



Statement of Principles on the Role of Governments in Regulating the Patient-Physician Relationship

A Statement of Principles of the
American College of Physicians
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This paper, written by Jack Ginsburg and Lois Snyder, JD, was developed for the Health and Public Policy Committee of the American College of Physicians (ACP); Robert M. Centor, MD, FACP, (Chair); Jacqueline W. Fincher, MD, MACP (Vice Chair); Vineet Arora, MD, FACP; Ankit Bhatia (Student); Douglas M. DeLong, MD, FACP; Richard M. Dupee, MD, FACP; Luke O. Hansen, MD; Gregory A. Hood, MD, FACP; Ali M. Khan, MD (Associate); Mary Newman, MD, FACP; Kenneth E. Olive, MD, FACP; P. Preston Reynolds, MD, FACP; Jeffrey G. Wiese, MD, FACP (Regent). The authors wish to thank the members of ACP's Ethics, Professionalism and Human Rights Committee for reviewing and contributing to the development of this paper; David A. Fleming, MD, MA, FACP (Chair); Ana Maria Lopez, MD, MPH, FACP (Vice Chair); Jeffrey T. Berger, MD, FACP; Thomas A. Bledsoe, MD, FACP; Clarence H. Braddock III, MD, MPH, FACP; Nitin S. Damle, MD, MS, FACP; Kathy Faber-Langendoen, MD, FACP; Nathaniel E. Lepp; Alejandro Moreno, MD, MPH, JD, FACP, FCLM; Upasna Swift, MBBS, FACP; Jon C. Tilburt, MD, FACP; Michael N. Young, MD. It was approved by the ACP Board of Regents on July 28, 2012.

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“Society has conferred professional prerogatives on physicians with the expectation that they will use their position for the benefit of patients. In turn, physicians are responsible and accountable to society for their professional actions. Society grants each physician the rights, privileges, and duties pertinent to the patient-physician relationship and has the right to require that physicians be competent and knowledgeable and that they practice with consideration for the patient as a person.”
- ACP Ethics Manual (sixth edition, 2012)¹

Introduction

The physician’s first and primary duty is to put the patient first. To accomplish this duty, physicians and the medical profession have been granted a privileged position in society conferred by society and government.^{1,2}

Several states have proposed or adopted legislation and/or regulations, however, that interfere, or have the potential to interfere, with appropriate clinical practice by (1) prohibiting physicians from discussing with or asking their patients about risk factors that may affect their health or the health of their families, as recommended by evidence-based guidelines of care; (2) requiring physicians to discuss specific practices that in the physician’s best clinical judgment are not individualized to the patient; (3) requiring physicians to provide diagnostic tests or medical interventions that are not supported by evidence or clinical relevance; or (4) limiting information that physicians can disclose to patients. This paper provides a framework for broadly addressing these issues without expressly taking positions on the controversial and related issues of abortion, reproductive rights, and gun control.

Of particular concern are laws and regulations that require physicians to provide care not supported by evidence-based guidelines and/or not individualized to the needs of the specific patient. Although it may be difficult to distinguish between mandates that interfere with clinical practice versus those that promote good public health, this paper attempts to provide a framework with principles that can provide some guidance. The need to address these issues was discussed in April by the Board of Regents, which charged the Health and Public Policy Committee (HPPC), with input from the Ethics, Professionalism and Human Rights Committee (EPhR), to develop a policy framework on laws and regulations that:

- 1) Prohibit physicians from discussing with or asking their patients about risk factors that may affect their health or the health of their families, as recommended by evidence-based guidelines of care;
- 2) Require physicians to discuss specific practices if, in the physicians’ best clinical judgment, it is not necessary or appropriate at the time of a specific patient encounter; or
- 3) Require physicians to provide—and patients to receive—diagnostic tests or medical interventions that are not supported by evidence-based guidelines, especially if such tests or interventions are invasive and required to be provided without the patient’s expressed consent.

Background

“The physician’s first and primary duty is to the patient...[T]he physician’s professional role is to make recommendations on the basis of the best available medical evidence and to pursue options that comport with the patient’s unique health needs, values, and preferences.” In an increasingly complex health care system, physicians have an obligation to help patients understand clinical recommendations to enable them to make informed choices among all appropriate care and referral options.¹

Government plays a key role in helping to provide the framework within which physicians carry out their ethical obligations. The many appropriate roles of government include licensing, protecting and improving public health, determining the safety and effectiveness of drugs and medical devices, and supporting medical education, training, and research, among others.

The federal government plays a major role in assuring public health, safety, and welfare. Responsibilities include a broad range of functions, such as approving drugs and medical devices for safety and effectiveness, assuring that drugs are manufactured according to proper dosages in safe and uncontaminated facilities, sponsoring clinical health research, supporting the education and training of the physician workforce, assuring a safe environment, and protecting and improving public health. The federal government has a major role in protecting the health and welfare of vulnerable populations, including the elderly (Medicare), the poor and disabled (Medicaid), children (CHIP), veterans (VHA), and other disadvantaged or special needs groups.

All states also have laws and regulations to protect public health, safety, and welfare. State medical practice acts “protect the public from the unprofessional, improper, incompetent, unlawful, fraudulent and/or deceptive practice of medicine.” State medical boards regulate the practice of medicine and grant privileges to practice under these laws. The primary responsibility and obligation of the state medical board is to protect the public. They establish requirements for licensure, administer licensure examinations, evaluate the medical education and training of applicants, evaluate previous professional performance of applicants, and establish and administer disciplinary procedures.³ In doing so, they ensure patients that licensed physicians meet professional standards of care, ethics, and professionalism that, if not met, could compromise patient safety.

These medical practice acts generally defer to the profession to establish and maintain standards of medical and ethical practice. However, medical practice acts can also be quite specific in directing physician behavior. Some state laws require specific actions by physicians and other health care professionals. Examples include laws and regulations requiring immunizations; screening for specific diseases; reporting contagious diseases, suspected cases of child/domestic partner abuse, and reporting of impaired drivers and neglected care of patients in nursing homes and other institutions; rules concerning the treatment of minors; and regulations of hospice care, to name a few. However, legislation can be slow and cumbersome in responding to medical advances or changes in scientific knowledge.

Examples of Legislation and Regulations that Appear to Interfere with Appropriate Clinical Medical Practice and Intrude on the Patient-Physician Relationship

Some recent laws and proposed legislation appear to inappropriately infringe on clinical medical practice and patient-physician relationships, crossing traditional boundaries and intruding into the realm of medical professionalism and could compromise patient safety.

Mandated Treatment and Procedures

Legislation in Alaska⁴ would allow patients and families to override a physician's do-not-resuscitate (DNR) order. This legislation fails to recognize the low success rate of cardiopulmonary resuscitation (CPR) and that CPR attempts could be harmful and painful for patients with extremely advanced medical conditions. As stated in the Ethics Manual, "Intervention in the case of a cardiopulmonary arrest is inappropriate for some patients, particularly those for whom death is expected, imminent, and unavoidable." ACP policy allows for unilateral DNR orders by physicians: "In the circumstance that no evidence shows that a specific treatment desired by the patient will provide any medical benefit, the physician is not ethically obliged to provide such treatment (although the physician should be aware of any relevant state law). The physician need not provide an effort at resuscitation that cannot conceivably restore circulation and breathing, but he or she should help the family to understand and accept this reality."¹ And, according to the Charter on Professionalism: "Physicians must have respect for patient autonomy. Physicians must be honest with their patients and empower them to make informed decisions about their treatment. Patients' decisions about their care must be paramount, as long as those decisions are in keeping with ethical practice and do not lead to demands for inappropriate care."² The Alaska legislation stipulates that all previously established health care directives and DNR orders become null and void if they are not in accord with the new law.⁴

In Connecticut, Texas, and Virginia, physicians providing mammograms are required to notify women about their breast density and potential benefits of additional screening. In vetoing legislation (SB 791) in California with similar requirements, Gov. Edmund G. Brown Jr. raised concerns about the potential anxiety that such breast density information might provoke. He warned, "The notice contained in this bill goes beyond information about breast density. It advises that additional screening may be beneficial. If the state must mandate a notice about breast density - and I am not certain it should - such a notice must be more carefully crafted, with words that educate more than they prescribe."⁵

Arizona women seeking an abortion must have an ultrasound at least 24 hours before the procedure. Under a recently signed law in Wisconsin, doctors must have three office visits with a woman before prescribing a drug-induced abortion. They also must determine that the woman is not being coerced into the procedure. Physicians who fail to abide by the mandate could be subject to criminal penalties, including imprisonment. In a number of other states, laws also place requirements on abortions.⁶

In Virginia, a bill would have required women to have fetal ultrasound imaging for the purpose of determining gestational age before receiving an abortion.⁷ As an external ultrasound would not be able to provide the mandated information early in pregnancy, this legislation would have resulted in the use of transvaginal ultrasound, as determined by her physician, for a woman in the very early stages of pregnancy. In a letter urging Virginia Governor Bob McDonnell to veto the bill, ACP's Virginia Chapter noted, "[W]e believe that this legislation represents a dangerous and unprecedented intrusion by the Commonwealth of Virginia into patient privacy and that it encroaches on the doctor-patient relationship." The letter continued, "[T]his legislation interferes with physicians' ability to make sound clinical judgments based on medical reasoning and in the best interest of our patients."⁸ A modified bill, which requires external ultrasound only, was signed into law by Governor Bob McDonnell in March 2012.⁹ Any physician who fails to comply is subject to a \$2500 civil penalty. Although abortion laws will not be the focus of the position paper since this procedure is not within the routine practice of internal medicine, we note the issue here because of its prominence

in debates about government mandates. It is our goal to develop principles that will be applicable in analyzing a wide variety of laws and regulations.

Prohibited Speech

Laws that restrict the content of patient-physician communications are problematic, especially considering that “[P]hysicians must provide information to the patient about all appropriate care and referral options.”¹

In Florida, legislation expressly restricted health care practitioners from asking patients questions related to gun safety or recording information from those conversations in patients’ medical records on penalty of harsh disciplinary sanctions, including fines and permanent revocation of their licenses to practice medicine.¹⁰ Under the law, physicians, following established protocol by informing patients how they may limit the lethal risks posed by firearms, could be at risk of losing their medical licenses. The ACP Florida Chapter joined in a suit contesting the law, arguing that it would deprive physicians and other health care practitioners of their First Amendment right to freedom of speech and also would deprive patients of their First Amendment right to receive potentially life-saving information on safety measures they can take to protect their children, families, and others from injury or death resulting from unsafe storage or handling of firearms.¹¹ The federal district court judge agreed, and a permanent injunction (subject to appeal) has been issued preventing the law from being enforced.¹²

In Pennsylvania, physicians can access information about chemicals used in the “fracking” process to extract oil and natural gas, but they are prohibited by law from discussing their findings with patients who may be suffering from consequent harm. Fracking can involve injecting into the ground toxic chemicals, such as benzene, toluene, ethylbenzene, and xylene.¹³ Low levels of exposure to those chemicals can trigger headaches, dizziness, and drowsiness, while higher levels of exposure may cause cancer. The law¹⁴ requires mining and drilling companies to disclose the identity and amount of any chemicals used in fracking fluids upon written request of any health professional seeking the information in order to diagnose or treat a patient that may have been exposed to a hazardous chemical, though health professionals seeking this information must sign a confidentiality agreement stating that they will not disclose the information. However, there is some controversy over whether the law does or does not allow for disclosure to the patient for the purpose of diagnosis and treatment. The following are relevant sections of the statute:

- (10) A vendor, service company, or operator shall identify the specific identity and amount of any chemicals claimed to be a trade secret or confidential proprietary information to any health professional who requests the information in writing if the health professional executes a confidentiality agreement and provides a written statement of need for the information indicating all of the following:
 - (i) The information is needed for the purpose of diagnosis or treatment of an individual.
 - (ii) The individual being diagnosed or treated may have been exposed to a hazardous chemical.
 - (iii) Knowledge of information will assist in the diagnosis or treatment of an individual.

- (11) If a health professional determines that a medical emergency exists and the specific identity and amount of any chemicals claimed to be a trade secret or confidential proprietary information are necessary for emergency treatment, the vendor, service provider, or operator shall immediately disclose the information to the health professional upon a verbal acknowledgment by the health professional that the information may not be used for purposes other than the health needs asserted and that the health professional shall maintain the information as confidential. The vendor, service provider, or operator may request, and the health professional shall provide upon request, a written statement of need and a confidentiality agreement from the health professional as soon as circumstances permit, in conformance with regulations promulgated under this chapter.¹³

Examples of Other Government Requirements that May be Inappropriate

Laws also govern vaccination of children, with many allowing exemptions for children with medical contraindications confirmed by a physician and exemptions for religious objections or personal beliefs. Concerned that the personal belief exemption is undermining immunization rates, physicians have supported recent bills in Washington state, Vermont, and California to either (1) make the exemption more difficult to obtain by requiring parents to get a physician or nurse practitioner signature affirming they have been provided the parent(s) information on the benefits and risks of immunization and the health risks of communicable diseases covered by the state vaccine mandate, or (2) eliminate the personal belief exemption altogether.¹⁵

Legislation in New York requires physicians and other health care practitioners, starting in 2011, to offer terminally ill patients “information and counseling regarding palliative care and end-of-life options appropriate to the patient, including... prognosis, risks and benefits of the various options; and the patient’s legal rights to comprehensive pain and symptom management.” Although the law only requires that the clinician offer to provide information, the Medical Society of the State of New York and others have criticized the law as failing to recognize the complexity and uncertainty involved in end-of-life discussions among a patient, the family, and his or her physician.^{16,17} Failure to comply with this law can result in fines of up to \$5,000 for repeated offenses, and a jail term of up to 1 year for willful violations. California adopted a similar law in 2009. The California Medical Society did not oppose it, but had opposed an earlier version that would have required doctors to specifically tell terminally ill patients about alternatives, such as palliative sedation and refusing food and water to speed the dying process.¹⁸

ACP Principles on the Role of Governments and Legislation in Regulating the Patient-Physician Relationship

“Through legislation, administrative action, or judicial decision, government is increasingly involved in medical ethics. The convergence of various forces—scientific advances, patient and public education, the Internet, the civil rights and consumer movements, the effects of law and economics on medicine, and the heterogeneity of our society—demands that physicians clearly articulate the ethical principles that guide their behavior in clinical care, research, and teaching, or as citizens or collectively as members of the profession. It is crucial that a responsible physician perspective be heard as societal decisions are made.”

- ACP Ethics Manual (sixth edition, 2012)

The ACP recommends the following principles for the roles of federal and state governments in health care and the patient-physician relationship.

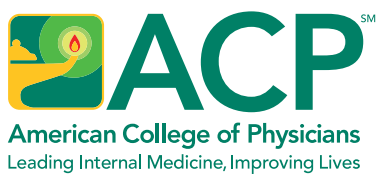
- 1) All parties involved in the provision of health care, including government, are responsible for acknowledging and lending support to the intimacy and importance of the patient-physician relationship and the ethical obligations of the physician to put the patient first. The fundamental ethical principles of beneficence, honesty, confidentiality, privacy, and advocacy are central to the delivery of evidence-based, individualized care and must be respected by all parties.¹
- 2) Physicians should not be prohibited by law or regulation from discussing with or asking their patients about risk factors, or disclosing information (including proprietary information on exposure to potentially dangerous chemicals or biological agents) to the patient, which may affect their health, the health of their families, sexual partners, and others who may be in contact with the patient. Rules limiting what may or may not be discussed, or the information that may be disclosed, during healthcare encounters undermine the patient-physician relationship and can inappropriately affect patient health. The patient and his or her physician are best positioned to determine what topics to discuss.
- 3) Laws and regulations should not mandate the content of what physicians may or may not say to patients or mandate the provision or withholding of information or care that, in the physician's clinical judgment and based on clinical evidence and the norms of the profession, are not necessary or appropriate for a particular patient at the time of a patient encounter:
 - Even laws and regulations that mandate a test, procedure, treatment, or provision of specific types of health information or counseling to the patient, when generally consistent with the standard of care and intended to provide benefit to the patient, should be approached cautiously, because they cannot allow for all potential situations in which their application would be unnecessary or even harmful to specific patients. Mandated care may also interfere with the patient-physician relationship and divert clinical time from more immediate clinical concerns.
 - Legislation and regulations should not prevent physicians from treating particular types of patients (e.g., based on immigration status, racial or ethnic origin, sexual orientation, religion).^{1,19,20}
 - The following questions may be helpful in providing general guidance for evaluating the appropriateness of proposed laws and regulations regarding the provision of medical care during the patient-physician encounter, *with the presumption being that the government should avoid regulating the content of the clinical encounter without a compelling and evidence-based benefit to the individual patient and/or substantial public health justification that can't be better met through other means*. The list is intended merely to suggest questions that should be raised—it is not meant to be all inclusive. The questions are not mutually exclusive; positive answers to all questions does not imply that a law or regulation is appropriate and is not necessary to support a proposed law or regulation.
 - a. Is the content and information or care consistent with the best available medical evidence on clinical effectiveness and appropriateness and professional standards of care?

- b. Is the proposed law or regulation necessary to achieve public health objectives that directly affect the health of the individual patient, as well as population health, as supported by scientific evidence, and if so, is there any other reasonable way to achieve the same objectives?
 - c. Could the presumed basis for a governmental role be better addressed through advisory clinical guidelines developed by professional societies?
 - d. Does the content and information or care allow for flexibility based on individual patient circumstances and on the most appropriate time, setting, and means of delivering such information or care?
 - e. Is the proposed law or regulation required to achieve a public policy goal –such as protecting public health or encouraging access to needed medical care – without preventing physicians from addressing the healthcare needs of individual patients during specific clinical encounters based on the patients’ own circumstances, and with minimal interference to patient-physician relationships?
 - f. Does the content and information to be provided facilitate shared decision-making between patients and their physicians, based on the best medical evidence, the physician’s knowledge and clinical judgment, and patient values (beliefs and preferences), or would it undermine shared decision-making by specifying content that is forced upon patients and physicians without regard to the best medical evidence, the physician’s clinical judgment and the patient’s wishes?
 - g. Is there a process for appeal to accommodate for specific circumstances or changes in medical standards of care?
- 4) In making decisions about counseling and treatment among evidence-based options, the patient’s values are paramount, although the physician is not required to violate standards of medical care or ethics, fundamental personal values, or the law. Patients should not be required to undergo tests or interventions, especially invasive and potentially harmful interventions, that violate the patient’s values, are not medically necessary, and are not supported by scientific evidence on clinical effectiveness or could expose the patient to unnecessary risk, and physicians should not be required to provide such services.
- 5) 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.
- 6) Laws governing medical practice must be revised as needed and regulatory rules should offer a process for timely appeal in an interval appropriate to the nature of the condition being treated.
- 7) Regulatory requirements should not create undue burdens that have the consequence of limiting access to needed care or unnecessarily divert from the precious time that physicians have to spend with patients.

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