THE AMENDMENT 7 CHALLENGE: IS A PSO HYPE OR HOPE?

APRIL 29, 2008

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The Amendment 7 Challenge: Is a PSO Hype or Hope?
Agenda

9:30
Welcome and Program Introduction
Richard W. Johns, Partner, Foley Orlando

9:45
Florida Peer Review After Amendment 7: Challenges and Solutions
Tina E. Dunsford, Senior Counsel, Foley Tampa
Nathaniel M. Lacktman, Associate, Foley Tampa

10:15
THE PATIENT SAFETY ACT AND PATIENT SAFETY ORGANIZATIONS
Jeffrey G. Micklos, Senior Vice President, Business Operations & General Counsel of the Federation of American Hospitals
J. Mark Waxman, Chair, Health Care Industry Team, Partner, Foley Boston

11:00
Break

11:15
The Health Care Quality Improvement Act -Is there a Federal Peer Review Privilege?
Gary D. Koch, M.D., Partner, Foley Tampa

11:25
REPORTING ADVERSE EVENTS: WHAT IS PRESENTLY REQUIRED?
Robert E. Slavkin, Senior Counsel, Foley Orlando

11:45
Practical Applications of PSOs
Richard W. Johns, Partner, Foley Orlando
J. Mark Waxman, Chair, Health Care Industry Team, Partner, Foley Boston

12:30
Lunch

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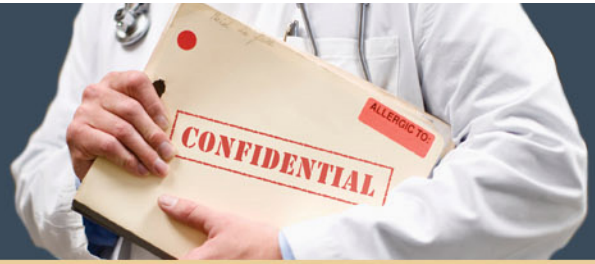
The Amendment 7 Challenge:
Is a PSO Hype or Hope?



Florida Peer Review After Amendment 7: Challenges and Solutions

Nathaniel M. Lacktman
Tina E. Dunsford

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FL Peer Review Confidentiality Statutes

- FL Stats. §395.0191(8)
- FL Stats. §395.0193(7),(8)
- FL Stats. §395.0197(6)(c), (7), (9), (11)
- FL Stats. §766.101(5)
- FL Stats. §766.1016(2)

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Amendment 7

- "Patient's Right to Know About Adverse Medical Incidents" passed in November, 2004 by over 81% of voters.
- FL Constitution, Article X, Section 25.
- In June, 2005, the Legislature attempted to limit amendment by statute (SB 938; FL Stats. §381.028).
- The enacting statute included provisions to preserve peer review confidentiality, despite the language in Amendment 7.
- Dozens of suits followed, with conflicting DCA opinions.

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Supreme Court Ruling

- On March 6, 2008, the Florida Supreme Court (4-3) found the 2005 statute unconstitutional and severed those portions seeking to preserve peer review confidentiality. *Florida Hospital Waterman, Inc. v. Buster; Notami Hospital of Florida, Inc. v. Bowen*.
- Resolved conflicting DCA opinions.
- Amendment 7 preempts all Florida statutory peer review privileges.

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Supreme Court Ruling

- *Florida Hospital Waterman, Inc. v. Buster:* plaintiff sought production of documents relating to the investigation of her husband's death.
- *Notami Hospital of Florida, Inc. v. Bowen*: plaintiffs sought documents relating to the selection, retention and termination of a physician.

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Supreme Court Ruling

- "We believe that Amendment 7 heralds a change in the public policy of this state to lift the shroud of privilege and confidentiality in order to foster disclosure of information that will allow patients to better determine from whom they should seek health care."

  - *Waterman, p. 31*, quoting Judge Thomas D. Sawaya (5th DCA) in *Buster*, 932 So.2d at 355-56.

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Supreme Court Ruling

- "While [a medical provider's] history was not previously accessible [due to peer review statutes], it became accessible when the electorate approved a constitutional override of the prior statutory restrictions." -*Waterman*, p. 18.

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Adverse Medical Incident

- The definition of "adverse medical incident" in Amendment 7 is broader than the definition used for purposes of State adverse incident reporting.

- What is an "adverse medical incident"?

Any Ideas?

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Adverse Medical Incident

- The phrase “adverse medical incident” means medical negligence, intentional misconduct, and any other act, neglect, or default of a health care facility or health care provider that caused or could have caused injury to or death of a patient, including, but not limited to, those incidents that are required by state or federal law to be reported to any governmental agency or body, and incidents that are reported to or reviewed by any health care facility peer review, risk management, quality assurance, credentials, or similar committee, or any representative of any such committees. FL Constitution, Art X, Sec 25(c)(3).

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Adverse Medical Incident

Who determines what constitutes an "adverse medical incident"?

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Adverse Medical Incident

- "... [§ 381.028(3)-(4), 7(b)] provides definitions of important terms, dictates that patient privacy restrictions be upheld, and identifies pursuant to other statutes the party responsible for identifying records of adverse medical incidents." - *Waterman*, p. 30 (upholding portions of the statute).
- 7(b) 1. Using the process provided in s. 395.0197, the health care facility shall be responsible for identifying records as records of an adverse medical incident, as defined in s. 25, Art. X of the State Constitution.
- 2. Using the process provided in s. 458.351, the health care provider shall be responsible for identifying records as records of an adverse medical incident, as defined in s. 25, Art. X of the State Constitution, occurring in an office setting.

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Who can access records?

- Patients seeking their own medical chart?
- Patients seeking documents outside their own chart, but concerning their care?
- Patients seeking medical records of other patients, treated by the same physician for the same condition?
- Patients seeking documents concerning peer review, credentialing, etc. of their treating physician?
- Patients seeking documents concerning peer review, credentialing, etc. of other physicians?

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Who can access records?

- "Here, the plain language of the amendment permits patients to access any record relating to any adverse medical incident, and defines "patient" to include individuals who had previously undergone treatment. The use of the word "any" to define the scope of discoverable records relating to adverse medical incidents, and the broad definition of "patient" to include those who "previously" received treatment expresses a clear intent that the records subject to disclosure include those created prior to the effective date of the amendment."
  - *Waterman* at p. 16 (quoting *Notami Hosp.*, 927 So.2d at 145) (emphasis in original).

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Who can access records?

- "[W]e also note that [§ 381.028(7)(a)] provides that patients can only access the records of the facility or provider of which they themselves are a patient, a restriction not contained within the amendment." -Waterman, p. 28 (striking down that requirement).

What medical records can a patient access?

- To what extent are patients entitled to records of other patients or records pertaining to other physicians?
- Amendment 7 states all HIPAA restrictions must be upheld and patient identifying information redacted.

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What peer review records can a patient access?

- So long as the credentialing file or peer review minutes contain "adverse medical incidents" information, they are arguably discoverable.
- To the extent such records do not relate to "adverse medical incidents," they are arguably not discoverable.

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What else?

- Only applies to written documents. Cannot compel physicians to testify.
- Identity of peer review committee members remains confidential.
- Does not eliminate immunity for participation in peer review activities.
- Applies retroactively to records created prior to enactment.
- "Immediate right to access existing medical records..." *Waterman* at p. 16-17.
- "[F]ees for the production of records cannot exceed the reasonable cost of complying with the request and that requests for production must be processed in a timely manner." -*Waterman*, p. 30.

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Response/Reactions

- How have your physicians responded?
- Medical staff reaction?
- Risk Management reaction?
- Compliance reaction?
- Legal reaction?

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Solutions?

- Minimizing the amount of records that must be reported.
- Limiting the type of incidents that must be revealed to peer review committees.
- Different approach to peer review (still required by JC), more conversation and little to no written notes.
- Cannot protect written complaint submitted by a patient.

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Solutions?

- From a medical malpractice trial perspective, a court must first determine such records are relevant before admissible at trial. FL Civ. Pro. Rule 1.280(b)(1); FL Evid. Rule 90.401.
- What about Peer Review Process?
  - doctors are unwilling to participate in the process and open communication is significantly chilled.

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Any other ideas?

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[1]SECTION 25. Patients' right to know about adverse medical incidents.--

(a) In addition to any other similar rights provided herein or by general law, patients have a right to have access to any records made or received in the course of business by a health care facility or provider relating to any adverse medical incident.

(b) In providing such access, the identity of patients involved in the incidents shall not be disclosed, and any privacy restrictions imposed by federal law shall be maintained.

(c) For purposes of this section, the following terms have the following meanings:

(1) The phrases "health care facility" and "health care provider" have the meaning given in general law related to a patient's rights and responsibilities.

(2) The term "patient" means an individual who has sought, is seeking, is undergoing, or has undergone care or treatment in a health care facility or by a health care provider.

(3) The phrase "adverse medical incident" means medical negligence, intentional misconduct, and any other act, neglect, or default of a health care facility or health care provider that caused or could have caused injury to or death of a patient, including, but not limited to, those incidents that are required by state or federal law to be reported to any governmental agency or body, and incidents that are reported to or reviewed by any health care facility peer review, risk management, quality assurance, credentials, or similar committee, or any representative of any such committees.

(4) The phrase "have access to any records" means, in addition to any other procedure for producing such records provided by general law, making the records available for inspection and copying upon formal or informal request by the patient or a representative of the patient, provided that current records which have been made publicly available by publication or on the Internet may be "provided" by reference to the location at which the records are publicly available.

History.--Proposed by Initiative Petition filed with the Secretary of State April 1, 2003; adopted 2004.

[1]Note.--

A. This section, originally designated section 22 by Amendment No. 7, 2004, proposed by Initiative Petition filed with the Secretary of State April 1, 2003, adopted 2004, was redesignated section 25 by the editors in order to avoid confusion with section 22, relating to parental notice of termination of a minor's pregnancy, as contained in Amendment No. 1, 2004, added by H.J.R. 1, 2004, adopted 2004.

B. Amendment No. 7, 2004, proposed by Initiative Petition filed with the Secretary of State April 1, 2003, adopted 2004, published "[f]ull [t]ext" consisting of a statement and purpose, the actual amendment "inserting the following new section at the end [of Art. X]," and an effective date and severability provision not specifically included in the amendment text. The effective date and severability provision reads:

3) Effective Date and Severability:

This amendment shall be effective on the date it is approved by the electorate. If any portion of this measure is held invalid for any reason, the remaining portion of this measure, to the fullest extent possible, shall be severed from the void portion and given the fullest possible force and application.

The 2007 Florida Statutes

381.028 Adverse medical incidents.--

(1) SHORT TITLE.--This section may be cited as the "Patients' Right-to-Know About Adverse Medical Incidents Act."

(2) PURPOSE.--It is the purpose of this act to implement s. 25, Art. X of the State Constitution. The Legislature finds that this section of the State Constitution is intended to grant patient access to records of adverse medical incidents, which records were made or received in the course of business by a health care facility or provider, and not to repeal or otherwise modify existing laws governing the use of these records and the information contained therein. The Legislature further finds that all existing laws extending criminal and civil immunity to persons providing information to quality-of-care committees or organizations and all existing laws concerning the discoverability or admissibility into evidence of records of an adverse medical incident in any judicial or administrative proceeding remain in full force and effect.

(3) DEFINITIONS.--As used in s. 25, Art. X of the State Constitution and this act, the term:

(a) "Agency" means the Agency for Health Care Administration.

(b) "Adverse medical incident" means medical negligence, intentional misconduct, and any other act, neglect, or default of a health care facility or health care provider which caused or could have caused injury to or the death of a patient, including, but not limited to, those incidents that are required by state or federal law to be reported to any

governmental agency or body, incidents that are reported to any governmental agency or body, and incidents that are reported to or reviewed by any health care facility peer review, risk management, quality assurance, credentials, or similar committee or any representative of any such committee.

(c) "Department" means the Department of Health.

(d) "Have access to any records" means, in addition to any other procedure for producing the records provided by general law, making the records available for inspection and copying upon formal or informal request by the patient or a representative of the patient, provided that current records that have been made publicly available by publication or on the Internet may be provided by reference to the location at which the records are publicly available.

(e) "Health care provider" means a physician licensed under chapter 458, chapter 459, or chapter 461.

(f) "Health care facility" means a facility licensed under chapter 395.

(g) "Identity" means any "individually identifiable health information" as defined by the Health Insurance Portability and Accountability Act of 1996 or its implementing regulations.

(h) "Patient" means an individual who has sought, is seeking, is undergoing, or has undergone care or treatment in a health care facility or by a health care provider.

(i) "Privacy restrictions imposed by federal law" means the provisions relating to the disclosure of patient privacy information under federal law, including, but not limited to, the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, and its implementing regulations, the Federal Privacy Act, 5 U.S.C. s. 552(a), and its implementing regulations, and any other federal law, including, but not limited to, federal common law and decisional law, that would prohibit the disclosure of patient privacy information.

(j) "Records" means the final report of any adverse medical incident. Medical records that

are not the final report of any adverse medical incident, including drafts or other nonfinal versions; notes; and any documents or portions thereof which constitute, contain, or reflect any attorney-client communications or any attorney-client work product may not be considered "records" for purposes of s. 25, Art. X of the State Constitution and this act.

(k) "Representative of the patient" means a parent of a minor patient, a court-appointed guardian for the patient, a health care surrogate, or a person holding a power of attorney or notarized consent appropriately executed by the patient granting permission to a health care facility or health care provider to disclose the patient's health care information to that person. In the case of a deceased patient, the term also means the personal representative of the estate of the deceased patient; the deceased patient's surviving spouse, surviving parent, or surviving adult child; the parent or guardian of a surviving minor child of the deceased patient; or the attorney for any such person.

(4) PATIENTS' RIGHT OF ACCESS.--Patients have a right to have access to any records made or received in the course of business by a health care facility or health care provider relating to any adverse medical incident. In providing access to these records, the health care facility or health care provider may not disclose the identity of patients involved in the incidents and shall maintain any privacy restrictions imposed by federal law.

(5) APPLICABILITY.--Section 25, Art. X of the State Constitution applies to records created, incidents occurring, and actions pending on or after November 2, 2004. Section 25, Art. X of the State Constitution does not apply to records created, incidents occurring, or actions pending before November 2, 2004. A patient requesting records on or after November 2, 2008, shall be eligible to receive records created within 4 years before the date of the request.

(6) USE OF RECORDS.--

(a) This section does not repeal or otherwise alter any existing restrictions on the discoverability or admissibility of records relating to adverse medical incidents otherwise provided by law, including, but not limited to, those contained in ss. 395.0191, 395.0193, 395.0197, 766.101, and 766.1016, or repeal or otherwise alter any immunity provided to, or prohibition against compelling testimony by, persons providing information or participating in any peer review panel, medical review committee, hospital committee, or other hospital

board otherwise provided by law, including, but not limited to, ss. 395.0191, 395.0193, 766.101, and 766.1016.

(b) Except as otherwise provided by act of the Legislature, records of adverse medical incidents, including any information contained therein, obtained under s. 25, Art. X of the State Constitution, are not discoverable or admissible into evidence and may not be used for any purpose, including impeachment, in any civil or administrative action against a health care facility or health care provider. This includes information relating to performance or quality improvement initiatives and information relating to the identity of reviewers, complainants, or any person providing information contained in or used in, or any person participating in the creation of the records of adverse medical incidents.

(7) PRODUCTION OF RECORDS.--

(a) Pursuant to s. 25, Art. X of the State Constitution, the adverse medical incident records to which a patient is granted access are those of the facility or provider of which he or she is a patient and which pertain to any adverse medical incident affecting the patient or any other patient which involves the same or substantially similar condition, treatment, or diagnosis as that of the patient requesting access.

(b)1. Using the process provided in s. 395.0197, the health care facility shall be responsible for identifying records as records of an adverse medical incident, as defined in s. 25, Art. X of the State Constitution.

2. Using the process provided in s. 458.351, the health care provider shall be responsible for identifying records as records of an adverse medical incident, as defined in s. 25, Art. X of the State Constitution, occurring in an office setting.

(c)1. Fees charged by a health care facility for copies of records requested by a patient under s. 25, Art. X of the State Constitution may not exceed the reasonable and actual cost of complying with the request, including a reasonable charge for the staff time necessary to search for records and prevent the disclosure of the identity of any patient involved in the adverse medical incident through redaction or other means as required by the Health Insurance Portability and Accountability Act of 1996 or its implementing regulations. The health care facility may require payment, in full or in part, before acting

on the records request.

2. Fees charged by a health care provider for copies of records requested by a patient under s. 25, Art. X of the State Constitution may not exceed the amount established under s. 456.057(18), which may include a reasonable charge for the staff time necessary to prevent the disclosure of the identity of any patient involved in the adverse medical incident through redaction or other means as required by the Health Insurance Portability and Accountability Act of 1996 or its implementing regulations. The health care provider may require payment, in full or in part, before acting on the records request.

(d)1. Requests for production of adverse medical incident records shall be processed by the health care facility or health care provider in a timely manner, after having a reasonable opportunity to determine whether or not the requested record is a record subject to disclosure and to prevent the disclosure of the identity of any patient involved in the adverse medical incident through redaction or other means.

2. A request for production of records must be submitted in writing and must identify the patient requesting access to the records by name, address, and the last four digits of the patient's social security number; describe the patient's condition, treatment, or diagnosis; and provide the name of the health care providers whose records are being sought.

History.--s. 1, ch. 2005-265; s. 5, ch. 2006-271; s. 75, ch. 2007-5.

The 2007 Florida Statutes

Title XXIX | Chapter 395 | View Entire Chapter

PUBLIC HEALTH HOSPITAL LICENSING AND REGULATION

395.0191 Staff membership and clinical privileges.--

(1) No licensed facility, in considering and acting upon an application for staff membership or clinical privileges, shall deny the application of a qualified doctor of medicine licensed under chapter 458, a doctor of osteopathic medicine licensed under chapter 459, a doctor of dentistry licensed under chapter 466, a doctor of podiatric medicine licensed under chapter 461, or a psychologist licensed under chapter 490 for such staff membership or clinical privileges within the scope of his or her respective licensure solely because the applicant is licensed under any of such chapters.

(2)(a) Each licensed facility shall establish rules and procedures for consideration of an application for clinical privileges submitted by an advanced registered nurse practitioner licensed and certified under part I of chapter 464, in accordance with the provisions of this section. No licensed facility shall deny such application solely because the applicant is licensed under part I of chapter 464 or because the applicant is not a participant in the Florida Birth-Related Neurological Injury Compensation Plan.

(b) An advanced registered nurse practitioner who is certified as a registered nurse anesthetist licensed under part I of chapter 464 shall administer anesthesia under the onsite medical direction of a professional licensed under chapter 458, chapter 459, or chapter 466, and in accordance with an established protocol approved by the medical staff. The medical direction shall specifically address the needs of the individual patient.

(c) Each licensed facility shall establish rules and procedures for consideration of an application for clinical privileges submitted by a physician assistant licensed pursuant to s.

458.347 or s. 459.022. Clinical privileges granted to a physician assistant pursuant to this subsection shall automatically terminate upon termination of staff membership of the physician assistant's supervising physician.

(d) Each hospital shall meet the requirements of the Medicare and Medicaid Conditions of Participation for Hospitals under 42 C.F.R. s. 482.51(a)(3) as they apply to registered nurses performing circulating duties in the operating room and as provided in the interpretive guidelines provided by the United States Department of Health and Human Services. A circulating nurse shall be present in the operating room for the duration of a surgical procedure.

(3) When a licensed facility requires, as a precondition to obtaining staff membership or clinical privileges, the completion of, eligibility in, or graduation from any program or society established by or relating to the American Medical Association or the Liaison Committee on Graduate Medical Education, the licensed facility shall also make available such membership or privileges to physicians who have attained completion of, eligibility in, or graduation from any equivalent program established by or relating to the American Osteopathic Association.

(4) Nothing herein shall restrict in any way the authority of the medical staff of a licensed facility to review for approval or disapproval all applications for appointment and reappointment to all categories of staff and to make recommendations on each applicant to the governing board, including the delineation of privileges to be granted in each case. In making such recommendations and in the delineation of privileges, each applicant shall be considered individually pursuant to criteria for a doctor licensed under chapter 458, chapter 459, chapter 461, or chapter 466, or for an advanced registered nurse practitioner licensed and certified under part I of chapter 464, or for a psychologist licensed under chapter 490, as applicable. The applicant's eligibility for staff membership or clinical privileges shall be determined by the applicant's background, experience, health, training, and demonstrated competency; the applicant's adherence to applicable professional ethics; the applicant's reputation; and the applicant's ability to work with others and by such other elements as determined by the governing board, consistent with this part.

(5) The governing board of each licensed facility shall set standards and procedures to be

applied by the licensed facility and its medical staff in considering and acting upon applications for staff membership or clinical privileges. These standards and procedures shall be available for public inspection.

(6) Upon the written request of the applicant, any licensed facility that has denied staff membership or clinical privileges to any applicant specified in subsection (1) or subsection (2) shall, within 30 days of such request, provide the applicant with the reasons for such denial in writing. A denial of staff membership or clinical privileges to any applicant shall be submitted, in writing, to the applicant's respective licensing board.

(7) There shall be no monetary liability on the part of, and no cause of action for injunctive relief or damages shall arise against, any licensed facility, its governing board or governing board members, medical staff, or disciplinary board or against its agents, investigators, witnesses, or employees, or against any other person, for any action arising out of or related to carrying out the provisions of this section, absent intentional fraud.

(8) The investigations, proceedings, and records of the board, or agent thereof with whom there is a specific written contract for the purposes of this section, as described in this section shall not be subject to discovery or introduction into evidence in any civil action against a provider of professional health services arising out of matters which are the subject of evaluation and review by such board, and no person who was in attendance at a meeting of such board or its agent shall be permitted or required to testify in any such civil action as to any evidence or other matters produced or presented during the proceedings of such board or its agent or as to any findings, recommendations, evaluations, opinions, or other actions of such board or its agent or any members thereof. However, information, documents, or records otherwise available from original sources are not to be construed as immune from discovery or use in any such civil action merely because they were presented during proceedings of such board; nor should any person who testifies before such board or who is a member of such board be prevented from testifying as to matters within his or her knowledge, but such witness cannot be asked about his or her testimony before such a board or opinions formed by him or her as a result of such board hearings.

(9)(a) If the defendant prevails in an action brought by an applicant against any person or entity that initiated, participated in, was a witness in, or conducted any review as

authorized by this section, the court shall award reasonable attorney's fees and costs to the defendant.

(b) As a condition of any applicant bringing any action against any person or entity that initiated, participated in, was a witness in, or conducted any review as authorized by this section and before any responsive pleading is due, the applicant shall post a bond or other security, as set by the court having jurisdiction of the action, in an amount sufficient to pay the costs and attorney's fees.

(10) Nothing herein shall be construed by the agency as requiring an applicant for a certificate of need to establish proof of discrimination in the granting of or denial of hospital staff membership or clinical privileges as a precondition to obtaining such certificate of need under the provisions of s. 408.043.

History.--ss. 26, 30, ch. 82-182; s. 48, ch. 83-218; s. 1, ch. 85-99; s. 2, ch. 85-175; s. 1, ch. 86-26; s. 1, ch. 86-287; s. 42, ch. 87-92; s. 2, ch. 88-361; s. 18, ch. 90-263; s. 5, ch. 91-22; ss. 11, 98, ch. 92-289; s. 725, ch. 95-148; s. 38, ch. 97-264; s. 5, ch. 98-49; s. 181, ch. 98-166; s. 93, ch. 2000-318; s. 3, ch. 2003-416; s. 1, ch. 2006-133.

Note.--Former s. 395.011.

The 2007 Florida Statutes

Title XXIX | Chapter 395 | View Entire Chapter

PUBLIC HEALTH HOSPITAL LICENSING AND REGULATION

395.0193 Licensed facilities; peer review; disciplinary powers; agency or partnership with physicians.--

(1) It is the intent of the Legislature that good faith participants in the process of investigating and disciplining physicians pursuant to the state-mandated peer review process shall, in addition to receiving immunity from retaliatory tort suits pursuant to s. 456.073(12), be protected from federal antitrust suits filed under the Sherman Anti-Trust Act, 15 U.S.C.A. ss. 1 et seq. Such intent is within the public policy of the state to secure the provision of quality medical services to the public.

(2) Each licensed facility, as a condition of licensure, shall provide for peer review of physicians who deliver health care services at the facility. Each licensed facility shall develop written, binding procedures by which such peer review shall be conducted. Such procedures shall include:

(a) Mechanism for choosing the membership of the body or bodies that conduct peer review.

(b) Adoption of rules of order for the peer review process.

(c) Fair review of the case with the physician involved.

(d) Mechanism to identify and avoid conflict of interest on the part of the peer review panel members.

(e) Recording of agendas and minutes which do not contain confidential material, for

review by the Division of Health Quality Assurance of the agency.

(f) Review, at least annually, of the peer review procedures by the governing board of the licensed facility.

(g) Focus of the peer review process on review of professional practices at the facility to reduce morbidity and mortality and to improve patient care.

(3) If reasonable belief exists that conduct by a staff member or physician who delivers health care services at the licensed facility may constitute one or more grounds for discipline as provided in this subsection, a peer review panel shall investigate and determine whether grounds for discipline exist with respect to such staff member or physician. The governing board of any licensed facility, after considering the recommendations of its peer review panel, shall suspend, deny, revoke, or curtail the privileges, or reprimand, counsel, or require education, of any such staff member or physician after a final determination has been made that one or more of the following grounds exist:

(a) Incompetence.

(b) Being found to be a habitual user of intoxicants or drugs to the extent that he or she is deemed dangerous to himself, herself, or others.

(c) Mental or physical impairment which may adversely affect patient care.

(d) Being found liable by a court of competent jurisdiction for medical negligence or malpractice involving negligent conduct.

(e) One or more settlements exceeding $10,000 for medical negligence or malpractice involving negligent conduct by the staff member.

(f) Medical negligence other than as specified in paragraph (d) or paragraph (e).

(g) Failure to comply with the policies, procedures, or directives of the risk management program or any quality assurance committees of any licensed facility.

(4) Pursuant to ss. 458.337 and 459.016, any disciplinary actions taken under subsection (3)

shall be reported in writing to the Division of Health Quality Assurance of the agency within 30 working days after its initial occurrence, regardless of the pendency of appeals to the governing board of the hospital. The notification shall identify the disciplined practitioner, the action taken, and the reason for such action. All final disciplinary actions taken under subsection (3), if different from those which were reported to the agency within 30 days after the initial occurrence, shall be reported within 10 working days to the Division of Health Quality Assurance of the agency in writing and shall specify the disciplinary action taken and the specific grounds therefor. The division shall review each report and determine whether it potentially involved conduct by the licensee that is subject to disciplinary action, in which case s. 456.073 shall apply. The reports are not subject to inspection under s. 119.07(1) even if the division's investigation results in a finding of probable cause.

(5) There shall be no monetary liability on the part of, and no cause of action for damages against, any licensed facility, its governing board or governing board members, peer review panel, medical staff, or disciplinary body, or its agents, investigators, witnesses, or employees; a committee of a hospital; or any other person, for any action taken without intentional fraud in carrying out the provisions of this section.

(6) For a single incident or series of isolated incidents that are nonwillful violations of the reporting requirements of this section or part II of chapter 408, the agency shall first seek to obtain corrective action by the facility. If correction is not demonstrated within the timeframe established by the agency or if there is a pattern of nonwillful violations of this section or part II of chapter 408, the agency may impose an administrative fine, not to exceed $5,000 for any violation of the reporting requirements of this section or part II of chapter 408. The administrative fine for repeated nonwillful violations may not exceed $10,000 for any violation. The administrative fine for each intentional and willful violation may not exceed $25,000 per violation, per day. The fine for an intentional and willful violation of this section or part II of chapter 408 may not exceed $250,000. In determining the amount of fine to be levied, the agency shall be guided by s. 395.1065(2)(b).

(7) The proceedings and records of peer review panels, committees, and governing boards or agent thereof which relate solely to actions taken in carrying out this section are

not subject to inspection under s. 119.07(1); and meetings held pursuant to achieving the objectives of such panels, committees, and governing boards are not open to the public under the provisions of chapter 286.

(8) The investigations, proceedings, and records of the peer review panel, a committee of a hospital, a disciplinary board, or a governing board, or agent thereof with whom there is a specific written contract for that purpose, as described in this section shall not be subject to discovery or introduction into evidence in any civil or administrative action against a provider of professional health services arising out of the matters which are the subject of evaluation and review by such group or its agent, and a person who was in attendance at a meeting of such group or its agent may not be permitted or required to testify in any such civil or administrative action as to any evidence or other matters produced or presented during the proceedings of such group or its agent or as to any findings, recommendations, evaluations, opinions, or other actions of such group or its agent or any members thereof. However, information, documents, or records otherwise available from original sources are not to be construed as immune from discovery or use in any such civil or administrative action merely because they were presented during proceedings of such group, and any person who testifies before such group or who is a member of such group may not be prevented from testifying as to matters within his or her knowledge, but such witness may not be asked about his or her testimony before such a group or opinions formed by him or her as a result of such group hearings.

(9)(a) If the defendant prevails in an action brought by a staff member or physician who delivers health care services at the licensed facility against any person or entity that initiated, participated in, was a witness in, or conducted any review as authorized by this section, the court shall award reasonable attorney's fees and costs to the defendant.

(b) As a condition of any staff member or physician bringing any action against any person or entity that initiated, participated in, was a witness in, or conducted any review as authorized by this section and before any responsive pleading is due, the staff member or physician shall post a bond or other security, as set by the court having jurisdiction of the action, in an amount sufficient to pay the costs and attorney's fees.

(10)(a) A hospital's compliance with the requirements of this chapter or s. 766.110(1) may

not be the sole basis to establish an agency or partnership relationship between the hospital and physicians who provide services within the hospital.

(b) A hospital may create an agency relationship with a physician by written contract signed by the hospital and:

1. The physician;

2. A health care professional association; or

3. A corporate medical group and its employees.

A written contract is not the exclusive means to establish an agency or partnership relationship between a hospital and any other person described in this paragraph.

History.--ss. 26, 30, ch. 82-182; s. 1, ch. 82-402; s. 3, ch. 85-175; s. 3, ch. 88-1; s. 2, ch. 88-277; s. 4, ch. 89-162; s. 14, ch. 90-344; ss. 12, 13, 98, ch. 92-289; s. 726, ch. 95-148; s. 213, ch. 96-406; s. 24, ch. 98-89; s. 21, ch. 98-166; s. 13, ch. 2000-160; s. 43, ch. 2007-230.

Note.--Former s. 395.0115.

The 2007 Florida Statutes

Title XXIX Chapter 395 View Entire Chapter

PUBLIC HEALTH HOSPITAL LICENSING AND REGULATION

395.0197 Internal risk management program.--

(1) Every licensed facility shall, as a part of its administrative functions, establish an internal risk management program that includes all of the following components:

(a) The investigation and analysis of the frequency and causes of general categories and specific types of adverse incidents to patients.

(b) The development of appropriate measures to minimize the risk of adverse incidents to patients, including, but not limited to:

1. Risk management and risk prevention education and training of all nonphysician personnel as follows:

a. Such education and training of all nonphysician personnel as part of their initial orientation; and

b. At least 1 hour of such education and training annually for all personnel of the licensed facility working in clinical areas and providing patient care, except those persons licensed as health care practitioners who are required to complete continuing education coursework pursuant to chapter 456 or the respective practice act.

2. A prohibition, except when emergency circumstances require otherwise, against a staff member of the licensed facility attending a patient in the recovery room, unless the staff member is authorized to attend the patient in the recovery room and is in the company of at least one other person. However, a licensed facility is exempt from the two-person

requirement if it has:

a. Live visual observation;

b. Electronic observation; or

c. Any other reasonable measure taken to ensure patient protection and privacy.

3. A prohibition against an unlicensed person from assisting or participating in any surgical procedure unless the facility has authorized the person to do so following a competency assessment, and such assistance or participation is done under the direct and immediate supervision of a licensed physician and is not otherwise an activity that may only be performed by a licensed health care practitioner.

4. Development, implementation, and ongoing evaluation of procedures, protocols, and systems to accurately identify patients, planned procedures, and the correct site of the planned procedure so as to minimize the performance of a surgical procedure on the wrong patient, a wrong surgical procedure, a wrong-site surgical procedure, or a surgical procedure otherwise unrelated to the patient's diagnosis or medical condition.

(c) The analysis of patient grievances that relate to patient care and the quality of medical services.

(d) A system for informing a patient or an individual identified pursuant to s. 765.401(1) that the patient was the subject of an adverse incident, as defined in subsection (5). Such notice shall be given by an appropriately trained person designated by the licensed facility as soon as practicable to allow the patient an opportunity to minimize damage or injury.

(e) The development and implementation of an incident reporting system based upon the affirmative duty of all health care providers and all agents and employees of the licensed health care facility to report adverse incidents to the risk manager, or to his or her designee, within 3 business days after their occurrence.

(2) The internal risk management program is the responsibility of the governing board of the health care facility. Each licensed facility shall hire a risk manager, licensed under s. 395.10974, who is responsible for implementation and oversight of such facility's internal

risk management program as required by this section. A risk manager must not be made responsible for more than four internal risk management programs in separate licensed facilities, unless the facilities are under one corporate ownership or the risk management programs are in rural hospitals.

(3) In addition to the programs mandated by this section, other innovative approaches intended to reduce the frequency and severity of medical malpractice and patient injury claims shall be encouraged and their implementation and operation facilitated. Such additional approaches may include extending internal risk management programs to health care providers' offices and the assuming of provider liability by a licensed health care facility for acts or omissions occurring within the licensed facility. Each licensed facility shall annually report to the agency and the Department of Health the name and judgments entered against each health care practitioner for which it assumes liability. The agency and Department of Health, in their respective annual reports, shall include statistics that report the number of licensed facilities that assume such liability and the number of health care practitioners, by profession, for whom they assume liability.

(4) The agency shall adopt rules governing the establishment of internal risk management programs to meet the needs of individual licensed facilities. Each internal risk management program shall include the use of incident reports to be filed with an individual of responsibility who is competent in risk management techniques in the employ of each licensed facility, such as an insurance coordinator, or who is retained by the licensed facility as a consultant. The individual responsible for the risk management program shall have free access to all medical records of the licensed facility. The incident reports are part of the workpapers of the attorney defending the licensed facility in litigation relating to the licensed facility and are subject to discovery, but are not admissible as evidence in court. A person filing an incident report is not subject to civil suit by virtue of such incident report. As a part of each internal risk management program, the incident reports shall be used to develop categories of incidents which identify problem areas. Once identified, procedures shall be adjusted to correct the problem areas.

(5) For purposes of reporting to the agency pursuant to this section, the term "adverse incident" means an event over which health care personnel could exercise control and which is associated in whole or in part with medical intervention, rather than the condition

for which such intervention occurred, and which:

(a) Results in one of the following injuries:

1. Death;

2. Brain or spinal damage;

3. Permanent disfigurement;

4. Fracture or dislocation of bones or joints;

5. A resulting limitation of neurological, physical, or sensory function which continues after discharge from the facility;

6. Any condition that required specialized medical attention or surgical intervention resulting from nonemergency medical intervention, other than an emergency medical condition, to which the patient has not given his or her informed consent; or

7. Any condition that required the transfer of the patient, within or outside the facility, to a unit providing a more acute level of care due to the adverse incident, rather than the patient's condition prior to the adverse incident;

(b) Was the performance of a surgical procedure on the wrong patient, a wrong surgical procedure, a wrong-site surgical procedure, or a surgical procedure otherwise unrelated to the patient's diagnosis or medical condition;

(c) Required the surgical repair of damage resulting to a patient from a planned surgical procedure, where the damage was not a recognized specific risk, as disclosed to the patient and documented through the informed-consent process; or

(d) Was a procedure to remove unplanned foreign objects remaining from a surgical procedure.

(6)(a) Each licensed facility subject to this section shall submit an annual report to the agency summarizing the incident reports that have been filed in the facility for that year. The report shall include:

1. The total number of adverse incidents.

2. A listing, by category, of the types of operations, diagnostic or treatment procedures, or other actions causing the injuries, and the number of incidents occurring within each category.

3. A listing, by category, of the types of injuries caused and the number of incidents occurring within each category.

4. A code number using the health care professional's licensure number and a separate code number identifying all other individuals directly involved in adverse incidents to patients, the relationship of the individual to the licensed facility, and the number of incidents in which each individual has been directly involved. Each licensed facility shall maintain names of the health care professionals and individuals identified by code numbers for purposes of this section.

5. A description of all malpractice claims filed against the licensed facility, including the total number of pending and closed claims and the nature of the incident which led to, the persons involved in, and the status and disposition of each claim. Each report shall update status and disposition for all prior reports.

(b) The information reported to the agency pursuant to paragraph (a) which relates to persons licensed under chapter 458, chapter 459, chapter 461, or chapter 466 shall be reviewed by the agency. The agency shall determine whether any of the incidents potentially involved conduct by a health care professional who is subject to disciplinary action, in which case the provisions of s. 456.073 shall apply.

(c) The report submitted to the agency shall also contain the name and license number of the risk manager of the licensed facility, a copy of its policy and procedures which govern the measures taken by the facility and its risk manager to reduce the risk of injuries and adverse incidents, and the results of such measures. The annual report is confidential and is not available to the public pursuant to s. 119.07(1) or any other law providing access to public records. The annual report is not discoverable or admissible in any civil or administrative action, except in disciplinary proceedings by the agency or the appropriate

regulatory board. The annual report is not available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the agency or the appropriate regulatory board. However, the agency or the appropriate regulatory board shall make available, upon written request by a health care professional against whom probable cause has been found, any such records which form the basis of the determination of probable cause.

(7) Any of the following adverse incidents, whether occurring in the licensed facility or arising from health care prior to admission in the licensed facility, shall be reported by the facility to the agency within 15 calendar days after its occurrence:

(a) The death of a patient;

(b) Brain or spinal damage to a patient;

(c) The performance of a surgical procedure on the wrong patient;

(d) The performance of a wrong-site surgical procedure;

(e) The performance of a wrong surgical procedure;

(f) The performance of a surgical procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition;

(g) The surgical repair of damage resulting to a patient from a planned surgical procedure, where the damage is not a recognized specific risk, as disclosed to the patient and documented through the informed-consent process; or

(h) The performance of procedures to remove unplanned foreign objects remaining from a surgical procedure.

The agency may grant extensions to this reporting requirement for more than 15 days upon justification submitted in writing by the facility administrator to the agency. The agency may require an additional, final report. These reports shall not be available to the public pursuant to s. 119.07(1) or any other law providing access to public records, nor be discoverable or admissible in any civil or administrative action, except in disciplinary

proceedings by the agency or the appropriate regulatory board, nor shall they be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the agency or the appropriate regulatory board. However, the agency or the appropriate regulatory board shall make available, upon written request by a health care professional against whom probable cause has been found, any such records which form the basis of the determination of probable cause. The agency may investigate, as it deems appropriate, any such incident and prescribe measures that must or may be taken in response to the incident. The agency shall review each incident and determine whether it potentially involved conduct by the health care professional who is subject to disciplinary action, in which case the provisions of s. 456.073 shall apply.

(8) The agency shall publish on the agency's website, no less than quarterly, a summary and trend analysis of adverse incident reports received pursuant to this section, which shall not include information that would identify the patient, the reporting facility, or the health care practitioners involved. The agency shall publish on the agency's website an annual summary and trend analysis of all adverse incident reports and malpractice claims information provided by facilities in their annual reports, which shall not include information that would identify the patient, the reporting facility, or the practitioners involved. The purpose of the publication of the summary and trend analysis is to promote the rapid dissemination of information relating to adverse incidents and malpractice claims to assist in avoidance of similar incidents and reduce morbidity and mortality.

(9) The internal risk manager of each licensed facility shall:

(a) Investigate every allegation of sexual misconduct which is made against a member of the facility's personnel who has direct patient contact, when the allegation is that the sexual misconduct occurred at the facility or on the grounds of the facility.

(b) Report every allegation of sexual misconduct to the administrator of the licensed facility.

(c) Notify the family or guardian of the victim, if a minor, that an allegation of sexual misconduct has been made and that an investigation is being conducted.

(d) Report to the Department of Health every allegation of sexual misconduct, as defined in chapter 456 and the respective practice act, by a licensed health care practitioner that involves a patient.

(10) Any witness who witnessed or who possesses actual knowledge of the act that is the basis of an allegation of sexual abuse shall:

(a) Notify the local police; and

(b) Notify the hospital risk manager and the administrator.

For purposes of this subsection, "sexual abuse" means acts of a sexual nature committed for the sexual gratification of anyone upon, or in the presence of, a vulnerable adult, without the vulnerable adult's informed consent, or a minor. "Sexual abuse" includes, but is not limited to, the acts defined in s. 794.011(1)(h), fondling, exposure of a vulnerable adult's or minor's sexual organs, or the use of the vulnerable adult or minor to solicit for or engage in prostitution or sexual performance. "Sexual abuse" does not include any act intended for a valid medical purpose or any act which may reasonably be construed to be a normal caregiving action.

(11) A person who, with malice or with intent to discredit or harm a licensed facility or any person, makes a false allegation of sexual misconduct against a member of a licensed facility's personnel is guilty of a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

(12) In addition to any penalty imposed pursuant to this section or part II of chapter 408, the agency shall require a written plan of correction from the facility. For a single incident or series of isolated incidents that are nonwillful violations of the reporting requirements of this section or part II of chapter 408, the agency shall first seek to obtain corrective action by the facility. If the correction is not demonstrated within the timeframe established by the agency or if there is a pattern of nonwillful violations of this section or part II of chapter 408, the agency may impose an administrative fine, not to exceed $5,000 for any violation of the reporting requirements of this section or part II of chapter 408. The administrative fine for repeated nonwillful violations may not exceed $10,000 for any violation. The administrative fine for each intentional and willful violation may not exceed

$25,000 per violation, per day. The fine for an intentional and willful violation of this section or part II of chapter 408 may not exceed $250,000. In determining the amount of fine to be levied, the agency shall be guided by s. 395.1065(2)(b).

(13) The agency shall have access to all licensed facility records necessary to carry out the provisions of this section. The records obtained by the agency under subsection (6), subsection (7), or subsection (9) are not available to the public under s. 119.07(1), nor shall they be discoverable or admissible in any civil or administrative action, except in disciplinary proceedings by the agency or the appropriate regulatory board, nor shall records obtained pursuant to s. 456.071 be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the agency or the appropriate regulatory board. However, the agency or the appropriate regulatory board shall make available, upon written request by a health care professional against whom probable cause has been found, any such records which form the basis of the determination of probable cause, except that, with respect to medical review committee records, s. 766.101 controls.

(14) The meetings of the committees and governing board of a licensed facility held solely for the purpose of achieving the objectives of risk management as provided by this section shall not be open to the public under the provisions of chapter 286. The records of such meetings are confidential and exempt from s. 119.07(1), except as provided in subsection (13).

(15) The agency shall review, as part of its licensure inspection process, the internal risk management program at each licensed facility regulated by this section to determine whether the program meets standards established in statutes and rules, whether the program is being conducted in a manner designed to reduce adverse incidents, and whether the program is appropriately reporting incidents under this section.

(16) There shall be no monetary liability on the part of, and no cause of action for damages shall arise against, any risk manager, licensed under s. 395.10974, for the implementation and oversight of the internal risk management program in a facility licensed under this chapter or chapter 390 as required by this section, for any act or proceeding undertaken or performed within the scope of the functions of such internal risk

management program if the risk manager acts without intentional fraud.

(17) A privilege against civil liability is hereby granted to any licensed risk manager or licensed facility with regard to information furnished pursuant to this chapter, unless the licensed risk manager or facility acted in bad faith or with malice in providing such information.

(18) If the agency, through its receipt of any reports required under this section or through any investigation, has a reasonable belief that conduct by a staff member or employee of a licensed facility is grounds for disciplinary action by the appropriate regulatory board, the agency shall report this fact to such regulatory board.

(19) It shall be unlawful for any person to coerce, intimidate, or preclude a risk manager from lawfully executing his or her reporting obligations pursuant to this chapter. Such unlawful action shall be subject to civil monetary penalties not to exceed $10,000 per violation.

History.--s. 3, ch. 75-9; s. 3, ch. 76-168; s. 2, ch. 76-260; s. 1, ch. 77-64; s. 1, ch. 77-457; s. 286, ch. 79-400; s. 3, ch. 81-318; ss. 9, 52, ch. 85-175; s. 2, ch. 86-287; s. 6, ch. 88-1; s. 3, ch. 88-97; s. 3, ch. 88-277; s. 14, ch. 89-527; s. 16, ch. 90-344; s. 23, ch. 92-33; ss. 15, 16, 98, ch. 92-289; s. 1, ch. 95-319; s. 214, ch. 96-406; s. 25, ch. 98-89; s. 22, ch. 98-166; s. 14, ch. 2000-160; s. 63, ch. 2001-277; s. 4, ch. 2003-416; s. 44, ch. 2007-230.

Note.--Former ss. 395.18, 768.41; s. 395.041.

The 2007 Florida Statutes

766.101 Medical review committee, immunity from liability.--

(1) As used in this section:

(a) The term "medical review committee" or "committee" means:

1.a. A committee of a hospital or ambulatory surgical center licensed under chapter 395 or a health maintenance organization certificated under part I of chapter 641,

b. A committee of a physician-hospital organization, a provider-sponsored organization, or an integrated delivery system,

c. A committee of a state or local professional society of health care providers,

d. A committee of a medical staff of a licensed hospital or nursing home, provided the medical staff operates pursuant to written bylaws that have been approved by the governing board of the hospital or nursing home,

e. A committee of the Department of Corrections or the Correctional Medical Authority as created under s. 945.602, or employees, agents, or consultants of either the department or the authority or both,

f. A committee of a professional service corporation formed under chapter 621 or a corporation organized under chapter 607 or chapter 617, which is formed and operated for the practice of medicine as defined in s. 458.305(3), and which has at least 25 health care providers who routinely provide health care services directly to patients,

g. A committee of a mental health treatment facility licensed under chapter 394 or a community mental health center as defined in s. 394.907, provided the quality assurance program operates pursuant to the guidelines which have been approved by the governing board of the agency,

h. A committee of a substance abuse treatment and education prevention program licensed under chapter 397 provided the quality assurance program operates pursuant to the guidelines which have been approved by the governing board of the agency,

i. A peer review or utilization review committee organized under chapter 440,

j. A committee of the Department of Health, a county health department, healthy start coalition, or certified rural health network, when reviewing quality of care, or employees of these entities when reviewing mortality records, or

k. A continuous quality improvement committee of a pharmacy licensed pursuant to chapter 465,

which committee is formed to evaluate and improve the quality of health care rendered by providers of health service or to determine that health services rendered were professionally indicated or were performed in compliance with the applicable standard of care or that the cost of health care rendered was considered reasonable by the providers of professional health services in the area; or

2. A committee of an insurer, self-insurer, or joint underwriting association of medical malpractice insurance, or other persons conducting review under s. 766.106.

(b) The term "health care providers" means physicians licensed under chapter 458, osteopathic physicians licensed under chapter 459, podiatric physicians licensed under chapter 461, optometrists licensed under chapter 463, dentists licensed under chapter 466, chiropractic physicians licensed under chapter 460, pharmacists licensed under chapter 465, or hospitals or ambulatory surgical centers licensed under chapter 395.

(2) A medical review committee of a hospital or ambulatory surgical center or health maintenance organization shall screen, evaluate, and review the professional and medical

competence of applicants to, and members of, medical staff. As a condition of licensure, each health care provider shall cooperate with a review of professional competence performed by a medical review committee.

(3)(a) There shall be no monetary liability on the part of, and no cause of action for damages shall arise against, any member of a duly appointed medical review committee, or any health care provider furnishing any information, including information concerning the prescribing of substances listed in s. 893.03(2), to such committee, or any person, including any person acting as a witness, incident reporter to, or investigator for, a medical review committee, for any act or proceeding undertaken or performed within the scope of the functions of any such committee if the committee member or health care provider acts without intentional fraud.

(b) The provisions of this section do not affect the official immunity of an officer or employee of a public corporation.

(4) Except as provided in subsection (3), this section shall not be construed to confer immunity from liability on any professional society or hospital or upon any health professional while performing services other than as a member of a medical review committee or upon any person, including any person acting as a witness, incident reporter to, or investigator for, a medical review committee, for any act or proceeding undertaken or performed outside the scope of the functions of such committee. In any case in which, but for the enactment of the preceding provisions of this section, a cause of action would arise against a hospital, professional society, or an individual health professional, such cause of action shall exist as if the preceding provisions had not been enacted.

(5) The investigations, proceedings, and records of a committee as described in the preceding subsections shall not be subject to discovery or introduction into evidence in any civil or administrative action against a provider of professional health services arising out of the matters which are the subject of evaluation and review by such committee, and no person who was in attendance at a meeting of such committee shall be permitted or required to testify in any such civil action as to any evidence or other matters produced or presented during the proceedings of such committee or as to any findings, recommendations, evaluations, opinions, or other actions of such committee or any members thereof. However, information, documents, or records otherwise available from

original sources are not to be construed as immune from discovery or use in any such civil action merely because they were presented during proceedings of such committee, nor should any person who testifies before such committee or who is a member of such committee be prevented from testifying as to matters within his or her knowledge, but the said witness cannot be asked about his or her testimony before such a committee or opinions formed by him or her as a result of said committee hearings.

(6) In the event that the defendant prevails in an action brought by a health care provider against any person that initiated, participated in, was a witness in, or conducted any review as authorized by this section, the court shall award reasonable attorney's fees and costs to the defendant.

(7)(a) It is the intent of the Legislature to encourage medical review committees to contribute further to the quality of health care in this state by reviewing complaints against physicians in the manner described in this paragraph. Accordingly, the Department of Health may enter into a letter of agreement with a professional society of physicians licensed under chapter 458 or chapter 459, under which agreement the medical or peer review committees of the professional society will conduct a review of any complaint or case referred to the society by the department which involves a question as to whether a physician's actions represented a breach of the prevailing professional standard of care. The prevailing professional standard of care is that level of care, skill, and treatment which, in light of all relevant surrounding circumstances, is recognized as acceptable and appropriate by reasonably prudent similar health care providers. The letter of agreement must specify that the professional society will submit an advisory report to the department within a reasonable time following the department's written and appropriately supported request to the professional society. The advisory report, which is not binding upon the department, constitutes the professional opinion of the medical review committee and must include:

1. A statement of relevant factual findings.

2. The judgment of the committee as to whether the physician's actions represented a breach of the prevailing professional standard of care.

(b) Cases involving possible criminal acts may not be referred to medical review committees, and emergency action by the department needed to protect the public against immediate and substantial threats must not be delayed by any referral of the case to a medical review committee. The department shall refer cases pursuant to this subsection prior to making determinations of probable cause.

(c) So as not to inhibit the willing and voluntary service of professional society members on medical review committees, the department shall use advisory reports from medical committees as background information only and shall prepare its own case using independently prepared evidence and supporting expert opinion for submission to the probable cause panel of a regulatory board formed under chapter 458 or chapter 459. Proceedings of medical review committees are exempt from the provisions of s. 286.011 and s. 24(b), Art. I of the State Constitution, and any advisory reports provided to the department by such committees are confidential and exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I of the State Constitution, regardless of whether probable cause is found. The medical review committee advisory reports and any records created by the medical review committee are not subject to discovery or introduction into evidence in any disciplinary proceeding against a licensee. Further, no person who voluntarily serves on a medical review committee or who investigates a complaint for the committee may be permitted or required to testify in any such disciplinary proceeding as to any evidence or other matters produced or presented during the proceedings of such committee or as to any findings, recommendations, evaluations, opinions, or other actions of such committee or any members thereof. However, nothing in this section shall be construed to mean that information, documents, or records otherwise available and obtained from original sources are immune from discovery or use in any such disciplinary proceeding merely because they were presented during proceedings of a peer review organization or committee. Members of medical review committees shall assist the department in identifying such original sources when possible.

(d) Professional society representatives who participate in medical reviews and preparation of advisory reports pursuant to this subsection will be reimbursed for per diem and travel expenses consistent with the provisions of s. 112.061 and as provided in the written agreement described in paragraph (a).

(e) There shall be no monetary liability on the part of, and no cause of action shall arise against, any state or local professional society of physicians licensed under chapter 458 or chapter 459, or any member thereof, acting pursuant to the provisions of this subsection without intentional fraud or malice. Further, this subsection does not supersede the provisions of paragraph (3)(a) relating to immunity from liability for medical review committees.

(8) No cause of action of any nature by a person licensed pursuant to chapter 458, chapter 459, chapter 461, chapter 463, part I of chapter 464, chapter 465, or chapter 466 shall arise against another person licensed pursuant to chapter 458, chapter 459, chapter 461, chapter 463, part I of chapter 464, chapter 465, or chapter 466 for furnishing information to a duly appointed medical review committee, to an internal risk management program established under s. 395.0197, to the Department of Health or the Agency for Health Care Administration, or to the appropriate regulatory board if the information furnished concerns patient care at a facility licensed pursuant to part I of chapter 395 where both persons provide health care services, if the information is not intentionally fraudulent, and if the information is within the scope of the functions of the committee, department, or board. However, if such information is otherwise available from original sources, it is not immune from discovery or use in a civil action merely because it was presented during a proceeding of the committee, department, or board.

History.--ss. 1, 2, ch. 72-62; s. 1, ch. 73-50; s. 1, ch. 77-461; s. 285, ch. 79-400; s. 3, ch. 80-353; s. 8, ch. 85-175; s. 1, ch. 87-342; s. 47, ch. 88-277; s. 34, ch. 88-392; s. 25, ch. 88-398; s. 4, ch. 89-281; s. 35, ch. 89-289; s. 16, ch. 89-374; s. 9, ch. 90-341; s. 92, ch. 92-289; s. 37, ch. 93-39; s. 1, ch. 93-155; s. 1, ch. 93-158; s. 1, ch. 94-73; s. 244, ch. 94-218; s. 6, ch. 95-140; s. 422, ch. 96-406; s. 1798, ch. 97-102; s. 80, ch. 97-237; s. 61, ch. 97-264; s. 31, ch. 98-89; ss. 228, 295, ch. 98-166; s. 23, ch. 98-191; s. 6, ch. 99-186; s. 143, ch. 2000-318; s. 86, ch. 2001-277.

Note.--Former s. 768.131; s. 768.40.

The 2007 Florida Statutes

766.1016 Patient safety data privilege.--

(1) As used in this section, the term:

(a) "Patient safety data" means reports made to patient safety organizations, including all health care data, interviews, memoranda, analyses, root cause analyses, products of quality assurance or quality improvement processes, corrective action plans, or information collected or created by a health care facility licensed under chapter 395, or a health care practitioner as defined in s. 456.001(4), as a result of an occurrence related to the provision of health care services which exacerbates an existing medical condition or could result in injury, illness, or death.

(b) "Patient safety organization" means any organization, group, or other entity that collects and analyzes patient safety data for the purpose of improving patient safety and health care outcomes and that is independent and not under the control of the entity that reports patient safety data.

(2) Patient safety data shall not be subject to discovery or introduction into evidence in any civil or administrative action. However, information, documents, or records otherwise available from original sources are not immune from discovery or use in any civil or administrative action merely because they were also collected, analyzed, or presented to a patient safety organization. Any person who testifies before a patient safety organization or who is a member of such a group may not be prevented from testifying as to matters within his or her knowledge, but he or she may not be asked about his or her testimony before a patient safety organization or the opinions formed by him or her as a result of the

hearings.

(3) Unless otherwise provided by law, a patient safety organization shall promptly remove all patient-identifying information after receipt of a complete patient safety data report unless such organization is otherwise permitted by state or federal law to maintain such information. Patient safety organizations shall maintain the confidentiality of all patient-identifying information and may not disseminate such information, except as permitted by state or federal law.

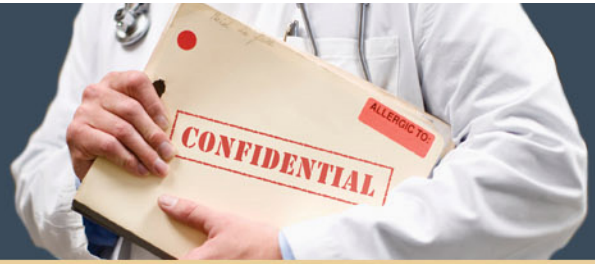
(4) The exchange of patient safety data among health care facilities licensed under chapter 395, or health care practitioners as defined in s. 456.001(4), or patient safety organizations which does not identify any patient shall not constitute a waiver of any privilege established in this section.

(5) Reports of patient safety data to patient safety organizations do not abrogate obligations to make reports to the Department of Health, the Agency for Health Care Administration, or other state or federal regulatory agencies.

(6) An employer may not take retaliatory action against an employee who in good faith makes a report of patient safety data to a patient safety organization.

History.--s. 10, ch. 2003-416.

The Amendment 7 Challenge:
Is a PSO Hype or Hope?



The Patient Safety Act and Patient Safety Organizations

J. Mark Waxman

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The Patient Safety Act

- Pub. Law 109-41 (July 29, 2005)
- The Goals
- A Voluntary Program
- How They Are To Be Achieved

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The Key Provisions

- Patient Safety Work Product (PSWP)
  - Privileged Material
  - Confidentiality Requirements
- Patient Safety Organizations
  - What are they?
  - How will they function?
  - How will they be funded?

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The Continuing Concerns

- Breadth of Protection
- Hurdles to PSO Formation and Operations
- Time to Finalization of the Regulations

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The Proposed Regulations

- 42 CFR Part 3
- 73 Fed. Reg. 8112 (February 12, 2008)
- Comments Filed
- Time Will Tell

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What's a PSO?

- Public on Private Entity "or component thereof"
- Excludes health insurance issuer or component thereof
- Excludes entities that conduct regulatory oversight, such as accreditation or licensure unless a component PSO
- That Meets the Requirements
  - Basic Requirements
  - Component PSOs

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Basic Requirements

- 15 "general PSO certification requirements"
  - 8 patient safety activities
    - Policies and Procedures
    - Certification requirements
  - 7 PSO criteria
    - Workforce requirements
    - 2 bona fide contracts
    - Standardized data collection approaches
    - PSWP used for providing direct feedback and assistance

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Component PSOs

- Separation of PSWP
  - Workforce requirements
  - Shared IS System requirements
  - Unless: Written Agreement regarding disclosure
- Non-disclosure of PSWP
- No Conflict of interest
- Notification requirements

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PSWP - What's Included (§3.204)

- "Any data, reports, records, memoranda, analyses (such as root cause analysis), or written or oral statements..."
- Assembled or developed
- By a provider (Licensed or a parent organization)
- For reporting to a PSO
- AND – are reported to a PSO
- OR – developed by a PSO or
- OR – deliverations or analysis...

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PSWP – What's Excluded

- Patient's medical record
- Billing and discharge information
- Any other original patient or provider information
- Information collected, maintained or developed separately, or exists separately from a PSES
- A PSES
  - Collection, management or analysis of information for reporting to or by a PSO

PSWP – Dual Use Issues

- Peer review materials
- JCAHO reporting

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Privilege of PSWP

- A broad privilege
  - Not subject to subpoena or discovery
  - Federal, state, local, administrative, civil or criminal proceedings, including proceedings against a provider
  - Not subject to FOI or any similar federal, state, local or tribal law.

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PSWP Privilege – The Exceptions

- Certain criminal proceedings – In camera determination
- Certain equitable relief proceedings
- Authorized by the provider
- Non-identifiable when meets de-identification standards

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Confidentiality of PSWP (§3.206)

- Confidential and "shall not be disclosed"
- Exceptions
  - Criminal proceedings after in camera determination
  - Equitable relief for reporters (i.e. whistleblowers)
  - Authorized by the provider
  - Patient Safety Activities
  - Non-identifiable
  - For research according to rules promulgated by the Secretary
  - To the FDA
  - Voluntary disclosures to an accrediting body
  - Business operations
  - Law enforcement

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Confidentiality – A Safe Harbor and Continued Protection

- No violation of:
  - Disclosure did not relate to an identifiable provider
  - If disclosed under an authorized exception or Disclosed impermissibly
    - Continues to be privileged and confidential or
    - Non identifiable PSWP that is disclosed is no longer privileged or confidential

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PSO – Security Requirements (§3.106)

- The Four Elements
  - Security management
  - Separation of systems
  - Security monitoring and control
  - System assessment
- Policies required – "appropriate and scalable"

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Becoming a PSO

- Certification form with attestation
- Prompt notification if fall out of compliance with criteria
- Secretary accepts, conditions or denies acceptance of a certification
  - Minimum contract requirement
  - Findings regarding relationships with contracting providers

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The Compliance Structure

- The Role of the Secretary
- Complaints, Investigations and CMPs
  - Up to $10,000
  - The Factors

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Questions?

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The Amendment 7 Challenge:
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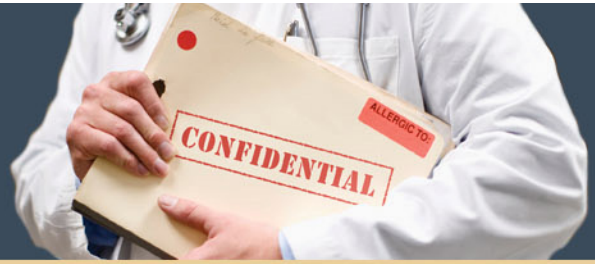

THE HEALTH CARE QUALITY IMPROVEMENT ACT

IS THERE A FEDERAL PEER REVIEW PRIVILEGE?

GARY D. KOCH, M.D. , J.D.

April 29, 2008

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CONGRESSIONAL FINDINGS

[42 U.S.C. § 11101]

- THE INCREASING OCCURRENCE OF MEDICAL MALPRACTICE AND THE NEED TO IMPROVE THE QUALITY OF MEDICAL CARE HAVE BECOME NATIONWIDE PROBLEMS THAT WARRANT GREATER EFFORTS THAN THOSE THAT CAN BE UNDERTAKEN BY ANY INDIVIDUAL STATE.
- THERE IS A NATIONAL NEED TO RESTRICT THE ABILITY OF INCOMPETENT PHYSICIANS TO MOVE FROM STATE TO STATE WITHOUT DISCLOSURE OR DISCOVERY OF THE PHYSICIAN'S PREVIOUS DAMAGING OR INCOMPETENT PERFORMANCE.

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CONGRESSIONAL FINDINGS

[42 U.S.C. § 11101]

- THIS NATIONWIDE PROBLEM CAN BE REMEDIED THROUGH EFFECTIVE PROFESSIONAL PEER REVIEW.
- THE THREAT OF PRIVATE MONEY DAMAGE LIABILITY UNDER FEDERAL LAWS, INCLUDING TREBLE DAMAGE LIABILITY UNDER FEDERAL ANTITRUST LAW, UNREASONABLY DISCOURAGES PHYSICIANS FROM PARTICIPATING IN EFFECTIVE PROFESSIONAL PEER REVIEW.
- THERE IS AN OVERRIDING NATIONAL NEED TO PROVIDE INCENTIVE AND PROTECTION FOR PHYSICIANS ENGAGING IN EFFECTIVE PROFESSIONAL PEER REVIEW.

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HEALTHCARE QUALITY IMPROVEMENT ACT OF 1986

[42 U.S.C. § 11101 ET SEQ.]

- DATA BANK:
  - ESTABLISHMENT OF A NEW NATIONAL REPORTING SYSTEM.
- REQUIRED REPORTS:
  - INSURANCE COMPANIES;
  - STATE MEDICAL BOARDS;
  - HOSPITALS.
- IMMUNITIES – HCQIA PROVIDES IMMUNITY TO HOSPITALS AND PHYSICIANS TO ENCOURAGE THEM TO PARTICIPATE IN PROFESSIONAL REVIEW ACTIVITIES.

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PROFESSIONAL REVIEW ACTIONS

- ACTIONS THAT MEET THE DEFINITION OF PROFESSIONAL REVIEW ACTION ARE ELIGIBLE FOR IMMUNITY UNDER HCQIA:

  > [A]N ACTION OR RECOMMENDATION OF A PROFESSIONAL REVIEW BODY WHICH IS TAKEN OR MADE IN THE CONDUCT OF A PROFESSIONAL REVIEW ACTIVITY, WHICH IS BASED ON THE COMPETENCE OR PROFESSIONAL CONDUCT OF AN INDIVIDUAL PHYSICIAN (WHICH CONDUCT AFFECTS OR COULD AFFECT ADVERSELY THE HEALTH OR WELFARE OF A PATIENT OR PATIENTS), AND WHICH AFFECTS (OR MAY AFFECT) ADVERSELY THE CLINICAL PRIVILEGES, OR MEMBERSHIP IN A PROFESSIONAL SOCIETY, OF THE PHYSICIAN.

[42 U.S.C. § 11151(9)]

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HCQIA IMMUNITY

- TO QUALIFY FOR HCQIA IMMUNITY, A PROFESSIONAL REVIEW ACTION MUST BE TAKEN:
  - IN THE REASONABLE BELIEF THAT THE ACTION WAS IN THE FURTHERANCE OF QUALITY HEALTH CARE;
  - AFTER A REASONABLE EFFORT TO OBTAIN THE FACTS OF THE MATTER;
  - AFTER ADEQUATE NOTICE AND HEARING PROCEDURES ARE AFFORDED TO THE PHYSICIAN INVOLVED, OR AFTER SUCH OTHER PROCEDURES AS ARE FAIR TO THE PHYSICIAN UNDER THE CIRCUMSTANCES; AND
  - IN THE REASONABLE BELIEF THAT THE ACTION WAS WARRANTED BY THE FACTS KNOWN AFTER REASONABLE EFFORTS TO OBTAIN THE FACTS AND AFTER PROVIDING ADEQUATE NOTICE AND HEARING PROCEDURES.

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SELECT HCQIA CASES

IN RE: *ADMINISTRATIVE SUBPOENA BLUE CROSS BLUE SHIELD OF MASSACHUSETTS, INC., 400 F.SUPP.2D 386 (D. Mass. 2005)*

FACTS

- FEDERAL CRIMINAL INVESTIGATION OF A PHYSICIAN FOR HEALTH CARE FRAUD;
- GOVERNMENT SERVED AN INSURER WITH AN ADMINISTRATIVE SUBPOENA UNDER HIPAA, REQUESTING DOCUMENTS REVIEWED AS PART OF ITS INTERNAL MEDICAL PEER REVIEW COMMITTEE'S ONGOING INQUIRY INTO THE PHYSICIAN'S ACTIVITIES;
- THE INSURER REFUSED, ASSERTING A FEDERAL MEDICAL PEER REVIEW PRIVILEGE;
- THE GOVERNMENT FILES MOTION TO COMPEL.

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SELECT HCQIA CASES

IN RE: *ADMINISTRATIVE SUBPOENA BLUE CROSS BLUE SHIELD OF MASSACHUSETTS, INC., 400 F.SUPP.2D 386 (D. Mass. 2005)*

FACTORS CONSIDERED IMPORTANT BY THE COURT

- NO COURT IN THE FIRST CIRCUIT OR DISTRICT OF MASSACHUSETTS HAD YET RECOGNIZED A FEDERAL MEDICAL PEER REVIEW PRIVILEGE.
- CONGRESS HAD NOT INCLUDED A MEDICAL PEER REVIEW PRIVILEGE IN HCQIA.

IN RE: *ADMINISTRATIVE SUBPOENA BLUE CROSS BLUE SHIELD OF MASSACHUSETTS, INC., 400 F.SUPP.2D 386 (D. Mass. 2005)*

FACTORS CONSIDERED IMPORTANT BY THE COURT

- WHETHER THE PRIVILEGE IS "INTRINSICALLY MERITORIOUS" WAS BASED ON FOUR FACTORS: (A) WHETHER THE COMMUNICATIONS ORIGINATE IN A CONFIDENCE THAT THEY WILL NOT BE DISCLOSED; (B) WHETHER THIS ELEMENT OF CONFIDENTIALITY IS ESSENTIAL TO THE FULL AND SATISFACTORY MAINTENANCE OF THE RELATIONSHIP BETWEEN THE PARTIES; (C) WHETHER THIS RELATIONSHIP IS ONE WHICH OUGHT TO BE DILIGENTLY FOSTERED; AND (D) WHETHER THE INJURY THAT WOULD RESULT FROM DISCLOSURE OF THE COMMUNICATIONS WOULD BE GREATER THAN THE BENEFIT THEREBY GAINED FOR THE CORRECT DISPOSAL OF LITIGATION.

SELECT HCQIA CASES

IN RE: *ADMINISTRATIVE SUBPOENA BLUE CROSS BLUE SHIELD OF MASSACHUSETTS, INC., 400 F.SUPP.2D 386 (D. Mass. 2005)*

FACTORS CONSIDERED IMPORTANT BY THE COURT

- GIVEN THAT HCQIA PROVIDES FOR QUALIFIED IMMUNITY FROM SUIT FOR THOSE PARTICIPATING IN PEER REVIEW AND THAT THE PRODUCTION OF DOCUMENTS WOULD BE SUBJECT TO A PROTECTIVE ORDER TO PRESERVE CONFIDENTIALITY, ANY CONCERNS ABOUT DISCOURAGING RIGOROUS AND HONEST EVALUATION OF PHYSICIAN CONDUCT BY PUBLIC DISCLOSURE HAVE BEEN MINIMIZED.
- IT WAS LIKELY THAT THE DOCUMENTS REQUESTED BY THE GOVERNMENT WOULD PROVIDE SUBSTANTIAL ASSISTANCE IN ITS INVESTIGATION, AND THERE WAS NOTHING IN THE RECORD THAT INDICATED THAT THE GOVERNMENT COULD EASILY GET THE INFORMATION ELSEWHERE.

IN RE: *ADMINISTRATIVE SUBPOENA BLUE CROSS BLUE SHIELD OF MASSACHUSETTS, INC., 400 F.SUPP.2D 386 (D. Mass. 2005)*

FACTORS CONSIDERED IMPORTANT BY THE COURT

- THE FEDERAL INTEREST IN THE INVESTIGATION WAS TO ENFORCE LAWS AGAINST HEALTH CARE FRAUD, AN INTEREST OTHER FEDERAL COURTS HAVE FOUND SUFFICIENTLY STRONG TO REFUSE TO RECOGNIZE A FEDERAL MEDICAL PEER REVIEW PRIVILEGE.
- REFUSAL TO RECOGNIZE A FEDERAL PEER REVIEW PRIVILEGE COMPORTED WITH THE FINDINGS OF THE VAST MAJORITY OF FEDERAL COURTS THAT HAVE FACED THIS ISSUE IN OTHER CONTEXTS (E.G., IN CASES ALLEGING DISCRIMINATION, IN THE CIVIL ANTITRUST CONTEXT, AND CASES UNDER THE FEDERAL TORT CLAIMS ACT).

SELECT HCQIA CASES

IN RE: *ADMINISTRATIVE SUBPOENA BLUE CROSS BLUE SHIELD OF MASSACHUSETTS, INC., 400 F.SUPP.2D 386 (D. Mass. 2005)*

HOLDING:

THE COSTS OF WITHHOLDING THE DOCUMENTS OUTWEIGHED THE BENEFITS OF RECOGNIZING A MEDICAL PEER REVIEW PRIVILEGE IN THE CONTEXT OF A FEDERAL CRIMINAL INVESTIGATION.

SELECT HCQIA CASES

AGSTER v. MARICOPA COUNTY, 422 F.3D 836 (2005)

FACTS

- PRISONER TAKEN TO THE COUNTY JAIL AND PLACED IN A RESTRAINT CHAIR;
- THE PRISONER'S RESPIRATIONS DECREASED, HE DEVELOPED AN IRREGULAR HEARTBEAT, AND RESUSCITATION EFFORTS FAILED;
- THE PATIENT WAS THEN TRANSPORTED TO A HOSPITAL WHERE HE WAS PLACED ON LIFE SUPPORT AND SUBSEQUENTLY DIED;
- CORRECTIONAL HEALTH SERVICES WAS OBLIGATED TO UNDERTAKE A MORTALITY REVIEW;
- ACTION FILED IN STATE COURT, AND THE COUNTY REMOVED TO FEDERAL COURT, WHERE PLAINTIFFS SOUGHT DISCOVERY OF THE MORTALITY REVIEW AND THE COUNTY OPPOSED BASED ON STATE LAW TO MAINTAIN ITS CONFIDENTIALITY.

SELECT HCQIA CASES

AGSTER v. MARICOPA COUNTY, 422 F.3D 836 (2005)

FACTORS CONSIDERED IMPORTANT BY THE COURT:

- NO CASE IN THE NINTH CIRCUIT HAD RECOGNIZED THE PRIVILEGE, BUT A NEW PRIVILEGE CAN BE CREATED AS A MATTER OF FEDERAL COMMON LAW WHEN THERE IS A PUBLIC GOOD TRANSCENDING THE NORMALLY PREDOMINANT PRINCIPLE.
- THE COURT WAS RELUCTANT TO RECOGNIZE A PRIVILEGE IN AN AREA WHERE IT APPEARS THAT CONGRESS HAS CONSIDERED THE RELEVANT COMPETING CONCERNS AND HAS NOT PROVIDED THE PRIVILEGE.
- HCQIA GRANTED IMMUNITY TO PARTICIPANTS IN MEDICAL PEER REVIEW, BUT DID NOT CREATE A PRIVILEGE FOR MEDICAL PEER REVIEW REPORTS THAT RESULT FROM THE PROCESS. CONGRESS TWICE HAD OCCASION AND OPPORTUNITY TO CONSIDER THE PRIVILEGE AND DID NOT GRANT IT EITHER EXPLICITLY OR BY IMPLICATION. THE COURT WAS CONCERNED THAT THE PRIVILEGE SOUGHT WOULD PROTECT A REPORT BEARING ON THE DEATH OF A PRISONER.

SELECT HCQIA CASES

WEISS v. COUNTY OF CHESTER, 231 F.R.D. 202 (2005)

FACTS

- THE DECEDENT ARRESTED AT HIS HOME AND TRANSFERRED TO THE COUNTY PRISON WHERE HIS MENTAL HEALTH DETERIORATED;
- AFTER MEETING SEVERAL TIMES WITH MENTAL HEALTH PROFESSIONALS AT THE PRISON THE DECEDENT HUNG HIMSELF IN HIS CELL;
- AFTER THE SUICIDE, A MORTALITY REVIEW COMMITTEE WAS CONVENED TO CONDUCT AN INTERNAL INVESTIGATION INTO THE DEATH, AND A MORTALITY REVIEW REPORT CONTAINING THE INVESTIGATION'S FINDINGS WAS CREATED;
- DURING DISCOVERY, THE DECEDENT'S ESTATE REQUESTED DOCUMENTS REGARDING THE INVESTIGATION, AND THE COUNTY OBJECTED TO PRODUCTION OF THE MORTALITY REVIEW REPORT, ARGUING THAT IT WAS PROTECTED BY PENNSYLVANIA'S PEER REVIEW PROTECTION ACT.

SELECT HCQIA CASES

WEISS v. COUNTY OF CHESTER, 231 F.R.D. 202 (2005)

FACTORS CONSIDERED IMPORTANT BY THE COURT:

- CONGRESS HAS CONSIDERED THE RELEVANT COMPETING CONCERNS AND NOT PROVIDED A FEDERAL PEER REVIEW PRIVILEGE;
- CONGRESS HAD TWO OCCASIONS TO CONSIDER WHETHER TO EXTEND THE PRIVILEGE TO MATERIALS PRODUCED BY MEDICAL PEER REVIEWS, FIRST, IN 1986, WHEN HCQIA WAS ENACTED, AND AGAIN IN 1987, WHEN CONGRESS AMENDED HCQIA. CONGRESS DECLINED THE OPPORTUNITY TO EXTEND THE PRIVILEGE TO MATERIALS PRODUCED BY PEER REVIEW COMMITTEES ON BOTH OCCASIONS.

SELECT HCQIA CASES

WEISS v. COUNTY OF CHESTER, 231 F.R.D. 202 (2005)

HOLDING:

NO FEDERAL PEER REVIEW PRIVILEGE CREATED BY HCQIA.

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SELECT HCQIA CASES

VIRMANI v. NOVANT HEALTH, INC., 259 F.3d 284 (2001)

- COURT DECLINES TO FIND FEDERAL PEER REVIEW PRIVILEGE IN CONTEXT OF CASE INVOLVING CLAIMS OF DISCRIMINATION UNDER FEDERAL LAW;
- SUGGESTS THAT SAME INTERESTS IN PRESERVING CONFIDENTIALITY OF PEER REVIEW RECORDS NOT PRESENT IN CASES INVOLVING DISCRIMINATION AS COMPARED WITH MEDICAL MALPRACTICE;
- NOTES CONGRESSIONAL EXCEPTION TO HCQIA IMMUNITY PROVISIONS FOR CASES INVOLOVING CLAIMS OF DISCRIMINATION UNDER STATE OR FEDERAL LAW.

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SELECT HCQIA CASES

JOHNSON v. NYACK HOSPITAL, 169 F.R.D. 550 (S.D.N.Y. 1996)

- CLAIMS OF RACIAL DISCRIMINATION BY SURGEON RELATED TO DENIAL OF STAFF PRIVILEGES;
- COURT ALLOWS DISCLOSURE OF PEER REVIEW RECORDS NOTWITHSTANDING NEW YORK AND NEW JERSEY PRIVILEGE STATUTES, HOLDING THAT NO FEDERAL PRIVILEGE EXISTS;
- HCQIA PROVIDES QUALIFIED IMMUNITY FROM SUIT, BUT BECAUSE IT DID NOT PROTECT DOCUMENTS CREATED IN THE PEER REVIEW PROCESS, THE COURT CONCLUDED CONGRESS DID NOT INTEND TO ESTABLISH A FEDERAL PRIVILEGE FOR PEER REVIEW DOCUMENTS.

SELECT HCQIA CASES

SWARTHMORE RADIATION ONCOLOGY, INC. v. LAPES, 1993 WL 517722 (E.D.PA. 1993)

- ANTITRUST CASE WHERE HOSPITAL REFUSED TO DISCLOSE STAFF PRIVILEGE FILES ON GROUNDS THEY WERE PROTECTED BY STATE AND FEDERAL PEER REVIEW STATUTES;
- STATE STATUTE FOUND TO BE INCOMPATIBLE WITH FEDERAL INTERESTS AND FAIR COMPETITION;
- NO FEDERAL PRIVILEGE UNDER HCQIA, AS THE ACT ONLY PROVIDES IMMUNITY FROM DAMAGES AND ONLY INFORMATION REPORTING ADVERSE ACTIONS TAKEN AGAINST PHYSICIAN TO A NATIONAL CLEARINGHOUSE IS CONFIDENTIAL AND NOT TO BE DISCLOSED UNDER 42 U.S.C. § 11137 (B)(1).

SELECT HCQIA CASES

TEASDALE v. MARIN GENERAL HOSPITAL, 138 F.R.D. 691 (N.D.CAL. 1991)

"...THE PASSAGE OF A STATUTE SPECIFICALLY ADDRESSING PEER REVIEW ISSUES AND, INDEED, THE GIVING OF QUALIFIED IMMUNITY TO PEER REVIEWERS, IS STRONG EVIDENCE THAT CONGRESS NOT ONLY CONSIDERED THE IMPORTANCE OF MAINTAINING THE CONFIDENTIALITY OF THE PEER REVIEW PROCESS, BUT TOOK THE ACTION IT BELIEVED WOULD BEST BALANCE PROTECTING SUCH CONFIDENTIALITY WITH OTHER IMPORTANT FEDERAL INTERESTS. **CONGRESS SPOKE LOUDLY WITH ITS SILENCE IN *NOT* INCLUDING A PRIVILEGE AGAINST DISCOVERY OF PEER REVIEW MATERIALS IN THE HCQIA."**

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EXPRESS FEDERAL PRIVILEGES

- 38 U.S.C. § 5705 – CERTAIN MEDICAL QUALITY ASSURANCE RECORDS PRIVILEGED IN CASES WHEN GENERATED BY HOSPITALS OPERATED BY THE VETERANS ADMINISTRATION/DEPARTMENT OF VETERANS AFFAIRS;
- 10 U.S.C.§ 1102 – PRIVILEGE AFFORDED TO CERTAIN PEER REVIEW DOCUMENTS GENERATED BY OR FOR DEFENSE DEPARTMENT HEALTH FACILITIES.

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"OUTLIER" CASES

HADIX v. CARUSO, 2006 WL 2925270 (W.D.MICH.)

- CASE INVOLVING PRISONER DEATH;
- CRITICIZES APPLICATION OF *UNIVERSITY OF PENNSYLVANIA* DECISION TO CONTEXT WHICH WAS NOT INTENDED BY THE SUPREME COURT AND THAT BELIES THE INTENT OF FEDERAL RULE 501 (TO ALLOW A FLEXIBLE APPROACH TO THE FEDERAL COMMON LAW OF PRIVILEGE WHICH SERVES IMPORTANT NATIONAL INTERESTS).

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"OUTLIER" CASES

HADIX v. CARUSO, 2006 WL 2925270 (W.D.MICH.)

- IF MEDICAL MALPRACTICE SUITORS ARE PERMITTED ACCESS TO INSTITUTIONAL SELF-CRITICAL ANALYSIS, THEN THE SELF-CRITICAL ANALYSIS AND ATTENDANT IMPROVEMENTS OF MEDICAL SERVICES WILL STOP.
- APPLIES A COMMON LAW PEER REVIEW PRIVILEGE TO PREVENT DISCOVERY OF PEER REVIEW MATERIALS;
- CONCLUDES THAT "A CONTRARY RULING WILL ELIMINATE CANDOR IN THE PEER REVIEW PROCESS AND TRANSLATE IT INTO A KIND OF PERFUNCTORY ADMINISTRATIVE REVIEW WHICH WOULD NOT PROTECT PRISONER LIFE OR HEALTH."

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"OUTLIER" CASES

WEEKOTY v. UNITED STATES, 30 F. SUPP. 2D 1343 (D.N.M. 1998)

- COURT RECOGNIZES THE SELF-CRITICAL ANALYSIS PRIVILEGE IN A FEDERAL TORT CLAIMS ACT CASE;
  - NOTED ESTABLISHMENT OF CONFIDENTIALITY BY HCQIA FOR CERTAIN RECORDS; HOWEVER, NO ATTEMPT MADE TO ADDRESS CONGRESS' FAILURE TO ENACT A BLANKET FEDERAL PEER REVIEW PRIVILEGE.

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OPPORTUNITY TO EXAMINE JUDICIAL CONCLUSIONS??

- **SYPOSS v. UNITED STATES, 63 F. SUPP.2D 301 (W.D.N.Y. 1999):**

  "...THE NEED OF THE INDIVIDUAL TO BE ASSURED THAT SENSITIVE PERSONAL INFORMATION [AS IN THE PSYCHOTHERAPIST PRIVILEGE SITUATION], A PRECONDITION TO OBTAIN COMPETENT CARE, WILL NOT BE REVEALED WITHOUT HIS OR HER CONSENT CANNOT BE COMPARED TO THE INSTITUTIONAL INTERESTS IN ELIMINATING INCOMPETENCY AND IMPROVING THE QUALITY OF CARE. PHYSICIANS AND HOSPITALS HAVE AN OVERRIDING PROFESSIONAL OBLIGATION AND ECONOMIC INCENTIVE TO APPROVE 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 JUSTICE."

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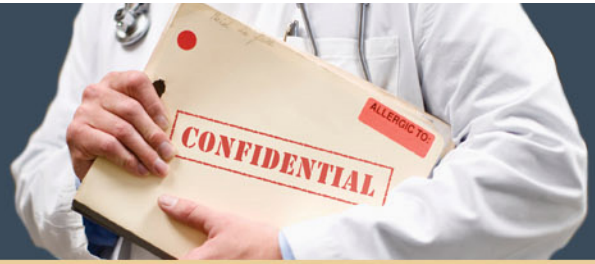
The Amendment 7 Challenge:
Is a PSO Hype or Hope?



Reporting Adverse Events: What is Presently Required?

Robert E. Slavkin

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What is an Adverse Incident?

- The Term “adverse incident” means an event over which health care personnel could exercise control and which is associated in whole or in part with medical intervention, rather than the condition for which such intervention occurred, and which results in one of the following injuries:

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Hospital Adverse Event Reporting - Florida

- Under the Florida Statute Chapter 395.0197 – Internal risk management program: Florida requires serious patient injury reporting within 15 days in hospitals and ambulatory care centers. Florida also requires facility tracking, trending, and problem resolution programs and an annual report to the state. Facility health care risk managers must also implement continuing quality assessment and improvement programs.

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Hospital Adverse Event Reporting – Florida (continued)

- The specified serious patient injuries are:
  - Death;
  - Fetal Death;
  - Brain or Spinal Damage;
  - Permanent Disfigurement;
  - Fracture or dislocation of bones or joints;
  - A resulting limitation of neurological, physical, or sensory function which continues after discharge from the facility;
  - Any condition that required specialized medical attention or surgical intervention resulting from non-emergency medical intervention, other than an emergency medical condition, to which the patient has not given his or her informed consent; or

Hospital Adverse Event Reporting – Florida (continued)

- Any condition that required the transfer of the patient, within or outside the facility, to a unit providing a more acute level of care due to the adverse incident, rather than the patient's condition prior to the adverse incident;
- The performance of a surgical procedure on the wrong patient, a wrong surgical procedure, a wrong-site surgical procedure, or a surgical procedure otherwise unrelated to the patient's diagnosis or medical condition;
- The surgical repair or damage resulting to a patient from a planned surgical procedure, where the damage was not a recognized specific risk, as disclosed to the patient and document through the informed-consent process; or
- A procedure to remove unplanned foreign objects remaining from a surgical procedure.

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AHCA – Determining an "Adverse Incident"

- In determining whether or not an incident meets the definition of an "adverse incident" and must be reported to the Agency for Health Care Administration (Agency), facilities should answer the following questions:

  Question 1: *Did an incident occur in which a resident was injured or a specific situation existed?*

- Reportable injuries/situations (outcomes) are:
  - Death
  - Brain or spinal damage
  - Permanent disfigurement
  - Fracture or dislocation of bones or joints
  - Any condition requiring medical attention to which the resident has not given informed consent, including failure to honor advanced directives. The "informed consent" outcome applies to surgical/diagnostic procedures and treatments performed when the patient has not given informed consent. This outcome applies more to acute care patients than ALF residents. The "transfer" outcome applies under most situations when a resident is transferred to a psych or acute care hospital, including Baker Act transfers.
  - Any condition that requires the transfer of the resident, within or outside the facility, to a unit providing a more acute level of care due to the adverse incident, rather than the resident's condition prior to the adverse incident

AND

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AHCA – Determining an "Adverse Incident"

Question 2: *Is the incident in which one or more of the injuries/situations listed above occurred, an event over which the facility's staff could have had control (prevented or influenced the occurrence or extent of injury/situation to the resident)?*

AND

Question 3: *Is the incident in which one or more of the injuries/situations listed above occurred, an event that is associated completely or partly with the facility staff's intervention or lack of intervention and not the result of a pre-existing condition that the intervention was trying to correct or control*?

For example, transfer of a resident to the hospital because a pre-existing condition of heart failure worsened, is not an adverse incident if facility staff intervention or lack of intervention was not directly or indirectly related to worsening of the condition. An expected death of a hospice patient is not an adverse incident unless staff intervention or lack of intervention contributed to the death.

- If the answer to Questions 1, 2 and 3 is **YES**, or if there is insufficient information to make this determination, begin the internal investigation of the incident and submit the completed 1-Day Adverse Incident Report (initial report) to the Agency. Continue the internal investigation and within 15 days of the occurrence of the incident and submit the completed 15-Day Adverse Incident Report.

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AHCA – Determining an "Adverse Incident"

- Automatically Defined as Adverse
  - Any one of the following is automatically defined as an "adverse incident" and must be reported on the 1-Day Adverse Incident Report to the Agency within one business day of the occurrence of the incident:
    - Abuse, neglect or exploitation as defined in s. 415.102, F.S., (Vulnerable Adult)
    - Resident elopement (based on the facility's definition of elopement)
    - An event that is reported to law enforcement. (Does not include notification for Baker Act transport or required notification of a death determined to be from natural causes.)
    - Continue the internal investigation and within 15 days of the occurrence of the incident and submit the completed 15-Day Adverse Incident Report.

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AHCA – Determining an "Adverse Incident"

- **Summary**
  - For an incident to be defined as "adverse":
    - "Yes" must be answered to questions 1, 2 and 3 or
    - One or more of the following outcomes must be present:
      - Abuse, neglect or exploitation as defined in 415.102, F.S. (Vulnerable adult)
      - Abuse, neglect and harm as defined in 39.01, F.S. (Child)
      - Resident elopement (as defined by the facility)
      - An event reported to law enforcement

  For every 1-Day Adverse Incident Report submitted to the Agency, a 15-Day Adverse Incident Report must also be completed and submitted.

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AHCA Incident Reporting Guide – Hospitals, ASCs and HMOs

Annual Report

Death;
Brain or spinal damage;
Permanent disfigurement;
Fracture or dislocation of bones or joints;

A resulting limitation of neurological, physical, or sensory function which continues after discharge from the facility;

Any condition that required specialized medical attention or surgical intervention resulting from non-emergency medical intervention, other than an emergency medical condition, to which the patient has not given his or her informed consent; or

Any condition that required the transfer of the patient, within or outside the facility, to a unit providing a more acute level of care due to the adverse incident, rather than the patient's condition prior to the adverse incident;

The performance of a surgical procedure on the wrong patient, a wrong surgical procedure, a wrong-site surgical procedure, or a surgical procedure otherwise unrelated to the patient's diagnosis or medical condition;

The surgical repair or damage resulting to a patient from a planned surgical procedure, where the damage was not a recognized specific risk, as disclosed to the patient and document through the informed-consent process; or

A procedure to remove unplanned foreign objects remaining from a surgical procedure.

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AHCA Incident Reporting Guide – Hospitals, ASCs and HMOs

24 Hour Report

The death of a patient;

Brain or spinal damage to a patient;

The performance of a surgical procedure on the wrong patient;

The performance of a wrong-site surgical procedure; or

The performance of a wrong surgical procedure

Code 15 Report

The death of a patient;

Brain or spinal damage to a patient;

The performance of a surgical procedure on the wrong patient;

The performance of a wrong-site surgical procedure; or

The performance of a wrong surgical procedure;

The performance of a surgical procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition;

The surgical repair of damage resulting to a patient from a planned surgical procedure, where the damage is not a recognized specific risk, as disclosed to the patient and documented through the informed consent process; or

The performance of procedures to remove unplanned foreign objects remaining from a surgical procedure

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AHCA Incident Reporting Guide – Nursing Homes

Annual Report

Death;

Brain or spinal damage;

The performance of a surgical procedure on the wrong patient

The performance of a wrong surgical procedure

The performance of a wrong-site surgical procedure

The performance of a surgical procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition

The surgical repair of damage resulting to a patient from a planned surgical procedure, where the damage was not a recognized specific risk, as disclosed to the patient **and** documented through the informed-consent process

The performance of procedures to remove unplanned foreign objects remaining from a surgical procedure

Permanent disfigurement

Fracture or dislocation of bones or joints

A resulting limitation of neurological, physical, or sensory function which continues after discharge from the facility

Any condition that required specialized medical attention or surgical intervention resulting from non-emergency medical intervention, other than an emergency medical condition, to which the patient has not given his or her informed consent

Any condition that required the transfer of the patient, within or outside the facility, to a unit providing a more acute level of care due to the adverse incident, rather than the patient's condition prior the adverse incident

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AHCA Incident Reporting Guide – Nursing Home

Code 15 Report

Death;

Brain or spinal damage;

The performance of a surgical procedure on the wrong patient

The performance of a wrong surgical procedure

The performance of a wrong-site surgical procedure

The performance of a surgical procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition

The surgical repair of damage resulting to a patient from a planned surgical procedure, where the damage was not a recognized specific risk, as disclosed to the patient **and** documented through the informed-consent process

The performance of procedures to remove unplanned foreign objects remaining from a surgical procedure

Any of the above incidents, whether occurring in the licensed facility or arising from health care prior to admission in the licensed facility, shall be reported by the facility to the agency within 15 calendar days after its occurrence.

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The Joint Commission - JCAHO

- Patient safety-related standards
  - Almost 50 percent of Joint Commission standards are directly related to safety
  - Standards address a number of significant patient safety issues

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The Joint Commission - JCAHO

- Sentinel Event Policy
  - Implemented in 1996
  - Designed to help health care organizations identify sentinel events and take action to prevent their recurrence
  - Sentinel Event Policy also encourages organizations to report to the Joint Commission, along with their root causes and related preventive actions, so that the Joint Commission can learn about the underlying causes of the sentinel events, share "lessons learned" with other health care organizations, and reduce the risk of future sentinel event occurrences

The Joint Commission - JCAHO

- The Universal Protocol
  - In July 2003, the Joint Commission's Board of Commissioners approved the Universal Protocol for Preventing Wrong Site, Wrong Procedure and Wrong Person Surgery™.
  - The principal components of the Universal Protocol include:
    - 1) the pre-operative verification process;
    - 2) marking of the operative site;
    - 3) taking a 'time out' immediately before starting the procedure; and
    - 4) adaptation of the requirements to non-operating room settings, including bedside procedures.

The Joint Commission - JCAHO

- Office of Quality Monitoring
  - Receives, evaluates and tracks complaints and reports of concerns about health care organizations relating to quality of care issues
  - Toll free hot line, (800) 994-6610, and also receives written reports by mail or e-mail

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Federation of American Hospitals

JEFFREY G. MICKLOS, ESQ.

Jeffrey G. Micklos is the Senior Vice President, Business Operations & General Counsel of the Federation of American Hospitals, a national trade association representing investor-owned and managed community-based hospitals. Mr. Micklos serves as lead policy counsel on legal and regulatory issues involving compliance and fraud and abuse, privacy, administrative procedure, EMTALA, medical liability, tax, labor, antitrust, and accreditation. He also has senior management responsibilities for the Federation's day-to-day business affairs. In his General Counsel role, Mr. Micklos provides guidance on operational matters involving lobbying disclosures, Federal Election Commission reporting, Congressional ethics rules, employment, and contracts.

Prior to joining the Federation in October 2004, Mr. Micklos was a partner in the Health Law Department of Foley & Lardner LLP, where he advised clients on all aspects of government regulation related to their participation in federal and state health care programs and represented clients in reimbursement and certification proceedings before the U.S. Department of Health and Human Services and in federal courts. Mr. Micklos also represented clients under investigation by federal and state governments for potential compliance violations.

Prior to his private practice, Mr. Micklos was an attorney in the Health Care Financing Division, Office of General Counsel, U.S. Department of Health and Human Services, where he defended the Department in Medicare litigation before numerous federal district and appellate courts, provided advice on health care policy and fraud and abuse matters, and negotiated settlements and data sharing arrangements with large insurance companies regarding Medicare Secondary Payer issues. He has also represented the Social Security Administration in numerous federal district court and appellate Social Security disability cases.

Mr. Micklos is a member of the bars of the District of Columbia and the State of Maryland, as well as the U.S. Court of Appeals for the D.C. Circuit, and the U.S. Court of Appeals for the Ninth Circuit. He is a member of the American Health Lawyers Association, the American Bar Association/Health Law and Administrative and Regulatory Practice Sections, and the Healthcare Financial Management Association.

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J. Mark Waxman is a partner with Foley & Lardner LLP, where he is chair of the Health Care Industry Team and a member of the White Collar Defense & Corporate Compliance Practice. Mr. Waxman's health care practice focuses on health care issues for providers and payers. His experience in this area includes issues related to research and technology, integrated delivery systems, governance, strategic business counseling, the antitrust implications of mergers and acquisitions, federal program fraud and abuse, reimbursement and managed care contracting.

His litigation experience includes jury and non-jury trials and extended arbitration proceedings. These disputes have involved complex commercial, class action, regulatory, health care and technology matters in state and federal trial and appellate courts, as well as the United States Supreme Court. He has resolved significant civil and criminal investigations in a number of states around the country.

Prior to joining Foley's Boston office, Mr. Waxman was president and general counsel of CareGroup, Inc., a nonprofit healthcare system which includes the Beth Israel Deaconess Medical Center, an academic health center affiliated with the Harvard Medical School, community hospitals and multiple physician organizations. During his tenure, the CareGroup System engaged in a unique turnaround, selling non-productive assets, reformed its board structures, dealt with state and federal regulators, engaged in a refinancing, and ultimately returned to financial health and investment grade in a new confederation model of nonprofit system activity.

While at CareGroup, Mr. Waxman also served as a board member of the CRICO Captive Insurance carrier, serving on its Underwriting and Intellectual Property Committees. He also became a board member and now serves as chairman of the Picker Institute. Mr. Waxman is a former

board member of MedVentive, a managed care data and contract management company. He also serves as a volunteer mentor with the MIT Venture Mentoring Services.

Chambers, a company based in London that reviews and rates American lawyers and publishes its ratings for European and American businesses, rated Mr. Waxman to be one of the top healthcare attorneys in the state of Massachusetts for 2007. In 2006 and 2007, Mr. Waxman was named a *Massachusetts Super Lawyer,* an honor received by only 5% of Massachusetts attorneys. In 2005, Mr. Waxman was recognized as a Finalist, Entrepreneur of the Year, by Ernst & Young for the New England Region.

Prior to February of 2000, Mr. Waxman was a partner in the Los Angeles and Washington, D.C., offices of Foley & Lardner. He chaired the firm's mid-Atlantic and eastern United States health law practice. He was an assistant United States attorney for the Central District of California before associating with Foley & Lardner.

Mr. Waxman writes and lectures extensively on a variety of health care issues including medical research and technology, compliance, managed care, antitrust issues, and health care fraud and abuse. He has served as the Chairman of the ABA Health Law Section Medical Research, Technology and Ethics Subcommittee. He has been a member of the American Hospital Association's Task Force on Antitrust and Business Coalitions and of the board of directors of the American Health Lawyers Association. He is a member of the BNA Health Law Reporter Advisory Board, BNA Medical Research Law & Policy Reporter Advisory Board, IRB Advisor Editorial Board, the American Health Lawyers Association, and the Healthcare Financial Management Association, serving as Chairman of the Massachusetts Chapter Research and Education Committee.

Mr. Waxman is a graduate of Boalt Hall School of Law, University of California, Berkeley (J.D., 1973), where he was articles and book review editor of the *Ecology Law Quarterly* and the University of California, San Diego (B.A.,

summa cum laude, 1970). He was admitted to the California Bar in 1973, and the Massachusetts Bar in 2001 and is admitted to practice before the United States District Court, Central, Southern, Eastern and Northern Districts of California, the United States Court of Appeals, Eighth and Ninth Circuits, the United States Claims Court and the United States Supreme Court.

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Richard W. Johns is a partner with Foley & Lardner LLP. Mr. Johns is a member of the Health Care Industry Team, as well as the Business Counseling & Technology Practice. His clients include publicly traded, multi-national, privately held and nonprofit organizations. His health care clients include a spectrum of health care providers with an emphasis in hospitals and physicians. Mr. Johns regularly advises clients regarding regulatory and compliance issues, information technology issues, as well as various state licensing and regulatory requirements. Mr. Johns represents clients in transactional matters, mergers and acquisitions, compliance and regulatory counseling, and state and federal investigations.

Mr. Johns was among 114 attorneys nationwide who made The BTI Consulting Group's coveted Client Service All Star Team for 2005. This honor is bestowed upon individual attorneys who deliver outstanding client service according to corporate counsel interviewed at Fortune 1000 companies. This is the second consecutive year he has received the honor and is among only 14 attorneys nationwide receiving the honor two or more times. Mr. Johns has been named as one of Florida's Legal Elite™ by *Florida Trend* magazine. He has also been selected by his peers for inclusion in the 2008 edition of *The Best Lawyers in America®.*

Mr. Johns has lectured on corporate, regulatory and health care issues before many professional and trade organizations, and has frequently written on these topics. Mr. Johns' most recent article is entitled "Successor Liability in Healthcare Mergers and Acquisitions" and appeared in the *Journal of Healthcare Compliance*.

Mr. Johns graduated from the University of Southern California School of Law in 1982. He attended the University of Maryland and Harvard University, and earned his undergraduate degree in social science from

Pacific Union College (B.S., 1979).

Mr. Johns is a member of compliance and health care trade organizations. He is admitted to practice law in California, Colorado, the District of Columbia, Florida and Maryland.

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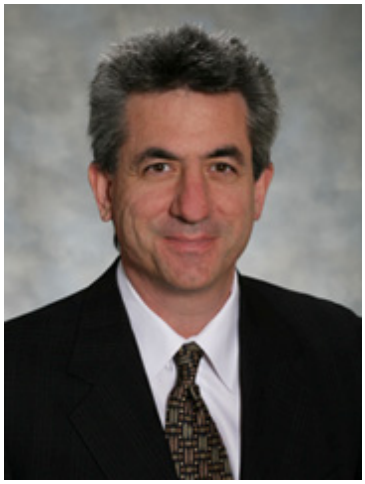

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Gary D. Koch is a partner with Foley & Lardner LLP. A member of the firm's Health Care Industry Team, his practice focuses on provider operations, fraud and abuse, compliance, litigation, and reimbursement matters.

Prior to beginning his career in law, Dr. Koch completed an internal medicine residency at Pacific Medical Center in San Francisco, California. He is a diplomate of the American Board of Internal Medicine, a fellow of the American College of Legal Medicine, and a member of the American Health Lawyers Association and the Florida Academy of Healthcare Attorneys.

Dr. Koch is a graduate of the University of California, Los Angeles, School of Law (J.D., 1989), where he was elected to the Order of the Coif, Thomas Jefferson University (M.D., 1982) and Pennsylvania State University (B.S., 1980). He was admitted to the California Bar in 1989 and The Florida Bar in 1995. He is also admitted to practice before the United States District Court, Central District of California and the Middle District of Florida.

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Tina Dunsford is senior counsel with Foley & Lardner. She is a member of the firm's Health Care Industry Team. Ms. Dunsford advises clients on managed care contracting, medical staff issues, compliance, fraud and abuse matters and physician contracting arrangements, and advises health care clients with specialized litigation including regulatory, fraud and abuse, and qui tam matters.

Prior to joining Foley, Ms. Dunsford was a shareholder at Dunsford & Associates, PA. She has also held in-house general counsel and legal counsel positions at health care entities where she advised senior management on structuring joint ventures and acquisitions; supervised federal and state health care programs; acted as company liaison at meetings and conferences with federal agencies, state agencies, political subdivisions, and advisory groups; and managed legal, compliance and litigation for 36 hospitals in 12 states.

Ms. Dunsford earned both her law degree (J.D., 1994) and her master of laws in taxation (LL.M., 1995) from Emory University School of Law. While attending law school, she was a Sol Golden Scholar. She graduated from Kennesaw State University with a bachelor's degree in business administration (1989, s*umma cum laude)*.

Ms. Dunsford is a member of the Florida State Bar and the Georgia State Bar.

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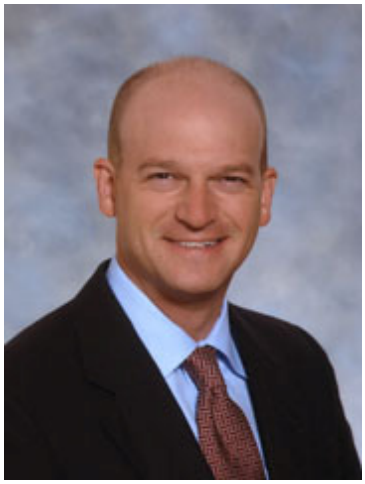

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Robert Slavkin is senior counsel with Foley & Lardner LLP and a member of the firm's Health Care and Life Sciences Industry Teams and its Business Counseling & Technology Practice.

Prior to joining Foley, Mr. Slavkin was corporate counsel and compliance and privacy officer for Priority Healthcare Corporation, where he oversaw the daily activities of the company's legal department. During his tenure, Mr. Slavkin provided detailed analysis and guidance pursuant to both FDA and state pharmacy laws, created and supervised the company's patient privacy program pursuant to HIPAA, provided general counsel regarding Stark and anti-kickback matters, and assisted in the oversight of the company's Sarbanes-Oxley compliance process. He has also worked for Adventist Health System, where he was a senior attorney focusing on home health care management, physician contracting, managed care contracting, landlord/tenant issues, HIPAA matters, fraud and abuse matters, tax issues, and appropriate corporate structures.

Mr. Slavkin recently co-authored the book "Healthcare Compliance Professional's Guide to the False Claims Act," (October 2007).

Mr. Slavkin also has experience representing long-term care providers, including guidance regarding Medicare and Medicaid issues related to billing, reimbursement, compliance, fraud, and abuse. He has extensive experience representing health care providers in reimbursement, licensure, certification and other regulatory matters, as well as provided guidance on formation of corporate entities and mergers and acquisitions. Early in his career, Mr. Slavkin interned with U.S. Senator John Heinz (Pittsburgh, Pa.).

Mr. Slavkin earned his J.D. from University of Pittsburgh School of Law. He also holds a bachelor's degree from

the University of Michigan.

Mr. Slavkin is a member of the American Health Lawyers Association and the American Bar Association. He is admitted to practice in Pennsylvania and Florida.

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Nathaniel (Nate) Lacktman, an associate with Foley & Lardner, is a member of the firm's Health Care Industry Team and the White Collar Defense & Corporate Compliance Practice.

Mr. Lacktman practices health care litigation and has focused experience in matters involving medical staff peer review, *qui tam* actions and the False Claims Act, fraud and abuse, long-term care and defense against enforcement actions by state and federal regulators. He also has experience in general business litigation, particularly for health care providers, and has represented clients in state, federal and appellate courts, administrative hearings, mediations and arbitrations.

Outside the litigation context, Mr. Lacktman advises health care clients on business and regulatory issues, including confidentiality and information sharing under HIPAA and CMIA, compliance with anti-kickback and self-referral laws, internal investigations and audits, codes of conduct, licensing and certification, medical staff credentialing, admission agreements, arbitration agreements, health care facility policies and procedures, hospital bylaws, plans of correction, patient transfer/discharge, informed consent, and mandatory reporting requirements.

Prior to joining Foley & Lardner, Mr. Lacktman was a judicial extern for the Honorable Ronald S.W. Lew of the United States District Court for the Central District of California. In 2004, he received the *Excellence in Preparation for Trial Practice Award* from the American Board of Trial Advocates. In 2007, he was one of 12 attorneys selected as Outstanding Healthcare Litigators by *Nightingale's Healthcare News*.

Pro Bono

Mr. Lacktman is committed to pro bono efforts and

community involvement. He helped a Congolese priest obtain political asylum, advised a co-op school on a parking lot easement, and counseled a non-profit residential care facility on the Patient Self Determination Act. For the past five years, he has been a volunteer judge for USC and UCLA undergraduate mock trial competitions.

Education

Mr. Lacktman received his law degree from the University of Southern California School of Law, where he was an editor for the *Hale Moot Court Honors Program*, president of the Animal Legal Protection Society, and secretary for the Asian Pacific American Law Students Association. Mr. Lacktman is a graduate of the University of Florida (B.A., *with honors*), where he was a University of Florida Scholar, member of Golden Key National Honor Society, Sigma Phi Epsilon fraternity, and recipient of Boston College's John D. Donovan Award.

Admissions and Professional Memberships

Mr. Lacktman is admitted to practice before all state and federal courts in California and the Ninth Circuit Court of Appeals. He has transferred from Foley's Los Angeles office to Tampa, where he is practicing under the supervision of a member of the Florida Bar while his application is pending.

He is a member of the American Bar Association's Health Law Litigation Committee, the American Health Lawyers Association, the Health Care Compliance Association, and the California Society for Healthcare Attorneys.

Publications

- "Hospitals Face Many Hurdles With Growing Role of Quality," *Report of Medicare Compliance* (March 24, 2008) (quoted)
- "CMS' Special Focus Facility Initiative and Nursing Home Compare," *HCCA Compliance Today* (February, 2008)

- "The Quality of Care Cerberus: Payments, Public Reporting, and Enforcement," *ABA The Health Lawyer* (December, 2007)
- "OIG Report on Board Oversight and Quality of Care: What It Means for Health Care Boards of Directors," *Legal News: Health Care* (October 16, 2007)
- "Compliance and the Quality of Care Revolution: Fitting the Pieces Together in the Government's New Enforcement Landscape," *AHLA Health Lawyers News* (September 2007)
- "Healthcare Arbitration Agreements Face New Attacks: How Providers Can Respond and Draft Effective Agreements," *California Health Law News* (Summer 2007)
- "Who's Watching? Strategic, Legal and Operational Issues for Long Term Care Facilities Considering Video Surveillance Monitoring," *ABA Health Law Litigation* (Summer 2007)
- "Another Blow to Medical Staff Peer Review Privilege," *Health Law360* (July 2, 2007)
- "Medical Staff Peer Review Privilege Is Dealt Yet Another Blow," *Health Law e-Alert* (June 20, 2007)
- "CMS Guidance Expands Emergency Services Requirements For Medicare Participating Hospitals," *Health Law e-Alert* (April 27, 2007)
- "Topical Reports," *California Health Law News* (Spring 2007)
- "Blurring the Line Between Termination and Exclusion? CMS Publishes Proposed Rule Revising Medicare Appeals Process and Implementing Three-Year Reenrollment Prohibition for Revoked Providers," *Legal News: Senior Living & Long-Term Care* (Spring 2007)
- "What's In Your Wallet? OIG Advisory Opinion Approves Credit Cards Rewards Program at Nursing Home," *Legal News: Senior Living & Long-Term Care* (Spring 2007)
- "States Address Evolving Long-Term Care Needs with Regulatory Changes and New Licensure Categories," *Legal News: Senior Living & Long-Term Care* (Spring 2007)
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Living & Long-Term Care (Spring 2007)

- "OIG Advisory Opinion Approves Credit Card Rewards Program," *Health Law e-Alert* (April 5, 2007)
- "New, Stricter CMS Requirements for Physical Restraints Have Facilities in a Bind," *Legal News: Senior Living & Long-Term Care* (Winter 2007)
- "As Many Seniors Choose Alternatives to Traditional Long-Term Care, Demand for Nursing Homes Declines," *Legal News: Senior Living & Long-Term Care* (Winter 2007)
- "Health Care Providers and the Automatic Stay: Is Medicare Termination Different than Exclusion?" *American Bankruptcy Institute Journal* (November 2006)
- "Arbitration Agreements for Health Care Providers: Recent Legal Changes and Strategies to Consider," *ABA Health Law Litigation* (Fall 2006)
- "CMS to Increase Payments for Skilled Nursing Facilities Under the Prospective Payment System by 3.1%," *Legal News: Senior Living & Long-Term Care* (Summer 2006)
- "OIG Report on Status of Nursing Home Complaint Investigations," *Legal News: Senior Living & Long-Term Care* (Summer 2006)
- "OIG Issues Report Regarding Access of Medicare Beneficiaries to Skilled Nursing Facilities Under Prospective Payment System," *Legal News: Senior Living & Long-Term Care* (Summer 2006)
- "Substantially Similar Superheroes? Marvel's Battle Against Online Game," *Intellectual Property Litigation Reporter* (December 2004)
- Mr. Lacktman has also been published in the *Entertainment Industry Litigation Reporter,* the *E-Business Law Bulletin,* and the *Software Law Bulletin*

Presentations

- "Quality of Care: Important Changes to Reimbursement and Enforcement," Foley & Lardner LLP Health Care Friday Focus Web Conference (March 28, 2008)
- "Quality of Care: Transforming Health Care Through Payment Reform, Public Reporting and

Enforcement," Healthcare Financial Management Association, Washington/Alaska Chapter (November 29, 2007)

- "Quality of Care: Transforming Health Care Through Payment Reform, Public Reporting and Enforcement," Healthcare Financial Management Association and Nebraska Hospital Association (November 1, 2007)
- "Recent Developments in Medical Staff Law: The Patient Safety and Quality Improvement Act: A New Opportunity to Protect Peer Review Information," California Association of Medical Staff Services, Long Beach Chapter (October 27, 2006)
- "Advance Health Care Directives," Beverly Hills Bar Association (March 25, 2006)