

Blog Post

What Consent for Which “Pelvic Examination?”

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Healthcare practitioners, including medical students, are now prohibited from performing pelvic examinations on female patients without first obtaining written consent, but many specific, logistical questions were left unanswered. The new [law](#) became effective July 1, 2020. “[P]elvic exams will now require specific consent, except in cases of emergency, finally halting the wholly inappropriate practice of unapproved pelvic exams on unconscious women...where at best, these exams have been wrongful learning experiences for medical students or at worst, the equivalent of a sexual assault.” ([Statement](#) by Senator Lauren Book, a co-introducer of the bill).

Determining how to implement the new requirements has been extremely difficult. The whole spectrum of the Florida medical community (medical doctors, osteopaths, nurses and medical students) have expressed criticism, concerned that the law is overly burdensome and left many questions unanswered. The [final order](#) (the Order) issued by the Florida Board of Medicine (the Board) on October 9, 2020, in response to the [Petition for Declaratory Statement](#) filed by the Florida Medical Association (FMA), four other medical associations, and one physician offers some clarity. The Order reflects the Board’s opinion that the pelvic examination consent requirement only applies to

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female patients and does not apply to mere visual examinations, or routine non-diagnostic medical care, treatments, or surgical procedures.

Compliance with the law is not optional. Consequently, we recommend moving forward with a conservative approach. Efforts to assure compliance with the new statute, and the spirit of the Board's Order is critical. Healthcare organizations must put in place robust policies and procedures that staff will be able to understand and follow.

Written Policies and Procedures

The policy and procedures need to specifically address the requirements outlined below.

1. Which patients are required to provide consent?

The Board's Order states that the law applies only to female patients, noting: "[T]he Board is of the opinion that the pelvic examination bill informed consent requirement does not apply to the examination of biologically male patients." The Board's guidance is interesting as the FMA issued legislative analysis that DOH "indicated that the provisions of the bill apply to both female and male patients." (See FMA's Analysis of Florida's New Law Regarding Pelvic Examinations).

Consent must be obtained from the patient or the patient's legal representative. As no specific age is referenced in the law, it appears to apply to all ages. For instance, in the case of a minor, consent must be provided by the person legally responsible for the minor, such as the natural or adoptive parent, legal custodian, or legal guardian, unless an exception applies. Florida Statute 743.0645.

2. Who is responsible for obtaining consent?

A healthcare practitioner, medical student, or any other student receiving training as a healthcare

practitioner may not perform a pelvic examination “without the written consent.” The law does not specify whether the practitioner is required to personally obtain the consent, or if it can be obtained by another individual. The written policies and procedures will need to clearly outline:

- When consent will be discussed with the patient
- Who will be responsible for obtaining consent
- How the practitioner, if not directly obtaining the consent, will be notified that the consent has been successfully obtained before the examination begins

A conservative approach is for the performing practitioner to discuss it with the patient prior to obtaining consent. This practice mirrors Florida Administrative Code 64B8-9.007(1) for surgical consents. The physician who will perform surgery must explain the procedure to the patient and has the duty to obtain the patient’s informed consent prior to performing the surgery. The physician is not required, however, to be the individual who obtains or witnesses the signature of the patient on the written form evidencing informed consent, which can be done by other medical personnel.

3. What constitutes a pelvic examination?

This has been the subject of considerable debate. Consent is required for all pelvic examinations unless an exception applies (as discussed below). Pelvic examinations include any combination of modalities (including, but not limited to, the provider’s gloved hand or instrumentation), during an examination of any of the following:

- Vagina
- Cervix
- Uterus
- Fallopian tubes
- Ovaries

- Rectum
- External pelvic tissue or organs

The Board's Order determined that the following are not considered pelvic examinations:

- Non-diagnostic medical care, treatments, or surgical procedures involving the designated body parts listed above
- Discrete visual examination of the designated body parts listed above

The DOH advised the FMA that consent is required for *each* examination. (see [here](#)). Based on this guidance, consent may not be obtained once to cover a series of future examinations. It is unclear whether one consent could, however, apply to multiple examinations during a single visit (e.g., delivering a baby). The FMA's, conservative approach for a single visit with multiple pelvic examinations is "to obtain a single written consent to cover the multiple examinations."

4. When is consent NOT required?

Written consent is not required when the pelvic examination is:

- Ordered by a court for the collection of evidence or
- Immediately necessary to avert a serious risk of imminent substantial and irreversible physical impairment of a major bodily function of the patient.

The Consent Form

The consent form must be "specific to, and expressly identify[], the pelvic examination." To be "specific" we recommend that the consent form should be separate from the organization's general informed consent form. To "expressly identify" the pelvic examination, space should also be allocated on the

consent form, which will allow for the type of pelvic examination to be added.

Penalties

Failure to obtain informed consent for a pelvic examination may be considered a battery. Florida Statute 784.03(1)(a). The offense of battery includes the actual and intentional touching of another person against the person's will. An individual who commits battery, without having had a prior conviction for battery, commits a misdemeanor in the first degree, Florida Statute 775.082(4)(a), which may include a sentence of imprisonment not to exceed one year.

Violations also may constitute grounds for administrative penalties against the "healthcare practitioner." Florida Statute 456.072(1)(dd). Penalties may include revocation of a healthcare practitioner's license, suspension of a license, imposition of administrative fines, and corrective action. Florida Statute 456.072(2). This chapter of the Florida Statutes defines "healthcare practitioner" very broadly, as it includes various licensed professionals. For instance, some of the licensed professionals include: massage therapists, physical therapists, osteopathic physicians, and allopathic physicians. The broadness of the statute's applicability has caused growing concern among health care practitioners that there are too many types of practitioners at risk for violating it and not enough guidance regarding how it applies to each of their professions.

Put the Policies in Place Now

The Board's final order addressed some questions but continues to leave many unanswered, such as whether one consent can apply to multiple examinations during a single visit. Healthcare organizations cannot wait for additional guidance to be issued before implementing policies and procedures to comply with the new law. The policies and procedures should specify who will obtain the

consent, which patients require that consent be obtained, and which types of examinations require consent. It is also necessary that a consent form be used that adheres to the law's requirements, as described above.

We are available for consultations if a healthcare organization would like guidance regarding interpreting the statute, how to implement compliant policies or procedures, or how to draft the consent form. It is important that each organization implement practices that will be successful for their specific organization while also staying within the bounds of the law.

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