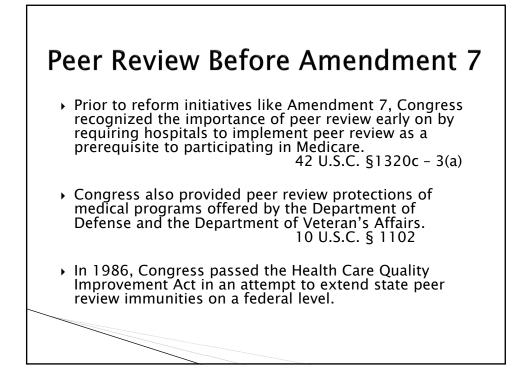
Amendment 7

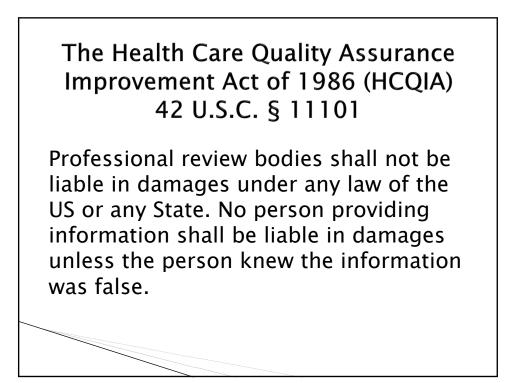
Current State of the Law and Strategies on How to Conduct Your Investigation

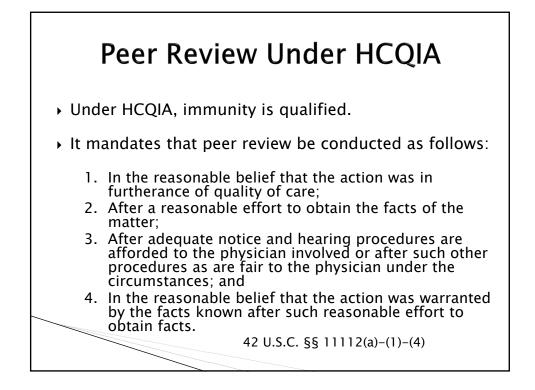
Joseph P. Menello

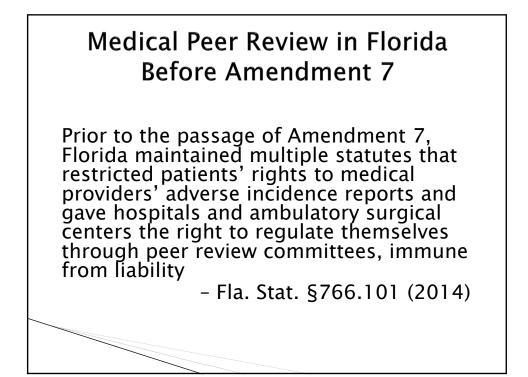
Partner Wicker, Smith, O'Hara, McCoy & Ford, P.A.

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 <u>Buster</u> decision Federal Law Steps In: The Patient Safety and Quality Improvement Act of 2005 (PSQIA) The <u>Edwards</u> Decision The <u>Charles</u> Decision The Future of Amendment 7 and Peer Review



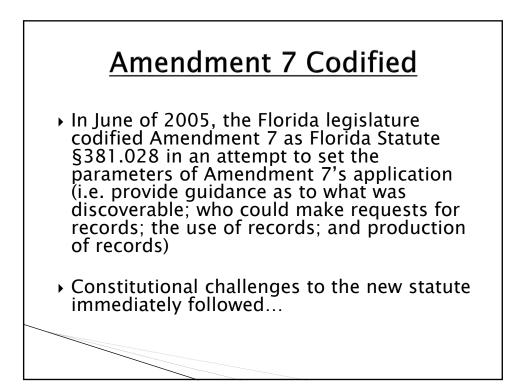


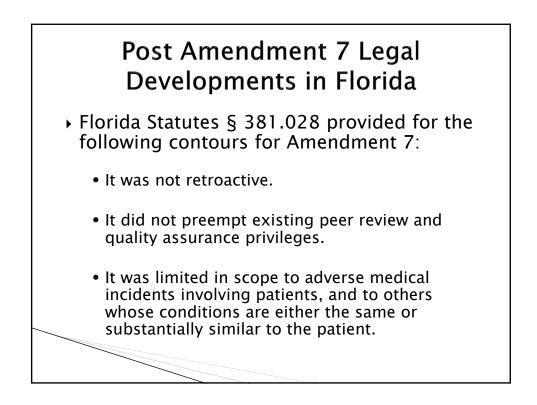


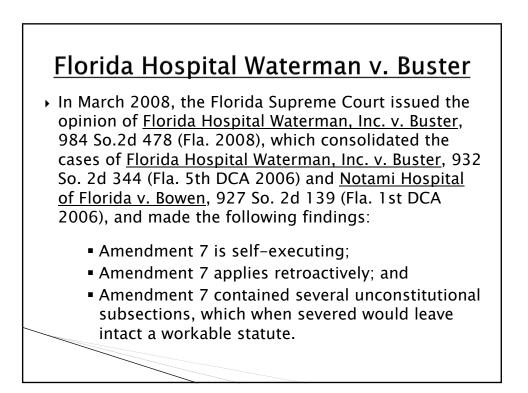


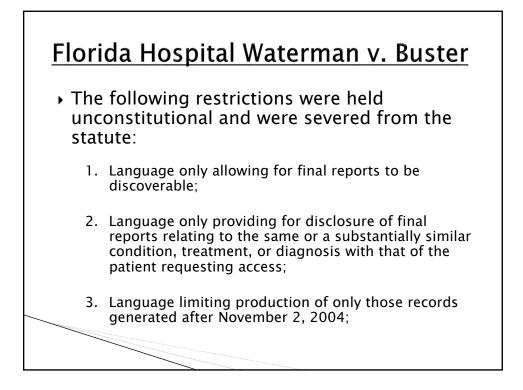
All of this changed with the passage of Amendment 7...

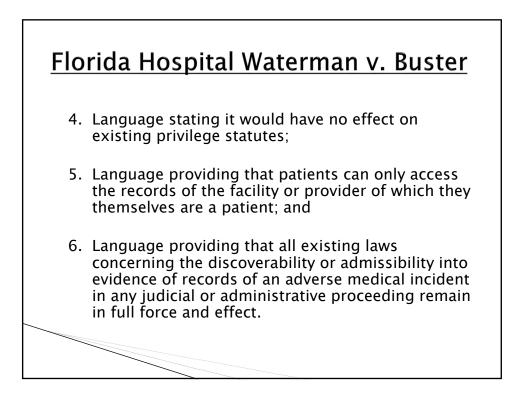
- Amendment 7, also known as the "Patients' Right to Know about Adverse Medical Incidents," was a constitutional amendment approved by the voters in the November 2004 general election
- The purpose of Amendment 7 was to create a right for patients and potential patients to have access to a health care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

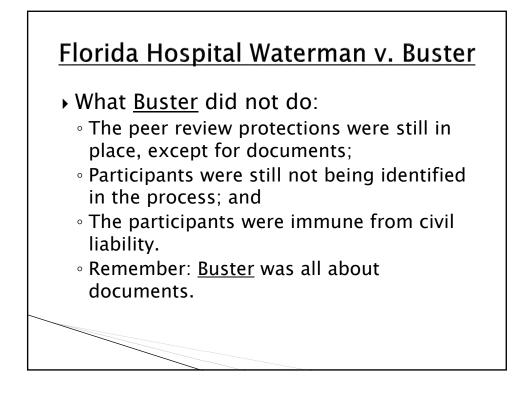












The Patient Safety Rule was the Regulation that implemented select provisions of the Patient Safety and Quality Improvement Act of 2005 (PSQIA)

>Published on November 21, 2008, and became effective on January 19, 2009

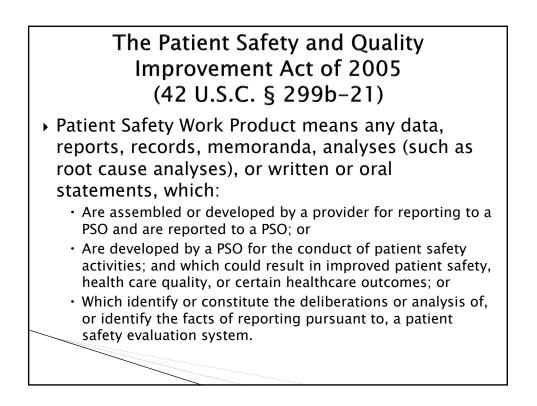
Brought on by the growing fear of discovery of peer deliberations, resulting in under-reporting of events and inability to aggregate sufficient patient safety event data for analysis

 The 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 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 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

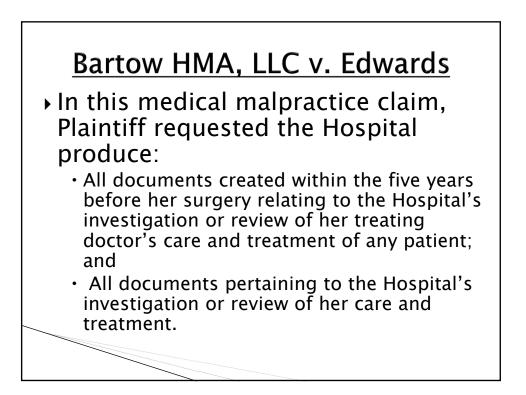
42 U.S.C. §299b-21(7)(B)(iii)

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;
 - \circ Encouraging sharing of information; and
 - Preventing circumvention through filing of a claim in federal court

Bartow HMA, LLC v. Edwards

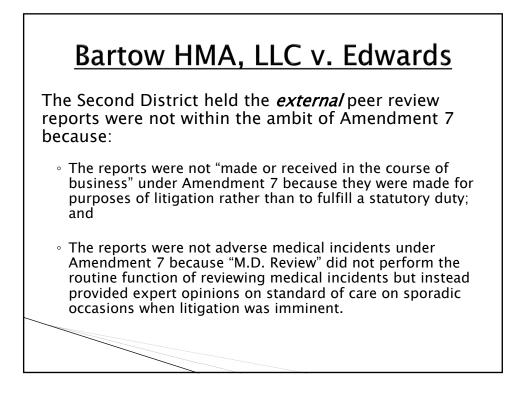
On July 10, 2015, in <u>Bartow HMA, LLC v.</u> <u>Edwards</u>, 175 So.3d 820 (Fla. 2d DCA 2015), the Second District Court of Appeals held that reports relating to "attorney requested *external* peer review" do not fall within the ambit of Amendment 7 and are therefore privileged

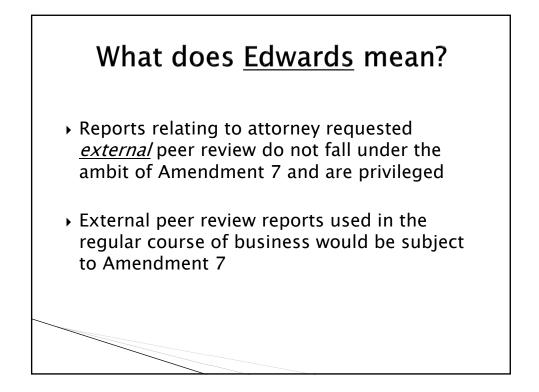


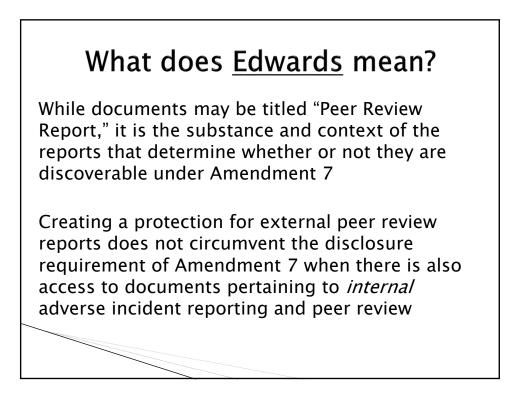
Bartow HMA, LLC v. Edwards

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."





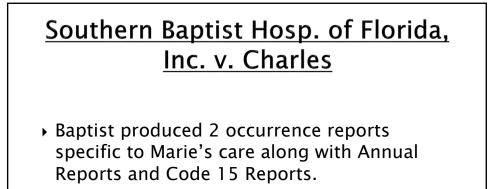


<u>Southern Baptist Hosp. of Florida,</u> <u>Inc. v. Charles</u>

On October 28, 2015, in <u>Southern</u> <u>Baptist Hosp. of Florida, Inc. v. Charles</u>, 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 <u>Charles</u>, 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.

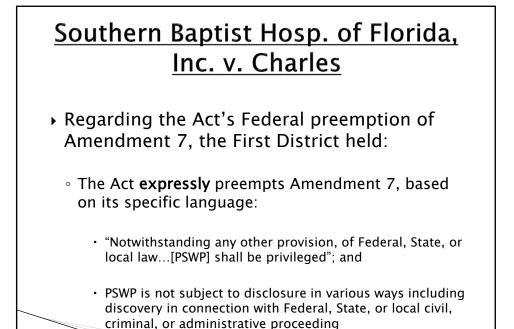


 Baptist refused to produce other occurrence reports claiming they were privileged and confidential under the act.

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.

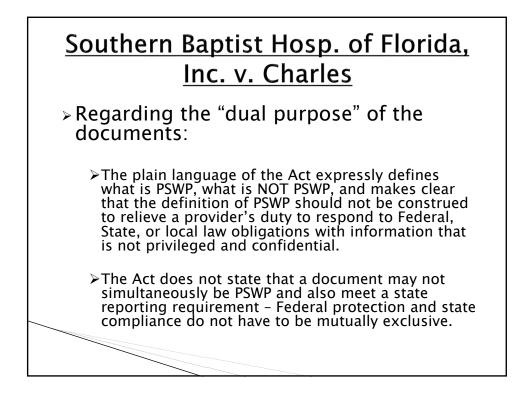
• i.e. PSWP is removed and the documents are stripped of Federal protection if they are also required to be produced under a state statute, rule, licensing provision, or accreditation requirement



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

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.



<u>Southern Baptist Hosp. of Florida,</u> 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))

