HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: PCS for HB 361 Consent for Pelvic Examinations
SPONSOR(S): Professions & Public Health Subcommittee
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Professions & Public Health Subcommittee		Guzzo	McElroy

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 enables a patient to make a competent decision about whether to undergo a procedure or treatment.

Current law defines a pelvic examination as the series of tasks that comprise 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 is not limited to, the health care provider's gloved hand or instrumentation. A health care practitioner must obtain a pelvic examination specific written informed consent from a patient before performing a pelvic examination. A health care practitioner does not have to obtain such 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. Questions have arisen within the medical community as to how to interpret the law's requirements.

PCS for HB 361 revises the definition of pelvic examination to mean a manual examination of the organs of the female reproductive system. The bill also revises the emergency exception to the informed consent requirement allowing a health care practitioner to perform a pelvic examination without the written consent of the patient if the pelvic examination is necessary for the provision of emergency services and care or the patient has an emergency medical condition. These changes address questions raised by the medical community regarding what constitutes a pelvic examination and when informed consent is required.

The bill has no fiscal impact on state or local government.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

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]

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

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.[9] 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.[10]

New clinical guidelines have recommended against pelvic examinations on asymptomatic, non-pregnant, adult women.[11] 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 Mar. 30, 2021).
[2] William Gossman, Imani Thornton, John Hipskind, *Informed Consent*, (July 2019), available at https://www.ncbi.nlm.nih.gov/books/NBK430827/ (last visited Mar. 30, 2021).
[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 Mar. 30, 2021).
[4] *Schloendorff v. Society of N.Y. Hosp.*, 105 N>E. 92, 93 (N.Y. 1914).
[5] Id.
[6] 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 Mar. 30, 2021).
[7] 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 Mar. 30, 2021).
[8] Id.
[9] 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 Mar. 30, 2021).
[10] Id.
[11] *Supra* note 7. This recommendation does not apply to pap smears.

that it rarely detects important disease and does not reduce mortality.[12] Several harms have been identified for the performance of pelvic examinations including fear, anxiety, embarrassment, pain, and discomfort.[13] Other physical harms include urinary tract infections and symptoms such as dysuria and frequent urination.[14]

The American College of Obstetricians and Gynecologists finds that data is currently insufficient to make a recommendation for or against routine pelvic examinations.[15] Therefore, it recommends that pelvic examinations be performed when indicated by medical history or symptoms, such as abnormal bleeding, pelvic pain, or urinary issues.[16]

Florida Requirements for Informed Consent of Pelvic Examinations

Pursuant to Florida statutes, a pelvic examination is the series of tasks that comprise 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 is not limited to the health care provider's gloved hand or instrumentation.[17]

Current law prohibits a health care practitioner from performing a pelvic examination on a patient without express written consent unless an exception applies.[18] 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.[19]

Following the enactment of s. 456.51, F.S., questions arose within the medical community as to how to interpret the law's requirements, and a Petition for Declaratory Statement was filed with the Florida Board of Medicine (BOM), requesting a determination of: [20]

- 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 examination 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.

[12] 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 Mar. 30, 2021).
[13] Id.
[14] Id.
[15] Id.
[16] Id.
[17] S. 456.51(1), F.S.
[18] S. 456.51(2), F.S.
[19] Id.
[20] 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. 30, 2021).

The BOM, in its Final Order, answered the above questions regarding what constitutes a pelvic examination under s. 456.51, F.S., as follows: [21]

- 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.

Effect of the Bill

PCS for HB 361 revises the definition of pelvic examination to mean a manual examination of the organs of the female reproductive system. The bill also revises the emergency exception to the informed consent requirement allowing a health care practitioner to perform a pelvic examination without the written consent of the patient if:

- The pelvic examination is necessary for the provision of emergency services and care, as defined in s. 395.002(9), F.S.,[22] or
- The patient has an emergency medical condition, as defined in s. 395.002(8), F.S.[23]

These changes address questions raised by the medical community regarding what constitutes a pelvic examination and when informed consent is required.

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

B. SECTION DIRECTORY:

Section 1: Amends s. 456.51, F.S., relating to consent for pelvic examinations.
Section 2: Provides an effective date of July 1, 2021.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

[21] *Id.*
[22] S. 395.002(9), F.S. Emergency services and care means medical screening, examination, and evaluation by a physician, or, to the extent permitted by applicable law, by other appropriate personnel under the supervision of a physician, to determine if an emergency medical condition exists and, if it does, the care, treatment, or surgery by a physician necessary to relieve or eliminate the emergency medical condition, within the service capability of the facility.
[23] S. 395.002(8), F.S. Emergency medical condition means s medical condition manifesting itself by acute symptoms of sufficient severity, which may include severe pain, such that the absence of immediate medical attention could reasonably be expected to result in any of the following: serious jeopardy to patient health, including a pregnant woman or fetus; serious impairment to bodily functions; serious dysfunction of any bodily organ or part; that there is inadequate time to effect safe transfer to another hospital prior to delivery; that a transfer may pose a threat to the health and safety of the patient or fetus; or that there is evidence of the onset and persistence of uterine contractions or rupture of the membranes.

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 PCS does not appear to affect county or municipal governments.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

No rule-making authority is necessary to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES