

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL: SB 716

INTRODUCER: Senator Book

SUBJECT: Consent for Pelvic Examinations

DATE: March 16, 2021

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Brown	HP	Pre-meeting
2.	_____	_____	JU	_____
3.	_____	_____	RC	_____

I. Summary:

SB 716:

- Amends and simplifies the definition of “pelvic examination;”
- Amends current law requiring written consent for all pelvic examinations performed by health care practitioners and trainees to require written consent only for anesthetized or unconscious patients, with exceptions;
- Directs that written consent for a pelvic examination may be obtained as part of a general consent form if it has its own provision on the form; and
- Directs that one written consent form may be used to authorize multiple health care practitioners or students to perform a pelvic examination.

The bill provides an effective date of July 1, 2021.

II. Present Situation:

The Department of Health

The Legislature created the Department of Health (DOH) to protect and promote the health of all residents and visitors in the state.¹ The DOH is charged with the regulation of health practitioners for the preservation of the health, safety, and welfare of the public. The Division of Medical Quality Assurance (MQA) is responsible for the regulatory boards² and professions within the DOH.³

¹ Section 20.43, F.S.

² Under s. 456.001(1), F.S., the term “board” is defined as any board, commission, or other statutorily created entity, to the extent such entity is authorized to exercise regulatory or rulemaking functions within the DOH or, in some cases, within the DOH, MQA.

³ Section 20.43, F.S.

Pelvic Examinations

In Florida, allopathic and osteopathic physicians, autonomous advanced practice registered nurses (autonomous APRNs), APRNs working under a protocol with a supervising physician which includes a pelvic examination, licensed midwives, and physician assistants supervised by a physician whose practice includes pelvic examinations, may perform pelvic examinations and are subject to regulation by their respective board or council.⁴

Pelvic Examinations on Unconscious or Anesthetized Patients

In recent years, articles have detailed reports of medical students performing pelvic examinations, without consent, on women who are anesthetized.⁵ This practice has been common since the late 1800s, and in 2003, a study reported that 90 percent of medical students who completed obstetrics and gynecology rotations at four Philadelphia-area hospitals performed pelvic examinations on anesthetized patients for educational purposes.⁶

Several medical organizations have taken positions that pelvic examinations under anesthesia by students in a teaching environment should require the patient's informed consent:

- The American Medical Association Council on Ethical and Judicial Affairs recommends that, in situations where the patient will be temporarily incapacitated (e.g., anesthetized) and where student involvement is anticipated, involvement should be discussed before the procedure is undertaken, whenever possible.⁷
- The Association of American Medical Colleges, reversing its prior policy position, offered that “performing pelvic examinations on women under anesthesia, without their knowledge or approval ... is unethical and unacceptable.”⁸
- The Committee on Ethics of the American College of Obstetricians and Gynecologists resolved that “pelvic examinations on an anesthetized woman that offer her no personal

⁴ *Supra*, note 2; and chs. 458, 459, 464, and 467, F.S.

⁵ For examples, see: Paul Hsieh, *Pelvic Exams on Anesthetized Women Without Consent: A Troubling and Outdated Practice*, FORBES (May 14, 2018), available at <https://www.forbes.com/sites/paulhsieh/2018/05/14/pelvic-exams-on-anesthetized-women-without-consent-a-troubling-and-outdated-practice/#74d152df7846> (last visited Mar. 8, 2021); Dr. Jennifer Tsai, *Medical Students Regularly Practice Pelvic Exams on Unconscious Patients. Should They?*, ELLE (June 24, 2019), available at <https://www.elle.com/life-love/a28125604/nonconsensual-pelvic-exams-teaching-hospitals/> (last visited Mar. 8, 2021); Lorelei Laird, *Pelvic Exams Performed without Patients' Permission Spur New Legislation*, ABA JOURNAL (Sept. 2019), available at <http://www.abajournal.com/magazine/article/examined-while-unconscious> (last visited Mar. 8, 2020); and Amanda Eisenberg, *New Bills Would Ban Pelvic Exams without Consent*, POLITICO (March, 2019), available at <https://www.politico.com/states/new-york/albany/story/2019/03/13/new-bills-would-ban-pelvic-exams-without-consent-910976> (last visited Mar. 8, 2021).

⁶ John Duncan, Dan Luginbill, Matthew Richardson, Robin Fretwell Wilson, *Using Tort Law to Secure Patient Dignity: Often Used as Teaching Tools for Medical Students, Unauthorized Pelvic Exams Erode Patient Rights, Litigation Can Reinstate Them*, 40 TRIAL 42 (Oct. 2004), available at https://www.researchgate.net/publication/256066192_Using_Tort_Law_to_Secure_Patient_Dignity (last visited Mar. 8, 2021).

⁷ AMA Council on Ethical and Judicial Affairs, *Medical Student Involvement in Patient Care: Report of the Council on Ethical and Judicial Affairs*, AMA Journal of Ethics (March 2001), available at <https://journalofethics.ama-assn.org/article/medical-student-involvement-patient-care-report-council-ethical-and-judicial-affairs/2001-03> (last visited Mar. 8, 2021).

⁸ Robin Fretwell Wilson, *Autonomy Suspended: Using Female Patients to Teach Intimate Exams Without Their Knowledge or Consent*, 8 J OF HEALTH CARE LAW AND POLICY 240, available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=880120 (last visited Mar. 8, 2021).

benefit and are performed solely for teaching purposes should be performed only with her specific informed consent obtained before her surgery.”⁹

Forty-two states do not require the informed consent to pelvic examinations under anesthesia by students and residents. California, Hawaii, Illinois, Iowa, Maryland, Oregon, Utah, and Virginia prohibit unauthorized pelvic examinations.¹⁰

The Association of American Medical Colleges (AAMC) has found that most teaching hospitals inform patients that trainees will be involved in their care and, generally, patients approve of the trainees’ involvement.¹¹ The chief health care officer for the AAMC notes that recent articles on unauthorized pelvic examinations rely on studies from more than 10 years ago and before more detailed informed consent forms were used.¹² Typically, students and residents practice pelvic examinations with special mannequins and standardized patients who are specifically trained for this purpose.¹³

Informed Consent

Informed consent for medical treatment is fundamental in both ethics and law.¹⁴ Informed consent is a process in which a health care provider educates a patient about the risks, benefits, and alternatives of a given procedure or intervention.¹⁵ A patient must be competent to make a voluntary decision about whether to undergo a procedure.

The idea of informed consent was established in 1914 in a case in which a patient was operated on without her consent.¹⁶ In determining whether she had a cause of action against the hospital in which the operation was formed, the judge in the case opined that “every human being of adult years and sound mind has a right to determine what shall be done to his own body, and a surgeon who performs an operation without his patient’s consent commits an assault, for which he is liable for damages.”¹⁷

⁹ American College of Obstetricians and Gynecologists, Committee on Ethics, *Professional Responsibilities in Obstetric-Gynecologic Medical Education and Training* (Aug. 2011), available at <https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Ethics/Professional-Responsibilities-in-Obstetric-Gynecologic-Medical-Education-and-Training?IsMobileSet=false> (last visited Mar. 8, 2021).

¹⁰ Lorelei Laird, *Pelvic Exams Performed without Patients’ Permission Spur New Legislation*, ABA JOURNAL (September 2019), available at <http://www.abajournal.com/magazine/article/examined-while-unconscious> (last visited Mar. 8, 2021).

¹¹ Stacy Weiner, *What “Informed Consent” Really Means* (Jan. 24, 2019), available at <https://www.aamc.org/news-insights/what-informed-consent-really-means> (last visited Mar. 8, 2021).

¹² *Id.*

¹³ See note 11.

¹⁴ American Medical Association, *Informed Consent: Code of Medical Ethics Opinion 2.1.1*, available at <https://www.ama-assn.org/delivering-care/ethics/informed-consent> (last visited Mar. 8, 2021).

¹⁵ William Gossman, Imani Thornton, John Hipskind, *Informed Consent* (Aug. 22, 2020), available at <https://www.ncbi.nlm.nih.gov/books/NBK430827/> (last visited Mar. 8, 2021).

¹⁶ *Schloendorff v. Society of N.Y. Hosp.*, 105 N.E. 92, 93 (N.Y. 1914).

¹⁷ *Id.*

Florida Requirements for Informed Consent

In Florida the only general law on medical consent appears in ch. 766, F.S., Medical Malpractice and Related matters.¹⁸ However, Florida physicians and physicians practicing within a postgraduate training program approved by the Board of Medicine (BOM) and the Board of Osteopathic Medicine (BOOM) must explain the medical or surgical procedure to be performed to the patient and obtain the informed consent of the patient. The physician is not required to obtain or witness the signature of the patient on a written form evidencing informed consent, and there is no requirement that the patient must use a written document, although hospitals and facilities where procedures are performed typically require consent in writing.^{19,20}

In 2020 the Florida Legislature created s. 456.51, F.S., *Consent for pelvic examination*,²¹ in response to media reports that medical students may be performing pelvic examinations on anesthetized or unconscious women without obtaining informed consent from the woman prior to anesthesia or from any other person who can provide consent.²²

Section 456.51(1), F.S., defines a “pelvic examination” to include a series of tasks that encompass an examination of the vagina, cervix, uterus, fallopian tubes, ovaries, rectum, or external pelvic tissue or organs using any combination of modalities, which may include, but need not be limited to, the health care provider’s gloved hand or instrumentation. Under current law, a health care practitioner, medical student, or any other student receiving training as a health care practitioner is not permitted to perform a pelvic examination on a patient without the written consent of the patient or the patient’s legal representative, executed specific to, and expressly identifying, the pelvic examination, unless:

- A court orders the performance of the examination for the collection of evidence; or
- The pelvic examination is immediately necessary to avert a serious risk of imminent substantial and irreversible physical impairment of a major bodily function.

Following the enactment of ch. 2020-31, s. 3, Laws of Florida (2020), conflicts in the medical community arose as to how the law’s language should be interpreted, and a Petition for

¹⁸ Section 766.103, F.S., provides: No recovery shall be allowed in any court in this state against any physician, chiropractor, podiatric physician, dentist, APRN, or PA in an action brought for treating, examining, or operating on a patient without his or her informed consent when: 1) The action of the practitioner in obtaining the consent of the patient, or another person authorized to give consent for the patient, was in accordance with an accepted standard of medical practice among members of the medical profession with similar training and experience in the same or similar medical community; and 2) A reasonable person, from the information provided under the circumstances, would have a general understanding of the procedure, the medically acceptable alternative procedures or treatments, and the substantial risks and hazards inherent in the proposed treatment or procedures, recognized among practitioners in the same or similar community who perform similar treatments or procedures; or 3) The patient would reasonably, under all the surrounding circumstances, have undergone the treatment or procedure had he or she been advised by practitioner in accordance with the provisions of the first.

¹⁹ Fla. Adm. Code R. 64B8-9.007, and 64B15-14.006 (2019).

²⁰ See The Joint Commission, Advisory on Safety Issues, Issue 21, (Feb. 2016), *Informed Consent: More than Getting a Signature*, available at https://www.jointcommission.org/-/media/tjc/documents/newsletters/quick_safety_issue_twenty-one_february_2016pdf.pdf (last visited Mar. 8, 2021).

²¹ CS/CS/SB 698, Ch. 2020-31, s. 3, Laws of Fla.

²² See New York Times, *She Didn’t Want a Pelvic Exam. She Received One Anyway*, Feb 17, 2020, updated Feb. 19, 2020, available at <https://www.nytimes.com/2020/02/17/health/pelvic-medical-exam-unconscious.html> (last visited Mar. 8, 2021).

Declaratory Statement²³ was filed with the Florida Board of Medicine (BOM), requesting a determination of:

- Whether the definition of pelvic examination applies only to female patients or to males as well;
- Whether performance of surgery on the vagina, cervix, uterus, fallopian tubes, ovaries, rectum, or external pelvic tissue or organs constitutes a pelvic examination;
- Whether a discrete visual examination of the vagina, cervix, uterus, fallopian tubes, ovaries, rectum, or external pelvic tissue or organs constitutes a pelvic examination;
- Whether a pelvic examination requires separate written consents every time a pelvic exam was performed during a course of treatment; and
- Whether a pelvic examination in emergent circumstances required a written consent when the patient or a legal representative were unable to give consent.

The BOM, in a Final Order²⁴ to a Petition for Declaratory Statement filed by numerous physician organizations, answered the above questions regarding what constitutes a pelvic examination under s. 456.51, F.S., as follows:

- A pelvic examination applies only to female patients;
- Surgery on the vagina, cervix, uterus, fallopian tubes, ovaries, rectum, or external pelvic tissue or organs does not constitute a pelvic examination; and
- Discrete visual examination of the vagina, cervix, uterus, fallopian tubes, ovaries, rectum, or external pelvic tissue or organs does not constitute a pelvic examination.

The BOM declined to answer the questions regarding informed consent.

III. Effect of Proposed Changes:

SB 716:

- Amends and simplifies the definition of “pelvic examination” to include an examination of the organs of the female internal reproductive system;
- Amends current law requiring written consent for all pelvic examinations performed by health care practitioners, medical students, and trainees, to require written consent only for anesthetized or unconscious patients, and provides three exceptions:
 - A court order;
 - Necessity due to the need for emergency care; or
 - When the exam is indicated as part of the standard of care for a procedure for which written consent has already been given.
- Directs that written consent for a pelvic examination may be obtained as part of a general consent form if it is included as its own provision on the form; and
- Directs that one written consent form may be used to authorize multiple health care practitioners or students to perform a pelvic examination.

The bill provides an effective date of July 1, 2021.

²³ See Florida Department of Health, Board of Medicine, Final Order NO DOH-20-1553-DS-MQA filed Oct. 9, 2020, available at https://s3.amazonaws.com/thenewsserviceofflorida/web/dist/downloads/2020/10/DOH_20-1553_DS_Doug_Murphy_FMA_etc_1.pdf (last visited Mar. 8, 2021).

²⁴ *Id.*

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 456.51 of the Florida Statutes.

IX. Additional Information:

- A. **Committee Substitute – Statement of Changes:**
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

- B. **Amendments:**

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.
