Maine Medical Association

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Testimony in support of LD 1948
An Act To Prohibit, Except in Emergency Situations, the Performance without Consent of Pelvic Examinations on Unconscious or Anesthetized Patients
Joint Committee on Health Coverage, Insurance and Financial Services
Tuesday, January 28, 2020

Senator Sanborn, Representative Tepler, and Members of the Committee, my name is Dan Morin, Director of Communications and Government Affairs for the Maine Medical Association (MMA).

The MMA is a professional organization of more than 4300 physicians, residents, and medical students in Maine whose mission is to support Maine physicians, advance the quality of medicine in Maine, and promote the health of all Maine citizens.

This legislation would prohibit any licensed allopathic (M.D.) or osteopathic (D.O.) physician from performing, or supervising, a pelvic examination on a patient who is under anesthesia or unconscious, unless informed consent was obtained; the exam is within the "scope" of care for the patient; or the patient is unconscious and the exam is 'medically necessary.'

The pelvic examination is a critical tool for the diagnosis of women's health conditions and remains an important skill necessary for students to master before becoming physicians. However, we wholeheartedly agree that when performed solely for educational purposes, with no expected health benefit to the patient, a pelvic exam under anesthesia should require informed consent. In fact, the American College of Obstetricians and Gynecologists (ACOG) committee opinion 439 on Informed Consent affirms that obtaining informed consent for medical treatment is an ethical requirement. The opinion reads:

"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."

Informed consent for medical interventions began as a legal requirement in the United States at the turn of the 20th century. Interestingly, the foundational consent case, Schloendorff v Society of New York Hospital (1914), was a gynecologic one. This and subsequent cases established that, if a clinician touches a patient in an "unconsented and offensive" fashion, the clinician may be held liable in a court of law.

Starting in 2004, states began passing laws mandating certain standards for pelvic examination under anesthesia, similar to the bill before you today. A snapshot in time from 2019 showed seven states (California, Hawaii, Illinois, Iowa, Oregon, Utah, and Virginia) with such laws, and others are considering them. Maryland is another that has recently adopted a similar law.

All clinicians, obstetrician–gynecologists (ob-gyns) included, are entrusted to preserve the health and dignity of their patients, and this remains an uncompromising priority. Medical educators must balance an obligation to develop the next generation of physicians with a patient's freedom to decide from whom they receive treatment and what aspects of their care are performed by learners. We want to reiterate that we are unaware of any reports that the physicians of Maine have acted otherwise and are confident from our discussions that Maine hospitals and physician practices all have informed consent as a best practice. And

while we typically offer resistance to proposed efforts at 'legislating medicine,' we understand the concerns expressed by the bill's sponsor, primary co-sponsor, and additional sponsors, including Dr. Sanborn, the need for such protections to be made explicit to protect patients and as an assurance for medical students.

We do however, have a few comments and suggestions for clarification.

- What is the definition of a pelvic exam and why does the bill apply only to physicians? Also, this seems to be most specifically be written for women but should it apply to all? For example, Maryland's law prohibits, "any health care practitioner or medical student from performing a pelvic, prostate, or rectal examination on a patient who is under anesthesia or unconscious, unless informed consent was obtained . . ."
- For women, would it prohibit visual examination/inspection of the external genitalia, bimanual exam of the uterus/ovaries, digital rectal exam, examination of the pelvic organs laparoscopically? One comment we received expressed a need for that to be better defined to avoid confusion.

Another comment we received was:

- Who decides if the pelvic exam was necessary to or an acceptable adjunct to the procedure? Typically, even a licensee finds an ovarian cyst and the surgery intends to remove it, an examination is done ahead of time to see if it can be felt and to confirm there isn't any additional information that may be gleened from the exam before proceeding with surgery but, is it absolutely necessary? They are likely to proceed with the surgery anyway even if I did or didn't feel a mass. The licensee may feel there's value in it from a preoperative planning standpoint, but someone may disagree.

In addition, there are references in current law, and by extension rules, which may already cover such instances. 32 M.R.S. § 3282-A(2)(H), allows investigation and potential discipline for, "A violation of this chapter or by a rule adopted by the board. The Board of Licensure in Medicine and the Board of Osteopathic Licensure have a joint rule covering sexual misconduct (02-373 & 383, ch. 10). Under Section 1, subsection B, you'll find the definition of sexual impropriety. Subsections 3, 8 and 9 seem to offer a remedy for the bill's intent.

3. subjecting a patient to an intimate examination in the presence of another when the physician/physician assistant has not obtained the verbal or written informed consent of the patient or when the informed consent has been withdrawn;

8. performing an intimate examination or consultation without clinical justification;

9. performing an intimate examination or consultation without explaining to the patient the need for such examination or consultation even when the examination or consultation is pertinent to the issue of sexual function or dysfunction;

Finally, I would refer the Committee to statutory precedent for specific informed consent considerations. The Maine Health Security Act (24 M.R.S. § 2905-A), covers informed consent for breast cancer.

Thank you for your consideration of our comments, questions and additional information. We will be happy to continue work with you, bill sponsors and other interested parties on a mutually agreeable solution to the issue.

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02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

373 BOARD OF LICENSURE IN MEDICINE
a joint rule with
383 BOARD OF OSTEOPATHIC LICENSURE

Chapter 10: SEXUAL MISCONDUCT

SUMMARY: This chapter defines sexual misconduct by physicians and physician assistants, sets forth the range of sanctions applicable to violations of this rule, and identifies the factors the Board should consider in imposing sanctions.

RULE INDEX

SECTION 1. DEFINITIONS

1. **"Board"** means the Board of Licensure in Medicine or the Board of Osteopathic Licensure.

2. **"Intimate examination"** means examination of the breasts, genitalia, or rectum and any anatomy immediately adjacent to these areas.

3. **"Key third party"** means immediate family members and others who would be reasonably expected to play a significant role in the health care decisions of a patient of the physician or physician assistant and includes, but is not limited to, the spouse, domestic partner, parent, child, guardian, or surrogate.

4. **"Legitimate health care purpose"** means activities for examination, diagnosis, treatment, and personal care of patients, including palliative care, as consistent with community standards in medicine. The activity must also be within the scope of practice of medicine.

5. **"Patient"** means an individual who currently receives health care from a physician or physician assistant, or who previously received health care from a physician or physician assistant within the preceding twelve (12) months. For physicians and physician assistants engaged in the practice of psychiatry, "patient" means an individual who currently receives or previously received health care from that physician or physician assistant.

6. **"Physician"** means an individual who is qualified and licensed according to the provisions of 32 M.R.S. §3270 *et seq.* and 32 M.R.S. §2571 *et seq.*

7. **"Physician Assistant"** means an individual who is qualified and licensed or certified according to the provisions of 32 M.R.S. §3270-E and 32 M.R.S. §2594-E.

8. **"Physician/physician assistant sexual misconduct"** means behavior that exploits the physician/physician assistant and patient/key third party relationship in a sexual way. This behavior is nondiagnostic and/or nontherapeutic, may be verbal or physical, and may include expressions or gestures that have a sexual connotation or that a reasonable person would construe as such. Sexual misconduct is considered incompetence and unprofessional conduct as defined by 32 M.R.S. §3282-A(2)(E) & (F) and 32 M.R.S. §2591-A(2)(E) & (F).

   There are two levels of sexual misconduct: sexual violation and sexual impropriety. Behavior listed in both levels may be the basis for disciplinary action.

   A. **"Sexual violation"** means any conduct by a physician/physician assistant with a patient and/or key third party that is sexual or may be reasonably interpreted as sexual, even when initiated by or consented to by a patient and/or key third party, including but not limited to:

      1. sexual intercourse, genital to genital contact;

      2. oral to genital contact;

      3. oral to anal contact or genital to anal contact;

      4. kissing in a sexual manner (e.g. - french kissing);

      5. any touching of breasts, genitals, or any sexualized body part for any purpose other than appropriate examination, treatment, or comfort, or where the patient has refused or has withdrawn consent;

      6. encouraging the patient to masturbate in the presence of the physician/physician assistant or masturbation by the physician/physician assistant while the patient is present;

      7. offering to provide practice-related services, such as drugs, in exchange for sexual favors;

      8. touching, fondling or caressing of a romantic or sexual nature;

      9. rubbing against a patient or key third party for sexual gratification;

      10. photographing, filming or digitally recording the body or any body part or pose of a patient or key third party, other than for legitimate health care purposes;

      11. showing a patient or key third party sexually explicit photographs or digital images, other than for legitimate health care purposes;

      12. requesting a patient or key third party to provide or display or email or text sexually explicit material to the physician or physician assistant;

      13. performing an intimate exam or consultation without the presence of a chaperone, if one was requested by the patient; and

14. a criminal conviction for any of the following involving a patient and/or key third party:

    a. Gross Sexual Assault in violation of 17-A M.R.S. §253;

    b. Unlawful Sexual Contact in violation of 17-A M.R.S. §255-A;

    c. Sexual Abuse of a Minor in Violation of 17-A M.R.S. §254;

    d. Visual Sexual Aggression Against a Child in violation of 17-A M.R.S. §256;

    e. Sexual Misconduct with a Child Under 14 Years of Age in violation of 17-A M.R.S. §258;

    f. Solicitation of a Child to Commit a Prohibited Act in violation of 17-A M.R.S. §259-A;

    g. Unlawful Sexual Touching in violation of 17-A M.R.S. §260;

    h. Sexual Exploitation of a Minor in violation of 17-A M.R.S. §282.

B. **"Sexual impropriety"** means behavior, gestures, or expressions by the physician/physician assistant towards the patient and/or key third party that are seductive, sexually suggestive, disrespectful of privacy, or sexually demeaning, including but not limited to:

    1. kissing;

    2. neglecting to employ disrobing or draping practices respecting the patient's privacy; touching of the patient's clothing that reflect a lack of respect for the patient's privacy; deliberately watching a patient dress or undress instead of providing privacy for disrobing;

    3. subjecting a patient to an intimate examination in the presence of another when the physician/physician assistant has not obtained the verbal or written informed consent of the patient or when the informed consent has been withdrawn;

    4. examination or touching of genitals without the use of gloves;

    5. inappropriate comments about or to the patient, including but not limited to making sexual comments or jokes about a patient's body or underclothing; making sexualized or sexually demeaning comments or jokes to a patient; criticizing the patient's sexual orientation (homosexual, heterosexual, or bisexual); making comments or jokes about potential sexual performance during an examination or consultation (except when the examination or consultation is pertinent to the issue of sexual function or dysfunction); requesting details of sexual history or sexual likes or dislikes when not clinically indicated;

    6. using the physician/physician assistant-patient relationship to solicit or initiate a date or sexual or romantic relationship;

7. initiation by the physician/physician assistant of conversation regarding the sexual problems, preferences, or fantasies of the physician/physician assistant;

8. performing an intimate examination or consultation without clinical justification;

9. performing an intimate examination or consultation without explaining to the patient the need for such examination or consultation even when the examination or consultation is pertinent to the issue of sexual function or dysfunction; and/or

10. requesting the details of sexual history or sexual likes or dislikes when not clinically indicated for the type of examination or consultation.

SECTION 2. SANCTIONS

If the Board finds that a licensee has engaged in sexual misconduct as defined in section 1 of these rules the licensee shall be disciplined in accordance with these rules.

1. All disciplinary sanctions under 32 M.R.S. §2591-A, 32 M.R.S. §3282-A and 10 M.R.S. §8003 are applicable.

2. Sexual Violations. Findings of sexual violations are egregious enough to warrant revocation of a physician/physician assistant's license. The Board may, at times, find that mitigating circumstances do exist and may impose a lesser sanction.

3. Sexual Impropriety. Findings of sexual impropriety will result in harsh sanction, which may include revocation.

4. Factors affecting sanctions. Special consideration should be given to at least the following factors when determining an appropriate sanction:

   a. patient and/or key third party harm;

   b. opportunity (type of practice) for past/future misconnduct;

   c. severity of impropriety or inappropriate behavior;

   d. context within which the impropriety or inappropriate behavior occurred;

   e. culpability of licensee;

   f. psychotherapeutic relationship;

   g. existence of a physician/physician assistant–patient and/or key third party relationship;

   h. scope and depth of the physician/physician assistant relationship with the patient and/or key third party;

   i. inappropriate termination of physician/physician assistant-patient relationship;

   j. age and competence of the patient and/or key third party;

k. physical/mental capacity of the patient and/or key third party;

l. vulnerability of the patient and/or key third party;

m. number of times behavior occurred;

n. number of patients and/or key third parties involved;

o. period of time relationship existed;

p. evaluation/assessment results;

q. prior professional disciplinary history; and

r. recommendation(s) of assessing/treating professional(s).

STATUTORY AUTHORITY: 32 M.R.S. §§ 3269 (3),(7)
32 M.R.S. §2562

EFFECTIVE DATE:
August 17, 2019 – filings 2019-146 (Medicine) *and* 2019-147 (Osteopathic)

§2905-A. Informed consent for breast cancer

1. Duty of physician. Notwithstanding section 2905, a physician who is administering the primary treatment for breast cancer shall inform the patient as provided in this section, orally and in writing, about alternative efficacious methods of treatment of breast cancer, including surgical, radiological or chemotherapeutic treatments or any other generally accepted medical treatment and the advantages, disadvantages and the usual and most frequent risks of each.
[PL 1989, c. 291, §1 (NEW).]

2. Written information. The duty to inform the patient in writing may be met by giving the patient a standardized written summary or brochure as described in subsections 3 and 4.
[PL 1989, c. 291, §1 (NEW).]

3. Standardized written summary. The standardized written summary may be developed by the Bureau of Health after consultation with the Cancer Advisory Committee.
[PL 1989, c. 291, §1 (NEW).]

4. Brochure. The brochure must be one which is approved or made available through the National Cancer Institute, the American Cancer Society, the American College of Surgeons or any other recognized professional organization approved by the Bureau of Health.
[PL 1989, c. 291, §1 (NEW).]

5. Signed form. A form, signed by the patient, indicating that the patient has been given the oral information required by this section and a copy of the brochure or the standardized written summary shall be included in the patient's medical record.
[PL 1989, c. 291, §1 (NEW).]

6. Extent of duty. A physician's duty to inform a patient under this section does not require disclosure of information beyond what a reasonably well-qualified physician licensed under Title 32 would know.
[PL 1989, c. 291, §1 (NEW).]

7. Actions barred. A patient who signs a form described in subsection 5 is barred from bringing a civil action against the physician, based on failure to obtain informed consent, but only in regard to information pertaining to alternative forms of treatment of breast cancer and the advantages, disadvantages, and risks of each method.
[PL 1989, c. 291, §1 (NEW).]

8. Application of this section to common law rights. Nothing in this section restricts or limits the rights of a patient under common law.
[PL 1989, c. 291, §1 (NEW).]

SECTION HISTORY

PL 1989, c. 291, §1 (NEW).

INFORMED CONSENT

Guidelines from the Maine Board of Licensure in Medicine[1]

Obtaining and recording informed consent before major diagnostic, therapeutic, and invasive procedures is a physician's professional and legal obligation. Patients have the legal right to grant or withhold informed consent, either personally or through lawful representatives.

The term "informed consent" first appeared in an *amicus curiae* brief filed by the American College of Surgeons in the case of *Salgo v. Leland Stanford University* in 1957.[2] While not all physicians and not all patients desire to be involved in a shared decision making process, prevailing negligence law and the legal right to self-determination now require some documentation of informed consent for most major treatments and procedures. Physicians therefore have a legal motivation for obtaining and recording informed consent for major treatments and procedures, subject to recognized legal exceptions such as in providing emergency medical care to incapacitated patients. In addition to this legal motivation, the Board believes physicians ought to be motivated by a commitment to the ethical value of patient self-determination, or personal autonomy. Therefore, the Board offers these guidelines for physicians practicing in Maine.

The Goal

The goal of offering these guidelines is to help physicians move beyond a limited consent model that emphasizes primarily the physician's legal obligation to disclose information and the patient's legal right to make independent decisions. The Board advocates a different model that emphasizes communication and encourages a certain kind of transaction between patient and physician. The norms that govern such transactions are clarity, relevance, accuracy, and sincerity. There is no standard form, nor any uniform procedure that will fit all cases calling for informed consent in this model, but there is an underlying ethical obligation to make it possible for the patient and the physician to participate together in a transaction that takes into account the norms of clarity, relevance, accuracy, and sincerity.

The Board is concerned here with major diagnostic, therapeutic, and invasive procedures, and not so much with routine decisions about minor medical problems. In certain cases, physicians may simply explain that they see many people with a particular problem and regularly with success treat the problem in a particular way, then ask if the patient has any questions about the problem or the treatment. In these cases, if the patient

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[1] Title 32 M.R.S.A. § 3269(3) authorizes the Board to "license and set standards of practice for physicians and surgeon practicing medicine in Maine." However, nothing in this document is intended to affect the definition of "informed consent" for civil medical malpractice actions as defined by Title 24 M.R.S.A. § 2905.

[2] 154 *Cal.App.*2d 564.

makes statements or asks questions indicating discomfort, lack of understanding, or continuing uncertainty, then the following guidelines apply.

Shared Decision Making

The primary value of documented informed consent is that it represents the existence of a relationship between physician and patient that is based upon, or at least includes, an element of shared decision making. Shared decision making for the patient is not the same as mere acquiescence, or compliance based on partial or slanted information, or indifference due to habit or apathy, nor is it the same as conformity to custom – such as the custom of "following doctor's orders."

Shared decision making is a process for reaching a shared conclusion through informed judgment. Such a process is an educational ideal in the field of medical care, as it is throughout most institutions in a democratic society. The heart of the matter is the control of information: to the extent information about a problem can be shared, decisions about potential solutions can be shared. Physicians have privileged access to medical information through their education, experience, and expertise. This privilege carries with it the duty to disclose *clearly* such information as is *relevant* and is supported by *accurate* scientific information in a *sincere* manner for consideration by the patient. Furthermore, this duty is itself governed by the physician's fiduciary obligation to protect the patient's best interests.

Generally, physicians control the medically relevant information patients need in order to ask the questions they may want to ask but might not be able to formulate on their own. Successfully sharing that information is a matter of 1) the physician's willingness to do so, and 2) the physician's ability to apply the skills of communication required to do so. It is also a matter of 3) the patient's willingness to participate in the process, and 4) the patient's ability to understand the information, apply it to his or her situation, and then express a reasoned judgment based on the relevant medical information as well as on personal values, wishes, and goals. If there is any doubt about the patient's ability in this regard, the physician should arrange an evaluation of the patient's capacity by a qualified colleague.

The physician personally initiates the process of informing the patient by presenting the medically reasonable options relevant to the patient's condition. The medical reasonableness of these options is tied to the available and reliable evidence base of expected benefit and risk for each alternative. The physician's judgment about these options should be free of personal self-interest, and religious, political, racial, and gender bias.

The Board encourages physicians to remind patients of their right to have someone with them (an advocate of some kind) during these discussions, as patients can be overwhelmed, frightened, and confused when confronting an important medical decision.

Skills for Eliciting Informed Consent

By far the most important skill is **empathetic listening**, which is the capacity for acquiring objective knowledge about the perspective taken by another person. It is a way of listening that requires temporary suspension of one's personal point of view while trying to assume another's point of view. It is a means for gathering data. It is not synonymous with being compassionate or sympathetic, even though its mere presence can have a beneficial effect. The primary purpose of empathy in this sense is to become well informed about the patient's point of view. It is important for the physician to find out what and how much the patient already knows and what more the patient wishes or needs to know, and to what extent the patient desires to participate in the decision making process. In disclosing medical information the physician can err in two ways – excess and deficiency. Empathetic understanding can help guard against going wrong in either of these ways.

Next is skill in **disclosing and explaining**. In trying to establish the basis for shared decision making, the physician discloses medical information relevant to the case at hand, and provides explanations of what that information means, in language that is intelligible to the patient.

It is important to distinguish between two useful but distinct kinds of explanation. The first is *scientific* explanation, which is making a case for why certain events are the way they are and for predicting future events. The second is *semantic* explanation, which by contrast is making the meaning of something clear to the listener. Semantic explanation is like translation or paraphrase, using different words and terms until the intended meaning is revealed and understood.

An explanation can be *satisfactory* from a formal (scientific) point of view, while at the same time failing to be *satisfying* from the patient's point of view. Another way to put this point is that while a medical explanation of risks and benefits associated with treatment options can be scientifically sound, the listener may find it to be unintelligible, and therefore not useful as information upon which to grant or withhold consent. Informed consent depends on the physician's success in providing both kinds of explanation.

Third is **framing**. Anything that can be said, can be said another way. Decisions are often influenced by the way alternatives are presented. For example, the outcome statistics for 100 middle-aged men undergoing surgery for lung cancer can be described as "90 survive the surgery . . . and of those 90, 34 are alive at the end of 5 years." An alternative way of expressing (framing) the same results might be: "10 die from surgery. . . and 66 more die within 5 years." Typically, for a patient choosing between surgery and radiation, surgery appears much less attractive when described using mortality rather than survival statistics. The difference between 10% mortality (for surgery) and 0% mortality (for radiation) is more impressive than the difference between 90% survival (for surgery) and 100% survival (for radiation). A physician may knowingly or unwittingly nudge a patient toward one option simply by the way the range of options is described, or framed. (Note that 5-year mortality statistics for radiation only have not been mentioned.)

Definition of Informed Consent

In conclusion, the Board recommends the following definition of informed consent be adopted and applied by Maine physicians.

Informed consent for treatment has been obtained when: 1) the physician has disclosed and explained *to the patient's satisfaction* the process used to arrive at the medically reasonable and recommended intervention(s), which is based on reliable evidence of expected benefit and risk of each alternative, and which is free of any impermissible bias; 2) the patient, who has demonstrated capacity, has been given ample opportunity to ask questions about the process and the recommended intervention(s), *to the extent the patient wishes*, all questions then having been answered *to the patient's satisfaction*; and 3) the patient gives consent in writing to major intervention(s) agreed to jointly with the physician.

Nota bene:

Obtaining informed consent is the physician's personal responsibility. This responsibility cannot be *wholly* delegated. Other medical staff (PA's, NP's, Physicians in training and others) may usefully participate in the process, but no amount of shared videos, questionnaires, and pamphlets can substitute *entirely* for personal communicative transaction with the responsible physician. Finally, proof of informed consent cannot be reduced merely to a signature on a form. A note from the physician about the process of gaining that signature should be attached to the form.

When a Physician Assistant, with proper delegation, performs a diagnostic, therapeutic, or invasive procedure for which the standard of care indicates informed consent is required, the Board expects the Physician Assistant to take the same actions as are described in this document for the physician.

Approved: April 13, 2010