Amendment 7

Current State of the Law and Strategies on How to Conduct Your Investigation

Joseph P. Menello
Partner
Wicker, Smith, O'Hara, McCoy & Ford, P.A.

Overview

- Federal peer review before Amendment 7: The Health Care Quality Assurance Improvement Act of 1986 (HCQIA)
- Peer Review in Florida before Amendment 7
- The Paradigm Shift: Passage of Amendment 7
- The Buster decision
- Federal Law Steps In: The Patient Safety and Quality Improvement Act of 2005 (PSQIA)
- The Edwards Decision
- The Charles Decision
- The Future of Amendment 7 and Peer Review

Peer Review Before Amendment 7

- Prior to reform initiatives like Amendment 7, Congress recognized the importance of peer review early on by requiring hospitals to implement peer review as a prerequisite to participating in Medicare.
  42 U.S.C. §1320c – 3(a)
- Congress also provided peer review protections of medical programs offered by the Department of Defense and the Department of Veteran's Affairs.
  10 U.S.C. § 1102
- In 1986, Congress passed the Health Care Quality Improvement Act in an attempt to extend state peer review immunities on a federal level.

The Health Care Quality Assurance Improvement Act of 1986 (HCQIA) 42 U.S.C. § 11101

Professional review bodies shall not be liable in damages under any law of the US or any State. No person providing information shall be liable in damages unless the person knew the information was false.

Peer Review Under HCQIA

- Under HCQIA, immunity is qualified.
- It mandates that peer review be conducted as follows:
    1. In the reasonable belief that the action was in furtherance of quality of care;
    2. After a reasonable effort to obtain the facts of the matter;
    3. 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
    4. In the reasonable belief that the action was warranted by the facts known after such reasonable effort to obtain facts.

42 U.S.C. §§ 11112(a)-(1)-(4)

Medical Peer Review in Florida Before Amendment 7

Prior to the passage of Amendment 7, Florida maintained multiple statutes that restricted patients' rights to medical providers' adverse incidence reports and gave hospitals and ambulatory surgical centers the right to regulate themselves through peer review committees, immune from liability

– Fla. Stat. §766.101 (2014)

All of this changed with the passage of Amendment 7…

- Amendment 7, also known as the "Patients' Right to Know about Adverse Medical Incidents," was a constitutional amendment approved by the voters in the November 2004 general election
- The purpose of Amendment 7 was to create a right for patients and potential patients to have access to a health care facility's or medical provider's adverse medical incident reports

Amendment 7 Codified

- In June of 2005, the Florida legislature codified Amendment 7 as Florida Statute §381.028 in an attempt to set the parameters of Amendment 7's application (i.e. provide guidance as to what was discoverable; who could make requests for records; the use of records; and production of records)
- Constitutional challenges to the new statute immediately followed…

Post Amendment 7 Legal Developments in Florida

- Florida Statutes § 381.028 provided for the following contours for Amendment 7:
  - It was not retroactive.
  - It did not preempt existing peer review and quality assurance privileges.
  - It was limited in scope to adverse medical incidents involving patients, and to others whose conditions are either the same or substantially similar to the patient.

Florida Hospital Waterman v. Buster

- In March 2008, the Florida Supreme Court issued the opinion of Florida Hospital Waterman, Inc. v. Buster, 984 So.2d 478 (Fla. 2008), which consolidated the cases of Florida Hospital Waterman, Inc. v. Buster, 932 So. 2d 344 (Fla. 5th DCA 2006) and Notami Hospital of Florida v. Bowen, 927 So. 2d 139 (Fla. 1st DCA 2006), and made the following findings:
  - Amendment 7 is self-executing;
  - Amendment 7 applies retroactively; and
  - Amendment 7 contained several unconstitutional subsections, which when severed would leave intact a workable statute.

Florida Hospital Waterman v. Buster

- The following restrictions were held unconstitutional and were severed from the statute:
  1. Language only allowing for final reports to be discoverable;
  2. Language only providing for disclosure of final reports relating to the same or a substantially similar condition, treatment, or diagnosis with that of the patient requesting access;
  3. Language limiting production of only those records generated after November 2, 2004;

Florida Hospital Waterman v. Buster

4. Language stating it would have no effect on existing privilege statutes;
5. Language providing that patients can only access the records of the facility or provider of which they themselves are a patient; and
6. Language providing that 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.

Florida Hospital Waterman v. Buster

- What Buster did not do:
  - The peer review protections were still in place, except for documents;
  - Participants were still not being identified in the process; and
  - The participants were immune from civil liability.
  - Remember: Buster was all about documents.

The Patient Safety and Quality Improvement Act of 2005 (42 U.S.C. § 299b-21)

- The Patient Safety Rule was the Regulation that implemented select provisions of the Patient Safety and Quality Improvement Act of 2005 (PSQIA)
- Published on November 21, 2008, and became effective on January 19, 2009
- Brought on by the growing fear of discovery of peer deliberations, resulting in under-reporting of events and inability to aggregate sufficient patient safety event data for analysis

The Patient Safety and Quality Improvement Act of 2005 (42 U.S.C. § 299b-21)

- The Act allowed each provider or member to establish a patient safety evaluation system (PSE system) in which relevant information would be collected and reported to a Patient Safety Organization (PSO)
- PSOs would collect, aggregate, and analyze confidential information reported by health care providers to the PSE system

The Patient Safety and Quality Improvement Act of 2005 (42 U.S.C. § 299b-21)

PSQIA Attached privilege and confidentiality protections to information submitted to PSOs deemed Patient Safety Work Product (PSWP), with the aim of improving patient safety and the quality of care nationwide

The Patient Safety and Quality Improvement Act of 2005 (42 U.S.C. § 299b-21)

- Patient Safety Work Product means any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements, which:
  - Are assembled or developed by a provider for reporting to a PSO and are reported to a PSO; or
  - Are developed by a PSO for the conduct of patient safety activities; and which could result in improved patient safety, health care quality, or certain healthcare outcomes; or
  - Which identify or constitute the deliberations or analysis of, or identify the facts of reporting pursuant to, a patient safety evaluation system.

The Patient Safety and Quality Improvement Act of 2005 (42 U.S.C. § 299b-21)

- The Act also defines what is ***NOT*** work product:
  - A patient's medical record, billing and discharge information, or any other original patient or provider record.
  - Information collected, maintained, or developed separately, or existing separately, from a PSE system. Information reported to a PSO shall not, by reason of its reporting, be considered patient safety work product.

The Patient Safety and Quality Improvement Act of 2005 (42 U.S.C. § 299b-21)

- The Act makes clear that the definition of PSWP should not be construed to relieve a provider's duty to respond to Federal, State, or local law obligations with information that is not privileged or confidential

42 U.S.C. §299b-21(7)(B)(iii)

The Patient Safety and Quality Improvement Act of 2005 (42 U.S.C. § 299b-21)

- Addresses three problems in the state peer review protection system by:
  - Creating a uniform national system of protections;
  - Encouraging sharing of information; and
  - Preventing circumvention through filing of a claim in federal court

Bartow HMA, LLC v. Edwards

On July 10, 2015, in Bartow HMA, LLC v. Edwards, 175 So.3d 820 (Fla. 2d DCA 2015), the Second District Court of Appeals held that reports relating to "attorney requested *external* peer review" do not fall within the ambit of Amendment 7 and are therefore privileged

Bartow HMA, LLC v. Edwards

- In this medical malpractice claim, Plaintiff requested the Hospital produce:
  - All documents created within the five years before her surgery relating to the Hospital's investigation or review of her treating doctor's care and treatment of any patient; and
  - All documents pertaining to the Hospital's investigation or review of her care and treatment.

Bartow HMA, LLC v. Edwards

The Hospital responded:

- Amendment 7 only provides patients the right to access records received in the course of business by a health care facility or a health care provider relating to adverse medical incidents; and
- The external peer review reports were not made or received in the course of business because they were generated in response to letters sent by the Hospital's counsel to the director of client services at a business called "M.D. Review."

Bartow HMA, LLC v. Edwards

The Second District held the ***external*** peer review reports were not within the ambit of Amendment 7 because:

- The reports were not "made or received in the course of business" under Amendment 7 because they were made for purposes of litigation rather than to fulfill a statutory duty; and
- The reports were not adverse medical incidents under Amendment 7 because "M.D. Review" did not perform the routine function of reviewing medical incidents but instead provided expert opinions on standard of care on sporadic occasions when litigation was imminent.

What does Edwards mean?

- Reports relating to attorney requested *external* peer review do not fall under the ambit of Amendment 7 and are privileged
- External peer review reports used in the regular course of business would be subject to Amendment 7

What does Edwards mean?

While documents may be titled "Peer Review Report," it is the substance and context of the reports that determine whether or not they are discoverable under Amendment 7

Creating a protection for external peer review reports does not circumvent the disclosure requirement of Amendment 7 when there is also access to documents pertaining to *internal* adverse incident reporting and peer review

Southern Baptist Hosp. of Florida, Inc. v. Charles

On October 28, 2015, in Southern Baptist Hosp. of Florida, Inc. v. Charles, 178 So.3d 102 (Fla. 1st DCA 2015) the First District Court of Appeals held that Amendment 7 is preempted by the federal Patient Safety and Quality Improvement Act

Southern Baptist Hosp. of Florida, Inc. v. Charles

- In Charles, Marie Charles' brother, as Plaintiff, brought this medical negligence action against Southern Baptist Hospital on Marie's behalf.
- Plaintiff filed three requests to produce pursuant to Amendment 7, requesting documents that:
  - Related to adverse medical incidents; and
  - Either related to any physician who worked for Baptist or arose from the care and treatment rendered by Baptist during the 3-year period precluding Marie's care and treatment and through the date of the third request.

Southern Baptist Hosp. of Florida, Inc. v. Charles

- Baptist produced 2 occurrence reports specific to Marie's care along with Annual Reports and Code 15 Reports.
- Baptist refused to produce other occurrence reports claiming they were privileged and confidential under the act.

Southern Baptist Hosp. of Florida, Inc. v. Charles

Plaintiff moved to compel production, arguing the Act only protects documents created ***solely*** for the purpose of submission to a PSO and does not constitute PSWP if it was collected or maintained for a ***dual purpose*** or is in any way related to a healthcare provider's obligation to comply with Federal, State, or local laws or accrediting or licensing requirements.

- i.e. PSWP is removed and the documents are stripped of Federal protection if they are also required to be produced under a state statute, rule, licensing provision, or accreditation requirement

Southern Baptist Hosp. of Florida, Inc. v. Charles

- Regarding the Act's Federal preemption of Amendment 7, the First District held:
  - The Act **expressly** preempts Amendment 7, based on its specific language:
    - "Notwithstanding any other provision, of Federal, State, or local law…[PSWP] shall be privileged"; and
    - PSWP is not subject to disclosure in various ways including discovery in connection with Federal, State, or local civil, criminal, or administrative proceeding

Southern Baptist Hosp. of Florida, Inc. v. Charles

- The Act also **impliedly** preempts Amendment 7, because compliance with both Federal and State law would be impossible.
- Documents that meet the definition of PSWP under the ACT are categorically protected and excluded from production.
- To produce PSWP in response to Amendment 7 discovery request would be in contravention of the Act.

Southern Baptist Hosp. of Florida, Inc. v. Charles

- Regarding the “dual purpose” of the documents:
  - The plain language of the Act expressly defines what is PSWP, what is NOT PSWP, and makes clear that the definition of PSWP should not be construed to relieve a provider’s duty to respond to Federal, State, or local law obligations with information that is not privileged and confidential.
  - The Act does not state that a document may not simultaneously be PSWP and also meet a state reporting requirement – Federal protection and state compliance do not have to be mutually exclusive.

Southern Baptist Hosp. of Florida, Inc. v. Charles

- Chief Judge L. Clayton wrote the opinion and noted that the purpose of the Act was to replace a “culture of blame” and punishment with a “culture of safety” that emphasizes communication and cooperation.

  (S. Rep. No. 108-196, at 2 (2003))

The Future of Charles

- On November 2, 2015, Respondent Charles filed a Motion for Certification to the First District citing:
  - A direct conflict with the Fourth DCA's unpublished opinion in Bethesda Hosp. Inc. v. Gomez-Colombo
  - A question of great public importance
- Rehearing was denied on November 24, 2015

The Future of Charles

- On November 25, 2015, Plaintiff appealed to the Supreme Court of Florida
- On December 15, 2015, in response, Baptist filed a Motion to Dismiss the Appeal
  - On February 5, 2016, the Supreme Court of Florida denied Baptist's Motion to Dismiss

The Future of Charles

- To date, the Florida Supreme Court has yet to rule on Appellants' Motion for Certification; however, Appellants' initial brief has been filed, as well as three amicus curiae briefs in support of Appellants by the following parties:
  - The American Association of Retired Persons (AARP)
  - The Florida Consumer Action Network (FCAN)
  - The Florida Justice Association (FJA)

What does Charles mean?

- A document is PSWP if it is placed into a PSE system for reporting to a PSO
- The Act gives the Healthcare Provider the flexibility to collect and maintain its information in the manner it chooses – the provider determines how information is stored and reported
  - CAUTION: nothing should be construed to limit any reporting or recordkeeping requirements under state of federal law

What does Charles mean?

- The solution to any “gamesmanship” of allowing a provider to potentially dump everything into a PSE system in an effort to evade discovery is not to allow someone to “rummage through” the provider’s PSE system
- The solution is to address the noncompliance of recordkeeping or reporting obligations

What does Charles mean?

- Absent an allegation that a provider is in some way in noncompliance with its reporting or recordkeeping requirements, there is no need for a court to consider whether documents at issue simultaneously satisfy any state law obligations

Protecting Investigations Moving Forward

- The Current Trend:
  - Less is being protected
  - It is a Constitutional Amendment
  - Plaintiffs are trying to expand beyond paper discovery to depositions – pending appeal in the Second DCA

Protecting Investigations Moving Forward

- What can be done to protect investigations:
  - PSOs
  - External Peer Review
  - Educate those who prepare the reports about what is and what is not required to be included
  - Avoid unnecessary commentary and opinions
  - Think about how it may be (mis)interpreted in litigation

QUESTIONS

For more information, contact:
JMenello@wickersmith.com