

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: CS/SB 1470

INTRODUCER: Health Policy Committee and Senator Book

SUBJECT: Informed Consent

DATE: February 20, 2020

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Brown	HP	Fav/CS
2.	_____	_____	JU	_____
3.	_____	_____	RC	_____

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1470 creates s. 456.51, F.S., and prohibits a health care provider from performing any examination of, or providing medical care or treatment to, a patient, with or without anesthesia, without first obtaining the patient's written informed consent or the written informed consent of the patient's representative, with exceptions.

The bill prohibits an attending health care practitioner from allowing medical or nursing students, resident physicians, interns, or fellows in fellowship training, from observing or participating in the patient's care or treatment while under anesthesia, with exceptions including the patient's, or the patient's legal representative's, written informed consent on forms with specific disclosures and requirements.

The bill permits the patient to revoke his or her consent verbally or in writing and provides for discipline of practitioners by the applicable regulatory boards or the Department of Health for violations.

The bill provides an effective 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 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 who's practice includes pelvic examinations, may perform pelvic examinations and are subject to regulation by their respective board or council.⁴

Examinations Under Anesthesia

An examination under anesthesia (EUA) is any operative or invasive procedure done while the patient is sedated, in order to improve patient tolerance, alleviate pain or anxiety, or improve the quality of the exam.⁵ There are many types of EUAs.

One of the most common is the pelvic examination under anesthesia. It is an integral part of a women's annual well-woman examination,⁶ labor and child birth, and the evaluation of numerous abnormal gynecological and obstetrical conditions.⁷ 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.⁸

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.

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

⁵ Farlex, The Free Medical Dictionary, *Examination Under Anesthesia*, available at <https://medical-dictionary.thefreedictionary.com/examination+under+anesthesia> (last visited Feb. 19, 2020).

⁶ 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).

⁷ 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).

⁸ *Id.*

Another common EUA is the eye examination under anesthesia done to diagnose different eye problems in children and adults. The eye EUA is especially safer and easier for children because a child will be asleep while the doctor uses bright lights and instruments near or on the eyes. This is often an outpatient procedure.⁹

Another common EUA is typically carried out on a patient that may have signs of bladder Cancer. A urologist, is a healthcare provider who specializes in bladder cancer and other health conditions related to the urinary tract. The procedure allows urologists to feel the bladder from the inside of the patient's body to check for signs of tumors. It also allows the urologist to carry out a more thorough physical exam of the outer surface of the bladder than is possible during a digital rectum exam or pelvic exam.¹⁰

Informed Consent

Informed consent for medical treatment is fundamental in both ethics and law.¹¹ 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.¹² 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.¹³

The idea of informed consent was established in 1914 in a case in which a patient was operated on without her consent.¹⁴ 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.”¹⁵

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.¹⁶ However, Florida physicians and physicians practicing within

⁹ University of Pennsylvania Medical Center, Children's Hospital of Pittsburgh, *Eye Examination Under Anesthesia*, available at <https://www.chp.edu/our-services/ophthalmology/ophthalmology-patient-procedures/eye-examination-under-anesthesia> (last visited Feb. 19, 2020).

¹⁰ American Cancer Society, *Tests for Bladder Cancer*, available at <https://www.cancer.org/cancer/bladder-cancer/detection-diagnosis-staging/how-diagnosed.html> (last visited Feb. 19, 2020).

¹¹ 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).

¹² 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).

¹³ 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).

¹⁴ *Schloendorff v. Society of N.Y. Hosp.*, 105 N.E. 92, 93 (N.Y. 1914).

¹⁵ *Id.*

¹⁶ 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

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.^{17, 18}

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.¹⁹ 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.²⁰

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.²¹

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.

¹⁷ Fla. Adm. Code R. 64B8-9.007, and 64B15-14.006 (2019).

¹⁸ 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).

¹⁹ 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).

²⁰ 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 Feb. 13, 2020).

²¹ 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).

- 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.”²²
- 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.”²³

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.²⁴

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.²⁵ 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.²⁶ Typically, students and residents practice pelvic examinations with special mannequins and standardized patients who are specifically trained for this purpose.²⁷

III. Effect of Proposed Changes:

CS/SB 1470 creates s. 456.51, F.S., and prohibits a health care provider from performing any examination, or providing medical care or treatment, to a patient, with or without anesthesia, without first obtaining the patient’s written informed consent, or the written informed consent of the patient’s representative, unless;

- A court orders the performance of an examination of or the provision of medical care or treatment to the patient, with or without anesthesia; or
- The performance of an examination or the provision of medical care or treatment is medically necessary to diagnose or treat the patient in a medical emergency.

The bill prohibits an attending health care practitioner from allowing medical or nursing students, resident physicians, interns, or fellows in fellowship training from observe or participate in the patient’s care or treatment while under anesthesia, unless:

²² 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).

²³ 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).

²⁴ 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).

²⁵ 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).

²⁶ Id.

²⁷ See note 32.

- A court orders the performance of an examination of or the provision of medical care or treatment to the patient, with or without anesthesia;
- The performance of an examination or the provision of medical care or treatment is medically necessary to diagnose or treat the patient in a medical emergency; or
- The attending health care practitioner obtains a separate written informed consent form from the patient, or the patient's legal representative, authorizing the medical or nursing students, resident physicians, interns, or fellows in fellowship training to:
 - Be present and observe only; or
 - Participate in the examination of or provision of medical care or treatment to the patient.

The separate written informed consent form must include:

- The name and title of the patient's attending health care practitioner;
- The name and title of any supervising medical educator;
- A statement that any observation or participation in the patient's medical care or treatment will be:
 - Directly related to the patient's diagnosis and medical care and treatment plan;
 - Part of medical research being conducted; or
 - Part of the clinical training being provided.
- A series of check boxes that allow the patient or the patient's legal representative to indicate whether he or she consents or withholds consent to:
 - The presence of students to observe the examination of or the provision of medical care and treatment to the patient while under anesthesia is for the purpose of conducting medical research or receiving clinical training; or
 - The participation of the students in the examination of or provision of medical care and treatment to the patient while anesthesia is for the purpose of conducting medical research or receiving clinical training.
- Three signature lines:
 - One for the patient or the patient's legal representative;
 - One for the attending health care practitioner, and
 - One for the supervising medical educator, if different from the attending health care practitioner.

The bill permits a patient to revoke or amend his or her consent, verbally or in writing, at any time before the procedure begins or before the anesthesia is administered, whichever occurs earlier.

If a patient consents to have medical or nursing students, resident physicians, interns, or fellows observe or participate in the examination of or the provision of medical care or treatment to the patient while under anesthesia, the patient's attending health care practitioner must:

- Inform the patient of his or her right to amend or revoke his or her consent at any time before the procedure begins or before anesthesia is administered, whichever occurs earlier; and
- Document in the patient's medical record the name of each medical or nursing student, resident physician, intern, or fellow who observed or participated in the examination of or the provision of medical care or treatment to the patient while the patient was under anesthesia.

The bill provides for discipline by the applicable board, or the department if there is no board, of a patient's attending health care practitioner and a supervising medical educator, if different from the attending health care practitioner, if either fails to comply with the informed consent requirements.

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:

None.

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 Substantial Changes:**
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on February 19, 2020:

The CS expands the underlying bill's requirement for informed consent by prohibiting a health care practitioner from performing any examination of, or providing medical care or treatment to, a patient, with or without anesthesia, unless the health care practitioner first obtains written informed consent from the patient or the patient's legal representative. The underlying bill applied only to pelvic examinations of an unconscious patient or a patient under anesthesia.

- B. **Amendments:**

None.