

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1289 Informed Consent for Pelvic Examinations

SPONSOR(S): Jenne

TIED BILLS: **IDEN./SIM. BILLS:** SB 1470

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Siples	McElroy
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

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. Such information will enable a patient to make a competent decision about whether to undergo a procedure or treatment.

Recently, news outlets have reported that medical students may be performing pelvic examinations on anesthetized or unconscious women, without obtaining informed consent from the woman prior to anesthesia or any other person who can provide consent. This practice had been standard since the 1800s, but in recent years the practice has been met with disapproval by professional medical associations. The American Association of Medical Colleges does not believe that this is a widespread practice, as many institutions have implemented comprehensive informed consent processes.

HB 1289 prohibits a health care provider from performing a pelvic examination on an unconscious or anesthetized patient without consent unless an exception applies. The bill requires a health care provider to obtain consent for a pelvic examination from the patient prior to the patient being anesthetized or rendered unconscious by providing the patient or patient's representative a written or electronic document that:

- Specifies the nature and purpose of the pelvic examination;
- List the name and titles of the health care providers authorized to perform the pelvic examination;
- States whether a student or resident is authorized to perform an additional pelvic examination or to observe or be present during a pelvic examination, for educational or training purposes;

A health care provider who fails to obtain the required informed consent is subject to discipline by the Department of Health. A health care provider does not have to obtain informed consent if the pelvic examination is required by a court order, is within the scope of the services for a procedure or diagnostic examination scheduled for the patient; or is immediately necessary for diagnosis and treatment of the patient.

The bill has an insignificant, negative fiscal impact on the Department of Health, which current resources are sufficient to absorb. The bill has no fiscal impact on local governments.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Informed Consent

Informed consent for medical treatment is fundamental in both ethics and law.¹ 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.² 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.³

The idea of informed consent was established in 1914, in a case in which a patient was operated on without her consent.⁴ In determining whether she had a cause of action against the hospital in which the operation was formed, Judge Cardozo 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.”⁵

Florida Requirements for Informed Consent

Florida law does not contain a general statute on informed consent. However, Florida physicians and physicians practicing within a postgraduate training program approved by the Board of Medicine must explain the medical or surgical procedure to be performed to the patient and obtain the informed consent of the patient.⁶ However, the physician does not have to obtain or witness the signature of the patient on a written form evidencing informed consent.

Pelvic Examinations

A pelvic examination involves the visual examination of the external genitalia and an internal visual examination of the vaginal walls and cervix using a speculum and palpation of the pelvic organs.⁷ Health care practitioners often perform pelvic examinations as a part of the annual well woman visit.⁸ A health care practitioner may also perform a pelvic examination 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 in

¹ 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 January 31, 2020).

² William Gossman, Imani Thornton, John Hipkind, *Informed Consent*, (July 2019), available at <https://www.ncbi.nlm.nih.gov/books/NBK430827/> (last visited January 31, 2020).

³ Phoebe Friesen, *Educational Pelvic Exams on Anesthetized Women: Why Consent Matters (Abstract)*, 32 *BIOETHICS* 298 (June 2018), available at <https://onlinelibrary.wiley.com/doi/abs/10.1111/bioe.12441> (last visited January 31, 2020).

⁴ *Schloendorff v. Society of N.Y. Hosp.*, 105 N.E. 92, 93 (N.Y. 1914).

⁵ *Id.*

⁶ Rule 64B8-9.007, F.A.C.

⁷ *Id.* 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 January 31, 2020).

⁸ 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 January 31, 2020).

⁹ *Id.*

¹⁰ *Supra* note 8. This recommendation does not apply to pap smears.

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

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 or unconscious.¹⁸ 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.¹⁹

Several medical organizations have taken positions that pelvic examinations should not be performed on anesthetized or incapacitated:

- 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.²⁰

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 January 31, 2020).

¹² Id.

¹³ Id.

¹⁴ American College of Obstetricians and Gynecologists, Committee on Gynecologic Practice, *ACOG Committee Opinion, Number 754*, 132(4) OBSTETRICS & GYNECOLOGY 174 (Oct. 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 January 31, 2020).

¹⁵ Id.

¹⁶ Id.

¹⁷ Id.

¹⁸ 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 January 31, 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 January 31, 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 January 31, 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 January 31, 2020).

¹⁹ 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).

²⁰ 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 (Mar. 2001), available at <https://journalofethics.ama-assn.org/article/medical-student-involvement-patient-care-report-council-ethical-and-judicial-affairs/2001-03> (last visited January 31, 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.”²¹
- 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.”²²

California, Hawaii, Illinois, Iowa, Maryland, Oregon, Utah, and Virginia prohibit unauthorized pelvic examinations.²³

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.²⁴ 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. ²⁵Typically, students and residents practice pelvic examinations with special mannequins and standardized patients who are specifically trained for this purpose.²⁶

Effect of Proposed Changes

HB 1289 prohibits a health care provider²⁷ from performing a pelvic examination on an unconscious or anesthetized patient without consent unless an exception applies. The bill defines pelvic examination as a medical examination that requires contact with a patient’s sexual organs.

A health care provider must obtain consent for a pelvic examination from the patient prior to the patient being anesthetized or rendered unconscious by providing the patient or patient’s representative a written or electronic document that:

- Is separate from any other notice or agreement;
- Contains the heading “CONSENT FOR EXAMINATION OF THE PELVIC REGION” in an 18-point bold font type;
- Specifies the nature and purpose of the pelvic examination;
- List the name and titles of the health care providers authorized by the patient or patient’s representative to perform the pelvic examination;
- States whether the patient or patient’s representative authorizes a student or resident to perform an additional pelvic examination or to observe or be present during a pelvic examination, in person or through electronic means, for educational or training purposes;
- Allows the patient or the patient’s representative to indicate, using checkboxes, for one of the following:
 - Consent to the pelvic examination for diagnosis or treatment and to the presence of or additional examination performed by a student or resident for educational or training purposes;
 - Consent to the pelvic examination only for diagnosis or treatment; or

²¹ 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 January 31, 2020).

²² 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 January 31, 2020).

²³ 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 January 31, 2020).

²⁴ 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 on January 31, 2020).

²⁵ Id.

²⁶ Id.

²⁷ The bill defines health care provider as a health care practitioner, as defined in 456.003, F.S., or a paramedic or emergency medical technician certified under part III of ch. 401, F.S.

- Refuse to consent to the pelvic examination.

The patient or patient's representative and the health care provider must sign the consent document, in writing or electronically.

The bill does not require a health care provider to obtain consent for a pelvic examination from a patient or patient's representative if:

- A court orders a pelvic examination be performed to collect evidence;
- The pelvic examination is within the scope of the services for a procedure or diagnostic examination scheduled for the patient; or
- The pelvic examination is immediately necessary for diagnosis and treatment of the patient.

Any health care provider who fails to get consent as required is subject to licensure discipline by the applicable regulatory board or the Department of Health, if there is no board.

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

B. SECTION DIRECTORY:

Section 1: Creates s. 456.51, F.S., relating to health care providers; consent for pelvic examinations.

Section 2: Provides an effective date of July 1, 2020.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

DOH may experience an increase in workload associated with additional complaints, investigations, and prosecutions, which current resources are adequate to absorb.²⁸

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

²⁸ Department of Health, *2020 Agency Legislative Bill Analysis for HB 1289*, (Jan. 27, 2020), on file with the Health Quality Subcommittee.

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES