The Patient Trust Act: Model Legislation for Getting Politics out of the Exam Room

Introduction

The Patient Trust Act addresses the serious and growing problem of laws that impose politics and ideology on clinical care. This dangerous trend threatens evidence-based, patient-centered medicine, the delivery of quality care, and public health. Restrictions on how providers may deliver care have impaired health care professionals' ability to give patients medically appropriate care and counseling on issues such as gun safety, environmental risk factors and abortion care.[1]

Health care providers have a professional and ethical obligation to provide care that is evidence-based, safe, individualized, and medically appropriate. Yet, politicians continue to pass laws that conflict with ethical and medical standards and thus could undermine health care. In order to remedy this, this bill would add a provision to state law that would protect health care providers who want to follow their professional and ethical responsibility and provide patients with the highest standards of care. The purpose of this legislation is to foster debate that focuses on the real-life impact of these laws and ensure that no health care provider is forced to choose between following the law and abiding by ethical, professional, and medical standards.

Recent polls have shows that there is near-universal support for laws that allow health care providers to care for patients based on their professional medical judgment without political interference. In a 2016 nationwide poll, the overwhelming majority of respondents said they would like an abortion to be informed by medically accurate information (94%), respectful of a woman's decision (84%) and supportive (74%). (See polling data below.) This model legislation would be a first step in that direction.

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About the Bill

The message of the Patient Trust Act is simple – patients and their health care providers, not politicians, should be making health care treatment decisions. The Act takes a strong stance that political bodies should not interfere with the judgment of health care providers in consultation with their patients and that laws and regulations should be guided by certain standards. Health care should be: evidence-based, medically accurate, and appropriate to the patient.

Ideally regulations that inappropriately interfere or infringe on the patient-provider relationship and undermine care would not be enacted and existing ones would be repealed. However, given the political realities in some states, the Act aims to compel legislators to take these standards into account and call into question laws and regulations that violate them. As noted above, restrictions on how providers may deliver care have impaired health care professionals' ability to give patients medically appropriate care and counseling on issues such as gun safety, environmental risk factors and abortion care. For example:

- In Florida, a law restricts health care providers' ability to counsel patients about gun safety– despite the fact that the American Academy of Pediatrics recommends such counseling to help prevent unintentional shooting deaths especially among children.[2] While Florida's law remains the most restrictive, Montana and Missouri have also enacted laws restricting conversations between health care providers and patients on gun safety.[3]
- In Pennsylvania, a provision in Act 13 of 2012 could prevent health care providers from sharing information with their patients about the potentially toxic chemicals to which they were exposed due to hydraulic fracturing ("fracking"). Thirteen states require that information regarding fracking chemicals to be shared with health professionals, but many of those requirements have provisions that may limit sharing that information with anyone else, including patients.[4]
- In five states, health care providers are required to give women seeking abortion care medically inaccurate information that falsely asserts a link between abortion and breast cancer.[5] Two states require providers to tell patients that medication abortion may be 'reversible,' an assertion with no medical support.[6] Thirteen states require health care providers to perform an ultrasound; in some states providers must describe and display the image, regardless of medical need or the wishes of the patient.[7] Twenty-eight states force providers to unnecessarily delay abortion care for up to 72 hours.[8] These are just a few examples of the widespread political interference in abortion care More than 300 abortion restrictions were introduced in state legislatures in just the first three months of 2015.[9]

Under the Patient Trust Act if, according to a health care provider's professional medical judgment, a law or regulation is medically inaccurate, is not evidence based, or is inappropriate for the patient, the provider does not have to follow that law or regulation and cannot be held liable under the law. By articulating the types of regulations that a physician should not be compelled to comply with, the Act delineates standards for future legislative action and promotes an important conversation about the role of government and the role of health care providers in determining appropriate care.

Polling Data

A January 2016 poll of over 1,100 registered voters nationwide, respondents showed strong support for policy proposals that aim to keep politics out of the exam room. Respondents strongly supported policies that would:

- Allow health care providers to care for patients based on their best medical expertise without interference from politicians 86%
- Ensure that laws regulating abortion providers are based on medical evidence and best practices instead of political beliefs 84%
- Prevent politicians from forcing doctors to give women medically inaccurate information about abortion 83%

In the same poll, when respondents were asked to think of a woman who has decided to have an abortion and how they would you want her experience to be, the results were strongly in support of respecting a woman's decision:

- Informed by medically accurate information 94%
- Safe 93%
- Respectful of her decision 82%
- Legal 76%
- Supportive 75%
- Without pressure 73%
- Affordable 72%
- Available in her community 72%

In a fall 2013 national poll of over 800 registered voters in swing and red states, voters were strongly in support of ensuring that patients get complete, accurate medical information.

- 86% of respondents felt that it is important for elected officials in their state to work on ensuring all patients get complete, accurate medical information on all their health care options, regardless of where they seek treatment (72% extremely important; 14% quite important).
- 64% of respondents favor possible legislation to bar the state from forcing doctors to provide medically inaccurate information to their patients (55% strongly favor; 9% somewhat favor).
- 54% of respondents favor possible legislation to prohibit penalizing providers for giving standard reproductive health care, including referral/counseling, or accepted medical procedures consistent with patient needs and consent (41% strongly favor; 13% somewhat favor).

- 45% of respondents would be more likely to vote for a candidate who supported the kinds of reproductive rights policies included in the poll; for 24%, it wouldn't affect their vote either way.
- 54% of respondents favor (including 37% who strongly favor) a state law that protects doctors from having to read pre-written scripts written by politicians to their patients before providing abortion services:
    - Applies across party lines (Democrats +32; Republicans +7; Independents +26)

      Framing pre-written scripts as forcing doctors to say things they may deem as medically inaccurate or unsound is extremely effective: This measure would force doctors to say things they deem medically inaccurate or unsound, add unnecessary bureaucracy, and interfere with doctors' ability to talk freely and openly with their patients.
- 61% of respondents favor (including 49% who strongly favor) a state law that protects the rights of women who specifically say they do not want to view their ultrasounds before having an abortion from having to do so.
    - Applies across party lines (Democrats +50; Republicans +7; Independents +32)
    - Stating that requiring women to view their ultrasounds is medically unnecessary and demeaning is more persuasive than stating that women need full information.
        - It is demeaning and intrusive to force women to view ultrasound images against their will, and all patients deserve to make their own personal health care decisions, especially in cases involving rape and incest or when there are severe fetal abnormalities.
        - Requiring women to view their ultrasounds is medically unnecessary and patients and doctors, not politicians, should decide what options are best in each individual situation, and politicians should not try to control personal, private health decisions.

In a fall 2014 poll of voters in Pennsylvania and New York, respondents supported proactive measures to protect abortion care.

- 82% of Pennsylvania respondents support making sure politicians can't force doctors to give patients medically inaccurate information about abortion (66% strongly support; 16% support).
- 73% of New York respondents support including proactive abortion policies in women's agenda legislation.
- 76% of Pennsylvania respondents support including proactive abortion policies in women's agenda legislation (42% very important; 34% somewhat important).

Model Legislative Language

(Annotated version below)

I. Purpose

It is the intent of the General Assembly to protect the health of patients under the care of a licensed physician or someone operating under his or her authority by ensuring that the practitioner is able to communicate freely with patients and exercise his or her medical judgment in order to provide the most beneficial medical treatment to the individual patient.

Health care practitioners have a professional and ethical responsibility to provide the best possible care to their patients.

This legislation does not alter existing accountability mechanisms for health care practitioners including in regards to medical malpractice, safety or licensing requirements.

STATE hereby enacts as follows:

II. Section 1. Definitions

The following words and phrases when used in this act shall have the meanings given to them in this section unless the context clearly indicates otherwise:

"Evidence Based." The conscientious, explicit and judicious use of current best evidence in making decisions about the care of the individual patient, integrating individual clinical expertise with the best available external clinical evidence from systematic research.

"Medically accurate." In relation to information, information that is:

1) verified or supported by the weight of peer reviewed medical research conducted in compliance with accepted scientific methods;
2) recognized as medically sound and objective by leading medical organizations with relevant expertise, such as the American Medical Association, the American Congress of Obstetricians and Gynecologists, the American Public Health Association, the American Psychological Association the American Academy of Pediatrics, the American College of Physicians and the American Academy of Family Physicians; or government agencies such as the Centers for Disease Control, the Food and Drug Administration, the National Cancer Institute, and the National Institutes of Health; and scientific advisory groups such as the Institute of Medicine and the Advisory Committee on Immunization Practices; or
3) recommended by or affirmed in the medical practice guidelines of a nationally recognized accrediting organization.

"Appropriate for the Patient" means care consistent with applicable health and professional standards; the patient's clinical and other circumstances; and the patient's reasonably known wishes and beliefs.

"State." means the state and every county, city, town, municipal corporation, and quasi-municipal corporation in the state as well as any branch, department, agency, instrumentality, or individual acting under color of law of the state or a subdivision of the State.

III. Section 2. Right to Practice Science-Based Medicine

a. 1. Notwithstanding any other provision of law, the state shall not require a licensed physician, or a person operating under his or her authority, to provide a patient with: Information that is not, in the physician's reasonable professional medical judgment, medically accurate and appropriate for the patient; or

b. A medical service in a manner that is not, in the physician's reasonable professional medical judgment, evidence-based and appropriate for the patient.

1) 2. Notwithstanding any other provision of law, the state shall not prohibit a licensed physician, or a person operating under his or her authority, from providing a patient with:

a. Information that is, in the physician's reasonable professional medical judgment, medically accurate and appropriate for the patient; or

b. A medical service in a manner that is, in the physician's reasonable professional medical judgment, evidence-based and appropriate for the patient.

IV. Section 3.

A physician who determines that a state requirement is not evidence-based or medically accurate, and determines that following a state requirement is not appropriate to the patient, shall document their decision in writing, including the medical basis for the determination. This documentation shall be retained in the patient's file for [seven years]. [Customize based on state law on retention of medical records]

V. Section 4.

Nothing in this act shall be construed to alter existing professional standards of care or abrogate the duty of a licensed health care practitioner to meet the applicable standard of care.

VI. The provisions of this Act shall be severable, and if any phrase, clause, sentence or provision is declared to be invalid or is preempted by federal law or regulation, the validity of the remainder of this Act shall not be affected

Model Language Annotated

The model bill language is in italics below and accompanied by information about its purpose in the bill or its source.

I. **Preamble**

> *It is the intent of the General Assembly to protect the health of patients under the care of a licensed physician or someone operating under his or her authority by ensuring that the practitioner is able to communicate freely with patients and exercise his or her medical judgment in order to provide the most beneficial medical treatment to the individual patient.*
>
> *Health care practitioners have a professional and ethical responsibility to provide the best possible care to their patients.*
>
> *This legislation does not alter existing accountability mechanisms for health care practitioners including in regards to medical malpractice, safety or licensing requirements.*

The preamble is non-binding language that aims to explain the purpose of the legislation. The use of preambles differs from state to state, with some including the language in the code and others only including the operative language.

II. **Section 1. Definitions of Key Terms**

Evidence Based

> *"Evidence Based." The conscientious, explicit and judicious use of current best evidence in making decisions about the care of the individual patient and integrating individual clinical expertise with the best available external clinical evidence from systematic research.*

The definition of evidence-based was developed by the leaders on evidence-based care and is articulated in an article, "Evidence based medicine: what it is and what it isn't," Published by the *BMJ* (formerly the British Medical Journal) an international peer reviewed medical journal. Sackett, D. L., Rosenberg, W. M. C., Gray, J. A. M., Haynes, R. B., Richardson, W. S. (1996, January). Evidence based medicine: what it is and what it isn't. *BMJ 312*, 71–72.

This definition is also endorsed by the Cochrane network, a leading non-profit medical collaborative that is a "global independent network of health practitioners, researchers, patient advocates and others…working together to produce credible, accessible health information that is free from commercial sponsorship and other conflicts of interest."

Medically Accurate

> *"Medically accurate." In relation to information, information that is:*

1) *verified or supported by the weight of peer reviewed medical research conducted in compliance with accepted scientific methods;*
2) *recognized as medically sound and objective by leading medical organizations with relevant expertise, such as the American Medical Association, the American Congress of Obstetricians and Gynecologists, the American Public Health Association, the American Psychological Association, the American Academy of Pediatrics, the American College of Physicians and the American Academy of Family Physicians; or government agencies such as the Centers for Disease Control, the Food and Drug Administration, the National Cancer Institute, and the National Institutes of Health; and scientific advisory groups such as the Institute of Medicine and the Advisory Committee on Immunization Practices; or*
3) *recommended by or affirmed in the medical practice guidelines of a nationally recognized accrediting organization.*

Medically accurate is defined in a number of state statutes in the context of sexuality education. An overview is available here: Santelli, J. S. (2008, October). Medical Accuracy in Sexuality Education: Ideology and the Scientific Process. *American Journal of Public Health, 98*(10), 1786–1792. This definition draws from those definitions as well as takes into account the various ways in which it might be applicable in ensuring medically accurate information and care in a clinical setting.

Appropriate for the Patient

"Appropriate for the Patient" Means care consistent with applicable legal, health and professional standards; the patient's clinical and other circumstances; and the patient's reasonably known wishes and beliefs.

The definition of appropriate in regards to health care is drawn from a definition that appears in a number of state laws including New York, Rhode Island, and Massachusetts and has been proposed in state legislation in a number of other states including Arizona and New Jersey.

State [State Dependent]

"State." means the state and every county, city, town, municipal corporation, and quasi-municipal corporation in the state as well as any branch, department, agency, instrumentality, or individual acting under color of law of the state or a subdivision of the State.

Defining "state" makes it clear that the legislation reaches enforcement bodies such as agencies that promulgate rules or boards that are established by the executive or legislative branch.

III. **Operational Language Section 2. Right to Practice Science-Based Medicine**

a. *1. Notwithstanding any other provision of law, the state shall not require a licensed physician, or a person operating under his or her*

authority, to provide a patient with: Information that is not, in the physician's reasonable professional medical judgment, medically accurate and appropriate for the patient; or

b. A medical service in a manner that is not, in the physician's reasonable professional medical judgment, evidence-based and appropriate for the patient.

c. 2. Notwithstanding any other provision of law, the state shall not prohibit a licensed physician, or a person operating under his or her authority, from providing a patient with:

d. Information that is, in the physician's reasonable professional medical judgment, medically accurate and appropriate for the patient; or

e. A medical service in a manner that is, in the physician's reasonable professional medical judgment, evidence-based and appropriate for the patient

The content of the operational language is based on analysis of laws that directly interfere in the patient-provider relationship with mandates in conflict with evidence-based, quality care. Much of this was garnered from statements published by leaders of the medical and advocacy communities, including:

American College of Physicians – According to its website, "[t]he American College of Physicians (ACP) is a national organization of internists — physician specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness. ACP is the largest medical-specialty organization and second-largest physician group in the United States. Its membership of 141,000 includes internists, internal medicine subspecialists, and medical students, residents, and fellows."

Its Statement of Principles includes guidelines for policy on the roles of federal and state governments in health care and the patient-physician relationship on p. 6. American College of Physicians. (2012, July). *Statement of Principles on the Role of Governments in Regulating the Patient-Physician Relationship*.

New England Journal of Medicine – A sounding board piece was authored by executive staff leadership of five professional societies that represent the majority of U.S. physicians providing clinical care — the American Academy of Family Physicians, the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, the American College of Physicians, and the American College of Surgeons. The piece was later endorsed by the American Medical Society.

Weinberger, S. E., Lawrence, III, H. C., Henley, D. E., Alden, E. R., and Hoyt, D. B. (2012, October). Legislative Interference with the Patient–Physician Relationship. *New England Journal of Medicine, 367*(16), 1557–1559.

Coalition to Protect the Patient-Provider Relationship – Comprised of professional, non-profit, and advocacy groups united in opposition to political interference in the content of the clinical relationship between a patient and provider. The Coalition believes that all parties involved in the provision of health care should respect the unique nature and importance of the patient-provider relationship and support the ethical obligation of the health care provider to follow the science and to put the patient first. Twenty-one members of the Coalition have endorsed the principles. Coalition to Protect the Patient-Provider Relationship. *Mission Statement*.

IV. **Operational Language Section 4**

Nothing in this act shall be construed to alter existing professional standards of care or abrogate the duty of a licensed health care practitioner to meet the applicable standard of care.

This section makes it clear we are not trying to change or alter standard of care for purposes of medical malpractice.

Statements on Political Interference by Medical Groups

Many leading medical organizations have issued statements on stopping political interference in the patient-provider relationship.

- **Leadership of the American Academy of Family Physicians, the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, the American College of Physicians, and the American College of Surgeons in the New England Journal of Medicine, October 2012**
  - "[L]egislators in the United States have been overstepping the proper limits of their role in the health care of Americans to dictate the nature and content of patients' interactions with their physicians. Some recent laws and proposed legislation inappropriately infringe on clinical practice and patient–physician relationships, crossing traditional boundaries and intruding into the realm of medical professionalism."

    (Weinberger, S. E., Lawrence, III, H. C., Henley, D. E., Alden, E. R., and Hoyt, D. B. (2012, October**). Legislative Interference with the Patient–Physician Relationship**. *New England Journal of Medicine, 367*(16), 1557–1559.)
  - "Legislators, regrettably, often propose new laws or regulations for political or other reasons unrelated to the scientific evidence and counter to the health care needs of patients. Legislative mandates regarding the practice of medicine do not allow for the infinite array of exceptions – cases in which the mandate may be unnecessary, inappropriate, or even harmful to an individual patient."

    (Weinberger, S. E., Lawrence, III, H. C., Henley, D. E., Alden, E. R., and Hoyt, D. B. (2012, October**). Legislative Interference with the Patient–Physician Relationship**.
- **American College of Obstetricians and Gynecologists**
  - "We maintain our position that decisions about an individual's medical care are best made between the patient and his or her physician. Lawmakers should not be taking it upon themselves to define, mandate, or prohibit medical practices or to require doctors to read any, especially inaccurate, information off a government script to their patients."

    (Breeden, J. & Lawrence, H. the American Congress of Obstetricians and Gynecologists. (2012, May 20). Letter to the Editor. *USA Today*.)
  - "The patient-physician relationship is essential to the provision of safe and quality medical care and should be protected from unnecessary governmental intrusion. Efforts to legislate elements of patient care and counseling can drive a wedge between a patient and her health care provider, be that a physician, certified nurse-midwife, certified midwife, nurse practitioner, or physician assistant. Laws should not interfere with the ability of physicians to determine appropriate treatment options and have open, honest, and confidential communications with their patients. Nor should laws interfere with the patient's right to be counseled by a physician according to the best currently available medical evidence and the physician's professional medical judgment."

(Executive Board, American College of Obstetricians and Gynecologists & American Congress of Obstetricians and Gynecologists. (2013). *Statement of Policy, Legislative Interference with Patient Care, Medical Decisions, and the Patient-Physician Relationship*.)

- **American Medical Association**
  - "Intrusive legislation sets a dangerous precedent that would allow government and/or other third parties to mandate what tests, procedures or medicines must be provided to patients. If these efforts are not stopped, patients and our health care system will lose."

    (Wah, R. of the American Medical Association. (2012, May 28). Letter to the Editor, *USA Today*.)
  - "1. Our AMA vigorously and actively defends the physician-patient-family relationship and actively opposes state and/or federal efforts to interfere in the content of communication in clinical care delivery between clinicians and patients. 2. Our AMA strongly condemns any interference by government or other third parties that compromise a physician's ability to use his or her medical judgment as to the information or treatment that is in the best interest of their patients."

    (House of Delegates, American Medical Association. (*2013*). *Resolution 717, Government Interference in the Patient-Physician Relationship*.)
- **American College of Physicians** – "Medical practice should reflect current scientific evidence and medical knowledge, which may evolve over time. Physicians should be guided by evidence-based clinical guidelines that allow flexibility to adapt to individual patient circumstances. Statutory and regulatory standards of care may become 'set in concrete' and not reflect the latest evidence and applicable medical knowledge."

  (American College of Physicians. (2012, July). ***Statement of Principles on the Role of Governments in Regulating the Patient-Physician Relationship*** (p. 6).)

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1 Weinberger, S.E., Lawrence, III, H.C., Henley, D.E., Alden, E.R., & Hoyt, D.B. (2012, October 18). Legislative Interference with the Patient–Physician Relationship. *New England Journal of Medicine 367,* p. 1557. Retrieved 9 September 2015, from http://www.nejm.org/doi/full/10.1056/NEJMsb1209858

2 Hagan, J.F., Shaw, J.S., Duncan, P.M. (2008). *Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents.* American Academy of Pediatrics. Retrieved 9 September 2015, from http://www.first5kids.org/sites/default/files/download/Appendix%20B%20Bright%20Futures%20Guidelines.pdf;

3 Law Center to Prevent Gun Violence. (2015, January 22). Summary of Enacted Laws since Newtown. Retrieved 18 September 2015, from http://smartgunlaws.org/summary-of-enacted-laws-since-newtown/

4 McFeeley, M. (2014). Falling Through the Cracks: Public Information and the Patchwork of Hydraulic Fracturing Disclosure Laws. *Vermont Law Review, 38.*

5 Guttmacher Institute. (2015, September 1). *State Policies in Brief: Counseling and Waiting Periods for Abortion*. Retrieved 2 September 2015, from http://www.guttmacher.org/statecenter/spibs/spib_MWPA.pdf. (Kansas and Texas; Alaska, Mississippi and Oklahoma include this information in their state-drafted written materials but it is not mandated by state law).

6 Ibid. In Arizona, enforcement is temporarily blocked by court order. Ibid. In Arkansas, the policy is scheduled to take effect on January 1, 2016. H.B. 1394, 90th Gen. Assemb., Reg. Sess. (Ark. 2015).

7 Guttmacher Institute. (2015, August). *State Policies in Brief: Requirements for Ultrasounds.* Retrieved August 6, 2015, from http://www.guttmacher.org/statecenter/spibs/spib_RFU.pdf

8 See note 5.

9 Guttmacher Institute. (2015, July 1). *Laws Affecting Reproductive Health and Rights: State Trends at Midyear, 2015.* Retrieved 18 September 2015, from http://www.guttmacher.org/media/inthenews/2015/07/01/