

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** CS/HB 1289 Informed Consent for Pelvic Examinations

**SPONSOR(S):** Health Quality Subcommittee, Jenne

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

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	13 Y, 0 N, As CS	Siples	McElroy
2) Health & Human Services Committee	17 Y, 0 N	Siples	Calamas

### 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 from 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.

CS/HB 1289 prohibits a health care practitioner from performing a pelvic examination on a patient without express written consent unless an exception applies. A health care practitioner does not have to obtain written consent if the pelvic examination is required by a court order or is immediately necessary to avert a serious risk of imminent substantial and irreversible physical impairment of a major bodily function 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.<sup>1</sup> 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.<sup>2</sup> 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.<sup>3</sup>

The idea of informed consent was established in 1914, in a case in which a patient was operated on without her consent.<sup>4</sup> 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.”<sup>5</sup>

##### *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.<sup>6</sup> 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.<sup>7</sup> Health care practitioners often perform pelvic examinations as a part of the annual well woman visit.<sup>8</sup> A health care practitioner may also perform a pelvic examination to diagnose specific health conditions, such as cancer and bacterial vaginosis.<sup>9</sup>

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<sup>1</sup> 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).

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

<sup>3</sup> 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).

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

<sup>5</sup> *Id.*

<sup>6</sup> Rule 64B8-9.007, F.A.C.

<sup>7</sup> *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](https://www.medicinenet.com/pelvic_exam/article.htm#why_is_a_pelvic_exam_performed) (last visited January 31, 2020).

<sup>8</sup> 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](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).

<sup>9</sup> *Id.*

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.<sup>10</sup> These examinations also give the health care practitioner an opportunity to establish open communication with the patient to answer specific questions and reassure her of normalcy.<sup>11</sup>

New clinical guidelines have recommended against pelvic examinations on asymptomatic, non-pregnant, adult women.<sup>12</sup> Routine pelvic examination has not been shown to benefit such women in that it rarely detects important disease and does not reduce mortality.<sup>13</sup> Several harms have been identified for the performance of pelvic examinations including fear, anxiety, embarrassment, pain, and discomfort.<sup>14</sup> Other physical harms include urinary tract infections and symptoms such as dysuria and frequent urination.<sup>15</sup>

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

### 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.<sup>18</sup> 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.<sup>19</sup>

Several medical organizations have taken positions that pelvic examinations should not be performed on anesthetized or incapacitated patients. 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.<sup>20</sup>

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

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<sup>10</sup> 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).

<sup>11</sup> *Id.*

<sup>12</sup> *Supra* note 8. This recommendation does not apply to pap smears.

<sup>13</sup> 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).

<sup>14</sup> *Id.*

<sup>15</sup> *Id.*

<sup>16</sup> *Id.*

<sup>17</sup> *Id.*

<sup>18</sup> 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).

<sup>19</sup> 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).

<sup>20</sup> 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).

solely for teaching purposes should be performed only with her specific informed consent obtained before her surgery”.<sup>21</sup>

The Association of American Medical Colleges (AAMC), reversing its prior policy position, offered that “performing pelvic examinations on women under anesthesia, without their knowledge or approval ... is unethical and unacceptable”.<sup>22</sup> However, 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.<sup>23</sup> The AAMC claims that students and residents typically practice pelvic examinations with special mannequins and standardized patients who are specifically trained for this purpose.<sup>24</sup>

California, Hawaii, Illinois, Iowa, Maryland, Oregon, Utah, and Virginia prohibit unauthorized pelvic examinations.<sup>25</sup>

### **Effect of Proposed Changes**

CS/HB 1289 prohibits a health care practitioner<sup>26</sup> from performing a pelvic examination on a patient without express written consent unless an exception applies. A health care practitioner must obtain written consent from the patient or the patient’s representative that expressly identifies that a pelvic examination will be performed. The bill does not require a health care practitioner does not have 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; or
- The pelvic examination is immediately necessary to avert a serious risk of imminent substantial and irreversible physical impairment of a major bodily function of the patient.

The bill defines pelvic examination as the direct palpation of the organs of the female internal reproductive system.

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 practitioners; 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.

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<sup>21</sup> 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).

<sup>22</sup> 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](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=880120) (last visited January 31, 2020).

<sup>23</sup> Id.

<sup>24</sup> Id.

<sup>25</sup> 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).

<sup>26</sup> Pursuant to s. 456.001(4), F.S., health care practitioners are defined to include acupuncturists, physicians, physician assistants, chiropractors, podiatrists, naturopaths, dentists, dental hygienists, optometrists, nurses, nursing assistants, pharmacists, midwives, speech language pathologists, nursing home administrators, occupational therapists, respiratory therapists, dieticians, athletic trainers, orthotists, prosthetists, electrologists, massage therapists, clinical laboratory personnel, medical physicists, dispensers of optical devices or hearing aids, physical therapists, psychologists, social workers, counselors, and psychotherapists, among others.

2. Expenditures:

DOH may experience an increase in workload associated with additional complaints, investigations, and prosecutions, which current resources are adequate to absorb.<sup>27</sup>

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:

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:

Rule-making authority is not required to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

### IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On February 3, 2020, the Health Quality Subcommittee adopted a strike-all amendment and reported the bill favorably as a committee substitute. The strike-all amendment:

- Revised the definition of “pelvic examination” to mean the direct palpation of the internal reproductive organs of a female.
- Prohibited a health care practitioner from performing any pelvic examination without written consent of the patient or his or her representative, unless it is court-order or necessary to avert a serious health risk to the patient.

The analysis is drafted to the committee substitute as passed by the Health Quality Subcommittee.

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