information;
- (3) Any "other original patient or provider information,"
- (4) Other information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation process.

HHS further limited the scope of patient safety work product by stating in the final PSQIA regulations that information that "such separate information or a copy thereof reported to a PSO shall not by reason of its reporting be considered patient safety work product."<sup>10</sup>

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<sup>&</sup>lt;sup>8</sup> 42 U.S.C. § 299b-21(7)(A).

<sup>&</sup>lt;sup>9</sup> 42 U.S.C. § 299b-21(7)(B).

<sup>&</sup>lt;sup>10</sup> 73 Fed. Reg. 70798 (Nov. 21, 2008).

### 3. PSQIA: Confidentiality

Patient Safety Work Product enjoys a strong federal privilege and confidentiality protections under the PSQIA. Subject to certain exceptions, <sup>11</sup> PSWP is not subject to civil subpoenas, discovery or even court orders in civil, criminal or administrative proceedings, and is not subject to disclosure under the Freedom of Information Act ("FOIA"). <sup>12</sup> Further, PSWP may not be used as evidence in any civil, criminal or administrative or in any "professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under state law." PSWP is also generally confidential (in situation other than legal proceedings), although the confidentiality provisions are weaker than the privilege and contain numerous exceptions.

PSQIA provides strong civil sanctions to preserve the confidentiality of PSWP. In particular, HHS may assess civil monetary penalties of up to \$10,000 per violation against any person who knowingly or recklessly divulges patient safety information in contravention of the PSQIA's confidentiality or privilege protections. Pursuant to Section 3.402(b) of the PSQIA regulations, a principal is independently liable, in accordance with the federal common law on agency, for a civil monetary penalty based on the act of the principal's agent.

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The exceptions to the confidentiality protections of the PSQIA are for: (1) disclosure in criminal proceedings; (2) disclosure to permit equitable relief for reporters; (3) disclosure authorized by identified providers; (4) disclosure for patient safety activities; (5) disclosure of nonidentifiable patient safety work product; (6) disclosure for research; (7) disclosure to the FDA and entities required to report to the FDA; (8) voluntary disclosure to accrediting body; (9) disclosure for business operations; (10) disclosure to law enforcement. See 73 Fed. Reg. 70806 (Nov. 21, 2008). The final PSQIA regulations describe each of these exceptions in detail.

<sup>&</sup>lt;sup>12</sup> 42 U.S.C. § 299b-22(a).

<sup>&</sup>lt;sup>13</sup> 42 U.S.C. § 299b-22(f).

- "Manufacturer" defined as "any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedure." 21 C.F.R. § 803.3(o).
- "Device user facility" defined as "a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility". 21 C.F.R. § 803.3(2)(f).
- "Serious injury" defined as any injury or illness that is life-threatening, results in permanent impairment to body function or permanent damage to body structure, or requires medical or surgical intervention to prevent such impairment or damage. 21 C.F.R. § 803.3(bb)(1).
- iv 65 Fed. Reg. 4112-4121.
- For a more detailed explanation of this process and additional information about medical device reporting requirements, <u>see</u> James G. Sheehan & Michael A. Morse, <u>Mandatory External Reporting of Adverse Events Near Misses and Unanticipated Consequences</u>, in HEALTH LAW HANDBOOK 197, 207-09 (Alice G. Gosfield ed., 2007).
- For a more extensive look at reporting procedures, vaccines subject to these procedures, and disciplinary actions see Sheehan, supra, n.9 at 209-210.
- vii 21 C.F.R. 1271.350(a).
- For further information on reporting requirements regarding HCT/P see Sheehan, supra, n. 9 at 211-12.
- A "manufacturer" includes any organization involved in the testing, processing, packing, labeling, storage, or distribution of blood or any blood product.
- <sup>x</sup> 21 C.F.R. § 606.171.
- <sup>xi</sup> 71 Fed. Reg. 71378 (December 8, 2006).
- <sup>xii</sup> 40 Pa. Cons. Stat. Ann. § 1303.313 (West 2006).
- viii Ohio Admin. Code 3701:83-47 (2006).
- There also is no uniformity as to the distribution of adverse event information. Some states publish periodic bulletins summarizing trends in the reported adverse events. Other states, however, do not publish any information about the adverse events that are reported by healthcare facilities.
- xv Md. Code Regs. 10.07.06.09 (2006).
- Tex. Health & Safety Code Ann. § 241.202 (Vernon 2006).
- There are a number of private resources that may assist healthcare providers in identifying and understanding their potential reporting obligations. For example, there are a number of web sites maintain lists of various reporting statutes. See e.g., National Academy of State Health Policy ("NASHP"). In addition, for a detailed discussion of federal and state reporting statutes see, James G. Sheehan & Michael A. Morse, Mandatory External Reporting of Adverse Events Near Misses and Unanticipated Consequences, in HEALTH LAW HANDBOOK 197, 207-09 (Alice G. Gosfield ed., 2007).

In Florida, for example, the failure to report adverse events, or file any required corrective action plan, may result in civil penalties and fines of up to \$5,000 for nonwillful violations, and \$250,000 for intentional and willful violations. Fla. Stat. Ann. § 395.0197 (12).

Cal. Code Regs. Title 22, Section 70737 (2006) (Failure to report as required is punishable as a misdemeanor offense under California's Criminal Code); Utah Admin. Code R380-200 (2006) (An entity that violates any provision of Utah reporting rules may be assessed a civil money penalty not to exceed the sum of \$5,000 or be punished for violation of a class B misdemeanor for the first violation and for any subsequent similar violation within two years for violation of a class A misdemeanor).