FJA ANNUAL CONVENTION: ADVANCED TRIAL SKILLS SEMINAR

New Ways to Overcome the Resistance to Amendment 7 Compliance

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Florida Constitution Art. X §25(a)(3)

(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.

Amendment 7 supersedes:

- Relevancy objections
- Burdensome objections
- Work product doctrine
- State privilege claims
- Claims of preemption under HCQIA

Morton Plant Hosp. Ass'n., Inc. v. Shahbas, 960 So. 2d 820 (Fla. 2nd DCA 2007); *Lakeland Reg'l Med. Ctr. v. Neely*, 8 So. 3d 1268 (Fla. 2d DCA 2009); *Fla. Eye Clinic v. Gmach*, 14 So. 3d 1044 (Fla. 5th DCA 2009); *Columbia Hosp. Corp. of S. Broward v. Fain*, 16 So. 3d 236 (Fla. 4th DCA 2009); *Baldwin v. Shands Teaching Hosp. and Clinics, Inc.*, 45 So. 3d 119 (Fla. 1st DCA 2010); *W. Florida Reg'l Med. Ctr., Inc. v. See*, 79 So. 3d 1 (Fla. 2012).

Latest Developments

S. Baptist v. Charles, 178 So. 3d 102 (Fla. 1st DCA 2015)

- First DCA held Amendment 7 preempted by the Patient Safety and Quality Improvement Act (PSQIA)
- Adopted the dissent in *Tibbs v. Bunnell*, 448 S.W.3d 796 (Ky. 2014)
- Florida Supreme Court, Oral Argument, Oct. 5, 2016

Latest Developments

Tibbs v. Bunnell, 448 S.W.3d 796 (Ky. 2014)

- 3/18/15 – Providers petitioned U.S. Supreme Court for cert.
- 10/5/15 – SCOTUS asks Solicitor General for views of the U.S.
- 5/24/16 – SG files amicus brief with views of the U.S.
- 5/24/16 – HHS issues new guidance clarifying 2008 rule
- TOMORROW (6/23/16) – SCOTUS considers petition at conference
- MONDAY (6/27/16) -- Likely decision on cert. petition released

Sec. 921 Definitions

(7) PATIENT SAFETY WORK PRODUCT.

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

(i) which—

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

(II) are developed by a patient safety organization for the conduct of patient safety activities; and which could result in improved patient safety, health care quality, or health care outcomes; or

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

Sec. 921 Definitions

(B) CLARIFICATION.—

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

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

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

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

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

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

Sec. 921 Subparagraph (B)

(iii) **Nothing in this part [this Act] shall be construed to limit**—

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

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

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

Sec. 921 Subparagraph (B)

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

Sec. 921 Subparagraph (B)

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

PSQIA Legislative History

- "It is not the intent of this legislation to establish a legal shield for information that is already currently collected or maintained separate from the new patient safety process . . . [I]nformation which is currently available to plaintiffs' attorneys or others will remain available just as it is today."

  151 Cong. Rec. S8741 (daily ed. July 22, 2005) (statement of Sen. Enzi, Chair, Health, Education, Labor and Pensions Committee).

- 2003 Senate Report on which the First District relied was written before the clarification language in subparagraph (B) was added to the bill.

2008 PSQIA Regulatory Guidance

73 Fed. Reg. 70732 (Nov. 21, 2008) (codified at 42 C.F.R. Pt. 3)

- No-duplication guidance: "[P]roviders need not maintain duplicate systems to separate information to be reported to a PSO from information that may be required to fulfill state reporting obligations. All of this information, collected in one [PSES], is protected as [PSWP] unless the provider determines that certain information must be removed from the [PSES] for reporting to the state."
- BUT: "Even when laws or regulations require the reporting of the information regarding the type of events also reported to PSOs, the [PSQIA] does not shield providers from their obligation to comply with such requirements. These external obligations must be met with information that is not [PSWP] . . . ."

2008 PSQIA Regulatory Guidance

81 Fed. Reg. 32,655 (May 24, 2016)

Providers are misusing the PSQIA

"[S]ome providers may be attempting to misuse the [PSQIA] protections to avoid their external obligations—in particular, to circumvent Federal or state regulatory obligations. . . .[S]ome providers with recordkeeping or record maintenance requirements appear to be maintaining the required records only in their [PSE system] and then refusing to disclose the records, asserting that the records in their [PSE system] fulfill the applicable regulatory requirements while at the same time maintaining that the records are privileged and confidential [patient safety work product]. . . .The [PSQIA] was not intended to give providers such methods to evade their regulatory obligations."

2008 PSQIA Regulatory Guidance

81 Fed. Reg. 32,655 (May 24, 2016)

Records required by state or federal law not privileged

"The intent of [the Act is] . . . not to protect records created through providers' mandatory information collection activities. For example, a provider may have an external obligation to maintain certain records about **serious adverse events that result in patient harm**. The document the provider prepares to meet its requirement about such adverse events is **not PSWP**."

State-mandated information

Internal risk management program **must** include:

- "[T]he investigation and analysis of the frequency and causes of . . . adverse incidents to patients."
- "[A]n incident reporting system based upon the affirmative duty of all health care providers . . . to report adverse incidents to the risk manager."
- "[A] system for informing a patient" that she "was the subject of an adverse incident."

Section 395.1097, Florida Statutes.

State-mandated information

Internal risk management reports:

- 3-day reports – not submitted to AHCA, but must be made available to AHCA upon request
- Code-15 reports – submitted to AHCA
- Annual Reports – submitted to AHCA

Sections 395.002, 395.1097, Florida Statutes; Fla. Admin Code R. 59A-10.0055(3)(b)

State-mandated information

Peer-review, medical review and root-cause analyses:

- Peer-review – Baptist admitted these are not PSWP
- Medical review committees – "complaints," "advisory report," "factual findings," and "judgment"
- Root-cause analyses

Sections 395.093, 766.101, 395.1097, Florida Statutes

Costs and Constitutional Right to Access

(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.

Florida Constitution Art. X §25(a)(4)

Creative Ideas

- **Separate declaratory action:**
  - Patient has stand-alone constitutional right to A7 records
  - This will enable immediate appeal
- **Spoliation of evidence**: seek sanctions or a jury instruction asking for an adverse inference or shifting the burden of proof. *Fla. Standard Civil Jury Instructions 301.11, 402.4d; League of Women Voters of Fla. v. Detzner*, 172 So. 3d 363, 391 (Fla. 2015).
- **FJA Database:** Central storage location to analyze records

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