

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 1470

INTRODUCER: Senator Book

SUBJECT: Informed Consent for Pelvic Examinations

DATE: February 17, 2020

REVISED: _____

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

I. Summary:

SB 1470 creates s. 456.51, F.S., and:

- Requires health care providers to obtain a patient’s informed consent, or the informed consent of the patient’s representative, for an examination of the patient’s pelvic region while the patient is under anesthesia or unconscious, with exceptions;
- Requires the use of a separate written or electronic document for pelvic examinations under anesthesia or while the patient is unconscious with specific formatting and content requirements;
- Requires the patient’s written informed consent to the presence of, or pelvic examinations by, students or residents for educational or training purposes; and
- Permits a patient to revoke or amend the consent, verbally or in writing, at any time before being anesthetized or rendered unconscious.

The bill has an effect date of July 1, 2020.

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

¹ Section 20.43, F.S.

Quality Assurance (MQA) is responsible for the regulatory boards² and professions within the DOH.³

In Florida, allopathic and osteopathic physicians, advanced practice registered nurses (APRNs) working under a protocol with a supervising physician that includes 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

The pelvic examination is an integral part of a women's annual well-woman examination,⁵ labor and child birth, and the evaluation of numerous abnormal gynecological and obstetrical conditions.⁶ It remains an important skill necessary for medical and nursing students to master before becoming physicians or APRNs. Pelvic examinations, both in the office and while under anesthesia, are also a crucial component of a physician's preoperative evaluation for gynecologic procedures to ensure safe completion of a planned procedure. Pelvic examination skills are, therefore, very important for physicians across specialties and must continue to be taught and mastered during undergraduate medical education.⁷

A pelvic examination involves the visual and physical examination of the female external and internal genitalia.⁸ A health care practitioner may also perform a pelvic exam to diagnose specific health conditions, such as cancer and bacterial vaginosis.⁹

New clinical guidelines have recommended against pelvic examinations on asymptomatic, non-pregnant, adult women.¹⁰ Routine pelvic examination has not been shown to benefit such women

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.

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

⁵ A pelvic examination usually involves an examination of woman's vulva, vagina, uterus, ovaries, and fallopian tubes. It may also include examination of the bladder and the rectum. Melissa Conrad Stoppler, MD, *Pelvic Exam*, MedicineNet, available at https://www.medicinenet.com/pelvic_exam/article.htm#why_is_a_pelvic_exam_performed (last visited Feb. 12, 2020).

⁶ Hammoud, Maya M. MD, MBA; Spector-Bagdady, Kayte JD, MBE; O'Reilly, Meg MD, MPH; Major, Carol MD; Baecher-Lind, Laura MD, MPH, Obstetrics & Gynecology, *Consent for the Pelvic Examination Under Anesthesia by Medical Students*, December 2019 - Volume 134 - Issue 6 - p 1303-1307, available at https://journals.lww.com/greenjournal/Fulltext/2019/12000/Consentfor_the_Pelvic_Examination_Under.24.aspx (last visited Feb. 12, 2020).

⁷ *Id.*

⁸ The female "external genitalia" includes the labia minora and majora (the vulva), and the clitoris. The female "internal genitalia" includes the ovaries, fallopian tubes, uterus, cervix, and vagina. William C. Shiel Jr., MD, FACP, FACR, *Medical Definition of Female genitalia*, MedicineNet, available at <https://www.medicinenet.com/script/main/art.asp?articlekey=33682> (last visited Feb. 12, 2020).

⁹ Amir Qaseem, et al., *Screening Pelvic Examination in Adult Women: A Clinical Practice Guideline from the American College of Physicians*, 161 *Ann Intern Med* 67 (2014), available at https://annals.org/aim/fullarticle/1884537/screening-pelvic-examination-adult-women-clinical-practice-guideline-from-american?_ga=2.7498674.1663533724.1580510917-1215329083.1580510917 (last visited Feb. 12, 2020).

¹⁰ *Supra* note 9. This recommendation does not apply to pap smears.

in that it rarely detects important disease and does not reduce mortality.¹¹ Several harms have been identified for the performance of pelvic examinations, including fear, anxiety, embarrassment, pain, and discomfort.¹² Other physical harms include urinary tract infections and symptoms such as dysuria and frequent urination.¹³

However, benefits of routine pelvic examinations include early detection of treatable gynecologic conditions before symptoms occur and incidental findings such as dermatologic changes and foreign bodies.¹⁴ It also gives the health care practitioner an opportunity to establish open communication with the patient to answer specific questions and reassure her of normalcy.¹⁵

The American College of Obstetricians and Gynecologists finds that data is currently insufficient to make a recommendation for or against routine pelvic examinations.¹⁶ Therefore, it recommends that pelvic examinations be performed when indicated by medical history or symptoms, such as abnormal bleeding, pelvic pain, or urinary issues.¹⁷

Informed Consent

Informed consent for medical treatment is fundamental in both ethics and law.¹⁸ 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.¹⁹ A patient must be competent to make a voluntary decision about whether to undergo a procedure. Foregoing the process of consent within medicine can result in violations of both autonomy and basic rights, as well as trust.²⁰

The idea of informed consent was established in 1914 in a case in which a patient was operated on without her consent.²¹ 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

¹¹ American College of Physicians, *American College of Physicians Recommends Against Screening Pelvic Examinations in Adult, Asymptomatic, Average Risk, Non-Pregnant Women* (July 1, 2014), available at <https://www.acponline.org/acp-newsroom/american-college-of-physicians-recommends-against-screening-pelvic-examination-in-adult-asymptomatic> (last visited on Feb. 12, 2020).

¹² *Id.*

¹³ *Supra* note 11.

¹⁴ American College of Obstetricians and Gynecologists, Committee on Gynecologic Practice, *ACOG Committee Opinion, Number 754*, 132(4) *OBSTETRICS & GYNECOLOGY* 174 (October 2018), available at <https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/The-Utility-of-and-Indications-for-Routine-Pelvic-Examination?IsMobileSet=false> (last visited Feb. 12, 2020).

¹⁵ *Id.*

¹⁶ *Supra* note 14.

¹⁷ *Supra* note 14.

¹⁸ 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 Feb. 12, 2020).

¹⁹ William Gossman, Imani Thornton, John Hipskind, *Informed Consent* (July 10, 2019), available at <https://www.ncbi.nlm.nih.gov/books/NBK430827/> (last visited Feb. 12, 2020).

²⁰ Phoebe Friesen, *Educational Pelvic Exams on Anesthetized Women: Why Consent Matters (Abstract)*, 32 *BIOETHICS* 298 (April 23, 2018), available at <https://onlinelibrary.wiley.com/doi/abs/10.1111/bioe.12441> (last visited Feb. 12, 2020).

²¹ *Schloendorff v. Society of N.Y. Hosp.*, 105 N.E. 92, 93 (N.Y. 1914).

who performs an operation without his patient's consent commits an assault, for which he is liable for damages."²²

Florida Requirements for Informed Consent

The only general law in Florida on medical consent appears in ch. 766, F.S., Medical Malpractice and Related matters.²³ 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.^{24, 25}

Pelvic Examinations of Patients Under Anesthesia

In recent years, articles have detailed reports of medical students performing pelvic examinations, without consent, on women who are anesthetized.²⁶ 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.²⁷

²² *Id.*

²³ 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.

²⁴ Fla. Adm. Code R. 64B8-9.007, and 64B15-14.006 (2019).

²⁵ See The Joint Commission, Hospital National Patient Safety Goals, (effective Jan. 1, 2020), *Introduction to the Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery*, pp.14-15, available at https://www.jointcommission.org/-/media/tjc/documents/standards/national-patient-safety-goals/npsg_chapter_hap_jan2020.pdf (last visited Feb. 13, 2020). The same standard applies to Ambulatory Health Care facility accreditation, available at https://www.jointcommission.org/-/media/tjc/documents/standards/national-patient-safety-goals/npsg_chapter_ahc_jan2020.pdf (last visited Feb. 12, 2020).

²⁶ 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 Feb. 12, 2020); 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 Feb. 13, 2020); 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 Feb. 13, 2020); and Amanda Eisenberg, *New Bills Would Ban Pelvic Exams without Consent*, POLITICO (March 14, 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 Feb. 12, 2020).

²⁷ 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

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.²⁸
- 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.”²⁹
- 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 benefit and are performed solely for teaching purposes should be performed only with her specific informed consent obtained before her surgery.”³⁰

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.³¹

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.³² 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.³³ Typically, students and residents practice pelvic examinations with special mannequins and standardized patients who are specifically trained for this purpose.³⁴

https://www.researchgate.net/publication/256066192_Using_Tort_Law_to_Secure_Patient_Dignity (last visited Feb. 13, 2020).

²⁸ 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 Feb. 13, 2020).

²⁹ 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 Feb. 13, 2020).

³⁰ American College of Obstetricians and Gynecologists, Committee on Ethics, *Professional Responsibilities in Obstetric-Gynecologic Medical Education and Training* (August 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 Feb. 13, 2020).

³¹ 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 Feb. 13, 2020).

³² Stacy Weiner, *What “Informed Consent” Really Means* (January 24, 2019), available at <https://www.aamc.org/news-insights/what-informed-consent-really-means> (last visited Feb. 13, 2020).

³³ Id.

³⁴ See note 32.

III. Effect of Proposed Changes:

SB 1470 creates s. 456.51, F.S., requiring health care providers to obtain a patient's informed consent, or the informed consent of the patient's representative, for an examination of the patient's pelvic region while the patient is under anesthesia or unconscious, unless:

- The health care provider obtains written consent from the patient, or the patient's representative, with specific formatting and content requirements;
- A court orders performance of the pelvic examination for the collection of evidence;
- The performance of the pelvic examination is within the scope of care for a procedure or diagnostic examination scheduled to be performed on the patient; or
- The pelvic examination is immediately necessary for diagnosis and treatment of the patient.

The bill defines several terms. The term "health care provider" includes those providers defined in s. 456.001, F.S., and adds paramedics and emergency medical technicians certified under part III of ch. 401, F.S. The term "pelvic examination" means a medical examination that requires contact with the patient's sexual organs.

Under the bill, for a health care practitioner to obtain a patient's informed consent to a pelvic examination under anesthesia, or while the patient is unconscious, the health care provider must provide the patient, or the patient's representative, with a written or electronic document, that is separate from any other notice or agreement, and contains a heading at the top in at least 18-point bold type that states: "CONSENT FOR EXAMINATION OF PELVIC REGION," and must:

- Specify the nature and purpose of the pelvic examination;
- List the names and titles of all health care providers whom the patient, or the patient's representative, has authorized to perform a pelvic examination on the patient;
- State whether the patient, or the patient's representative, has authorized students or residents, for educational and training purposes, to:
 - Perform any additional pelvic examinations;
 - Observe or be present at the pelvic examination, either in person or electronically.
- Include a series of check-off boxes that allow the patient, or the patient's representative, to:
 - Consent to the pelvic examination;
 - Withhold consent to the pelvic examination;
 - Consent to the presence of students or residents for educational or training purposes;
 - Withhold consent to the presence of students or residents for educational or training purposes;
 - Consent to additional pelvic examinations by students or residents for educational or training purposes;
 - Withhold consent to any additional pelvic examinations by students or residents for educational or training purposes.
- Be signed by the patient, or the patient's representative, and witnessed by a third party; and
- Be signed by the health care practitioner.

A patient may revoke or amend consent, verbally or in writing, at any time before being anesthetized or rendered unconscious.

A student or resident may not observe or perform a pelvic examination on a patient unless the health care practitioner has obtained a fully executed informed consent form which indicates the patient's consent to the presence of, or pelvic examination by, the student or resident. If a patient consents to a student or resident's observation of, or performance of, a pelvic examination before the patient is anesthetized and rendered unconscious, the health care provider must:

- Notify the patient of the name of each student or resident who will be observing or performing a pelvic examination; and
- Inform the patient of the patient's right to amend or revoke the consent.

A health care provider who fails to comply with the bill's requirements is subject to discipline by the applicable board, or the DOH if there is no board.

The bill provides an effective date of July 1, 2020.

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:

The DOH has not provided an analysis of SB 1470, but for a similar bill, HB 1289, the DOH reported that it may experience an increase in workload associated with additional complaints, investigations, and prosecutions, which current resources are adequate to absorb.³⁵

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates 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.

³⁵ Department of Health, *House Bill 1289 Analysis* (January 27, 2020), companion bill to SB 1470 (on file with the Senate Committee on Health Policy).