American College of Physicians Ethics Manual
Sixth Edition

Lois Snyder, JD, for the American College of Physicians Ethics, Professionalism, and Human Rights Committee*

Medicine, law, and social values are not static. Reexamining the ethical tenets of medicine and their application in new circumstances is a necessary exercise. The sixth edition of the American College of Physicians (ACP) Ethics Manual covers emerging issues in medical ethics and revisits older issues that are still very pertinent. It reflects on many of the ethical tensions in medicine and attempts to shed light on how existing principles extend to emerging concerns. In addition, by reiterating ethical principles that have provided guidance in resolving past ethical problems, the Manual may help physicians avert future problems. The Manual is not a substitute for the experience and integrity of individual physicians, but it may serve as a reminder of the shared duties of the medical profession.

Changes to the Manual from the fifth edition are noted in Box 1.

The Manual is intended to facilitate the process of making ethical decisions in clinical practice, teaching, and medical research and to describe and explain underlying ethics principles, as well as the physician’s role in society and with colleagues. Because ethics and professionalism must be understood within a historical and cultural context, the second edition of the Manual included a brief overview of the cultural, philosophical, and religious underpinnings of medical ethics in Western cultures. In this edition, we refer the reader to that overview (2, 3) and to other sources (4, 5) that more fully explore this rich heritage.

The Manual raises issues and presents general guidelines. In applying these guidelines, physicians should consider the circumstances of the individual patient and use their best judgment. Physicians have moral and legal obligations, and the two may not be concordant. Physician participation in torture is legal in some countries but is never morally defensible. Physicians must keep in mind the distinctions and potential conflicts between legal and ethical obligations and seek counsel when concerned about the potential legal consequences of decisions. We refer to the law in this Manual for illustrative purposes only; this should not be taken as a statement of the law or the legal consequences of actions, which can vary by state and country. Physicians must develop and maintain an adequate knowledge of key components of the laws and regulations that affect their patients and practices.

Medical and professional ethics often establish positive duties (that is, what one should do) to a greater extent than the law. Current understanding of medical ethics is based on the principles from which positive duties

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Conversion of graphics into slides

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Emerging Ethical Issues

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.

From genetic testing before conception to dilemmas at the end of life, physicians, patients, and their families are called upon to make difficult decisions. The 1970s saw the development of bioethics as a field. Important issues then (and now) include informed consent, access to health care, genetic screening and engineering, and forgoing life-sustaining treatment. These and other issues—physician-assisted suicide, technological changes, and the physician as entrepreneur—challenge us to periodically reconsider such topics as the patient–physician relationship, relationships with family caregivers, decisions to limit treatment, conflict of interest, physician–industry relations, changing communication modalities, and confidentiality.

This Manual was written for our colleagues in medicine. The College believes that the Manual provides the best approach to the challenges addressed in it. We hope it stimulates reasoned debate and serves as a reference for persons who seek the College’s position on ethical issues. Debates about medical ethics may also stimulate critical evaluation and discussion of law and public policy on the difficult ethical issues facing patients, physicians, and society.

**Professionalism**

Medicine is not a trade to be learned, but a profession to be entered. A profession is characterized by a specialized body of knowledge that its members must teach and expand, by a code of ethics and a duty of service that put patient care above self-interest, and by the privilege of self-regulation granted by society. Physicians must individually and collectively fulfill the duties of the profession. While outside influences on medicine and the patient–physician relationship are many, the ethical foundations of the profession must remain in sharp focus.

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<th>Table 1. Principles That Guide the ACP Ethics Manual Recommendations</th>
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<td>Principle</td>
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<td>Respect for patient autonomy</td>
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VIP = very important person.
The definition of medical profession is noted in Box 2.

### The Physician and the Patient

The patient–physician relationship entails special obligations for the physician to serve the patient’s interest because of the specialized knowledge that physicians possess, the confidential nature of the relationship, and the imbalance of power between patient and physician. Physicians publicly profess that they will use their skills for the benefit of patients, not their own benefit (10). Physicians must uphold this declaration, as should their professional associations as communities of physicians that put patient welfare first (10).

The physician’s primary commitment must always be to the patient’s welfare and best interests, whether in preventing or treating illness or helping patients to cope with illness, disability, and death. The physician must respect the dignity of all persons and respect their uniqueness. The interests of the patient should always be promoted regardless of financial arrangements; the health care setting; or patient characteristics, such as decision-making capacity, behavior, or social status. Although the physician should be fairly compensated for services rendered, a sense of duty to the patient should take precedence over concern about compensation.

#### Initiating and Discontinuing the Patient–Physician Relationship

At the beginning of and throughout the patient–physician relationship, the physician must work toward an understanding of the patient’s health problems, concerns, goals, and expectations. After patient and physician agree on the problem and the goals of therapy, the physician presents one or more courses of action. The patient may authorize the physician to initiate a course of action; the physician can then accept that responsibility. The relationship has mutual obligations. The physician must be professionally competent, act responsibly, seek consultation when necessary, and treat the patient with compassion and respect, and the patient should participate responsibly in the care, including giving informed consent or refusal to care as the case might be.

Effective communication is critical to a strong patient–physician relationship. The physician has a duty to promote patient understanding and should be aware of barriers, including health literacy issues for the patient. Communication through e-mail or other electronic means can supplement face-to-face encounters; however, it must be done under appropriate guidelines (11). "Issuance of a prescription or other forms of treatment, based only on an online questionnaire or phone-based consultation, does not constitute an acceptable standard of care" (12). Exceptions to this may include on-call situations in which the patient has an established relationship with another clinician in the practice and certain urgent public health situations, such as the diagnosis and treatment of communicable infectious diseases. An example is the Centers for Disease Control and Prevention–endorsed practice of expedited partner therapy for certain sexually transmitted infections. However, aspects of a patient–physician relationship, such as the physician’s responsibilities to the patient, attach even in the absence of interpersonal contact between the physician and patient (12).

Care and respect should guide the performance of the physical examination. The location and degree of privacy should be appropriate for the examination being performed, with chaperone services as an option. An appropriate setting and sufficient time should be allocated to encourage exploration of aspects of the patient’s life pertinent to health, including habits, relationships, sexuality, vocation, culture, religion, and spirituality.

By history, tradition, and professional oath, physicians have a moral obligation to provide care for ill persons. Although this obligation is collective, each individual physician is obliged to do his or her fair share to ensure that all ill persons receive appropriate treatment (13). A physician may not discriminate against a class or category of patients.

An individual patient–physician relationship is formed on the basis of mutual agreement. In the absence of a preexisting relationship, the physician is not ethically obliged to provide care to an individual person unless no other physician is available, as is the case in some isolated communities, or when emergency treatment is required. Under these circumstances, the physician is morally bound to provide care and, if necessary, to arrange for proper follow-up. Physicians may also be bound by contract to provide care to beneficiaries of health plans in which they participate.

Physicians and patients may have different concepts of or cultural beliefs about the meaning and resolution of medical problems. The care of the patient and satisfaction of both parties are best served if physician and patient discuss their expectations and concerns. Although the physician must address the patient’s concerns, he or she is not required to violate fundamental personal values, standards of medical care or ethical practice, or the law. When the patient’s beliefs—religious, cultural, or otherwise—run counter to medical recommendations, the physician is obliged to try to understand clearly the beliefs and the viewpoints of the patient. If the physician cannot carry out the patient’s wishes after seriously attempting to resolve...
Individuals or the public or to disclose or report information not absolute. It may have to be overridden to protect personal medical information (often termed a “privileged priesthood”). The physician must respect the privacy of patients, encouraging them to follow appropriate security protocols for storage and transmission in the era of electronic health records and electronic data processing, e-mail, faxing of patient information, third-party payment for medical services, and sharing of patient care among numerous health professionals and institutions. Physicians must follow appropriate security protocols for storage and transfer of patient information to maintain confidentiality, adhering to best practices for electronic communication and use of decision-making tools. Confidentiality is a matter of respecting the privacy of patients, encouraging them to seek medical care and discuss their problems candidly, and preventing discrimination on the basis of their medical conditions. The physician should not release a patient’s personal medical information (often termed a “privileged communication”) without that patient’s consent.

However, confidentiality, like other ethical duties, is not absolute. It may have to be overridden to protect individuals or the public or to disclose or report information when the law requires it. The physician should make every effort to discuss the issues with the patient. If breaching confidentiality is necessary, it should be done in a way that minimizes harm to the patient and heeds applicable federal and state law.

Physicians should be aware of the increased risk for invasion of patient privacy and should help ensure confidentiality. They should be aware of state and federal law, including the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy rule (18). Within their own institutions, physicians should advocate policies and procedures to secure the confidentiality of patient records. To uphold professionalism and protect patient privacy, clinicians should limit discussion of patients and patient care issues to professional encounters. Discussion of patients by professional staff in public places, such as elevators or cafeterias, violates confidentiality and is unethical. Outside of an educational setting, discussion of patients with or near persons who are not involved in the care of those patients impairs the public’s trust and confidence in the medical profession. Physicians of patients who are well-known to the public should remember that they are not free to discuss or disclose information about any patient’s health without the explicit consent of the patient.

In the care of the adolescent patient, family support is important. However, this support must be balanced with confidentiality and respect for the adolescent’s autonomy in health care decisions and in relationships with clinicians (19). Physicians should be knowledgeable about state laws governing the right of adolescent patients to confidentiality and the adolescent’s legal right to consent to treatment.

Occasionally, a physician receives information from a patient’s friends or relatives and is asked to withhold the source of that information from the patient (20). The physician is not obliged to keep such secrets from the patient. The informant should be urged to address the patient directly and to encourage the patient to discuss the information with the physician. The physician should use sensitivity and judgment in deciding whether to use the information and whether to reveal its source to the patient. The physician should always act in the best interests of the patient.

The Medical Record

Physician entries in the medical record, paper and electronic, should contain accurate and complete information about all communications, including those done in person and by telephone, letter, or electronic means. Ethically and legally, patients have the right to know what is in their medical records. Legally, the actual chart is the property of the physician or institution, although the information in the chart is the property of the patient. Most states have laws that guarantee the patient personal access to the medical record, as does the federal HIPAA privacy rule. The physician must release information to the patient or to a third party at the request of the patient. Information may not be withheld, including because of nonpayment of medi-
Disclosing information to patients is necessary to promote their well-being. Errors do not necessarily constitute the course of care if such information is material to the formation about procedural or judgment errors made inquired (25).

If a physician leaves a group practice or dies, patients must be notified and records forwarded according to patient instructions.

Disclosure

To make health care decisions and work in partnership with the physician, the patient must be well-informed. Effective patient–physician communication can dispel uncertainty and fear and enhance healing and patient satisfaction. Information should be disclosed to patients and, when appropriate, family caregivers or surrogates, whenever it is considered material to the understanding of the patient’s situation, possible treatments, and probable outcomes. This information often includes the costs and burdens of treatment, the experience of the proposed clinician, the nature of the illness, and potential treatments.

However uncomfortable for the clinician, information that is essential to and desired by the patient must be disclosed. How and when to disclose information, and to whom, are important concerns that must be addressed with respect for patient wishes. In general, individuals have the right to full and detailed disclosure. Some patients, however, may make it known that they prefer limited information or disclosure to family members or others they choose (21).

Information should be given in terms that the patient can understand. The physician should be sensitive to the patient’s responses in setting the pace of communication, particularly if the illness is very serious. Disclosure and the communication of health information should never be a mechanical or perfunctory process. Upsetting news and information should be presented to the patient in a way that minimizes distress (22, 23). If the patient cannot comprehend his or her condition, it should be fully disclosed to an appropriate surrogate.

Therapeutic nondisclosure, also called “therapeutic privilege,” is the withholding of relevant health information from the patient if disclosure is believed to be medically contraindicated (24). Because this exception could swallow the rule of informed consent, therapeutic privilege should be rarely invoked and only after consultation with a colleague. A thorough review of the benefits and harms to the patient and ethical justification of nondisclosure is required (25).

In addition, physicians should disclose to patients information about procedural or judgment errors made in the course of care if such information is material to the patient’s well-being. Errors do not necessarily constitute improper, negligent, or unethical behavior, but failure to disclose them may.

Informed Decision Making and Consent

The patient’s consent allows the physician to provide care. The unauthorized touching of a person is battery, even in the medical setting. Consent may be either expressed or implied.Expressed consent most often occurs in the hospital setting, where patients provide written or oral consent for a particular procedure. In many medical encounters, when the patient presents for evaluation and care, consent can be implied. The underlying condition and treatment options are explained to the patient or authorized surrogate and treatment is rendered or refused. In medical emergencies, consent to treatment necessary to maintain life or restore health is usually presumed unless it is known that the patient would refuse the intervention.

The doctrine of informed consent goes beyond the question of whether consent was given. Rather, it focuses on the content and process of consent. The physician must provide enough information for the patient to make an informed judgment about how to proceed. The physician’s presentation should include an assessment of the patient’s understanding, be balanced, and include the physician’s recommendation. The patient’s or surrogate’s concurrence must be free and uncoerced.

The principle and practice of informed consent rely on patients to ask questions when they are uncertain about the information they receive; to think carefully about their choices; and to be forthright with their physicians about their values, concerns, and reservations about a particular recommendation. Once patients and physicians decide on a course of action, patients should make every reasonable effort to carry out the aspects of care under their control or inform their physicians promptly if it is not possible to do so.

The physician must ensure that the patient or the surrogate is adequately informed about the nature of the patient’s medical condition and the objectives of, alternatives to, possible outcomes of, and risks of a proposed treatment.

Competence is a legal determination. All adult patients are considered competent to make decisions about medical care unless a court has declared them incompetent. In clinical practice, however, physicians and family members usually make decisions without a formal competency hearing in the court for patients who lack decision-making capacity (that is, the ability to receive and express information and to make a choice consonant with that information and one’s values). This clinical approach can be ethically justified if the physician has assessed decision-making capacity and determined that the patient is incapable of understanding the nature of the proposed treatment; the alternatives to it; and the risks, benefits, and consequences of it. Assessing a patient’s understanding can be difficult. Decision-making capacity should be evaluated for a particular decision at a particular point in time. The capacity to

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express a particular goal or wish can exist without the ability to make more complex decisions. The greater the consequences of the decision, the more important the assessment of decision-making capacity.

When a patient lacks decision-making capacity, an appropriate surrogate should make decisions with the physician. Treatment should conform to what the patient would want on the basis of written or oral advance care planning. If these preferences are not known, care decisions should be based on the best evidence of what the patient would have chosen based on the patient’s values, previous choices, and beliefs (substituted judgments) or, failing that, on the best interests of the patient. However, there may be situations in which best-interest decisions should supersede substituted judgments (26).

If the patient has designated a proxy, as through a durable power of attorney for health care, that choice should be respected. Some states have health care consent statutes that specify who and in what order of priority family members or close others can serve as surrogates. When patients have not selected surrogates, a family member—which could be a domestic partner—should serve as surrogate. Physicians should be aware of legal requirements in their states for surrogate appointment and decision making. In some cases, all parties may agree that a close friend is a more appropriate surrogate than a relative.

Surrogate preferences can conflict with the preferences and best interests of a patient. Physicians should take reasonable care to ensure that the surrogate’s decisions are consistent with patient preferences and best interests. When possible, these decisions should be reached in the medical setting. Physicians should emphasize to surrogates that decisions should be based on what the patient would want, not what surrogates would choose for themselves. Hospital ethics committees can be valuable resources in difficult situations. Courts should be used when doing so serves the patient, such as to establish guardianship for an unbefriended incompetent patient, to resolve a problem when other processes fail, or to comply with state law.

Physicians must strive to create an environment in which honesty can thrive and patients feel that concerns and questions are elicited.

**Decisions About Reproduction**

The ethical duty to disclose relevant information about human reproduction to the patient may conflict with the physician’s personal moral standards on abortion, sterilization, contraception, or other reproductive services. A physician who objects to these services is not obligated to perform, or prescribe them. As in any other medical situation, however, the physician has a duty to inform the patient about care options and alternatives, or refer the patient for such information, so that the patient’s rights are not constrained. Physicians unable to provide such information should transfer care as long as the health of the patient is not compromised.

If a patient who is a minor requests termination of pregnancy, advice on contraception, or treatment of sexually transmitted diseases without a parent’s knowledge or permission, the physician may wish to attempt to persuade the patient of the benefits of having parents involved, but should be aware that a conflict may exist between the legal duty to maintain confidentiality and the obligation toward parents or guardians. Information should not be disclosed to others without the patient’s permission (19). In such cases, the physician should be guided by the minor’s best interest in light of the physician’s conscience and responsibilities under the law.

**Genetic Testing, Privacy, and Confidentiality**

Presymptomatic and diagnostic testing raises issues of education, counseling, privacy, confidentiality, cost, and justice. Such testing may allow clinicians to predict diseases or detect susceptibility without the ability to prevent, treat, or cure the conditions identified. Genetic testing presents unique problems by identifying risk for disease for patients but also for family members who may not be under the care of the clinician providing the test.

Genetic testing includes predictive testing done in asymptomatic individuals and diagnostic testing done to rule out or confirm the suspicion of a genetic condition based on clinical characteristics in an already affected individual. The public and health care professionals often have a limited understanding of the distinction between prediction and susceptibility or risk.

Because the number of qualified clinical geneticists and genetic counselors is small and is unlikely to meet the demand generated by the exponential growth in genetic testing, clinicians will be increasingly expected to convey the meaning of genetic test results. Only physicians with the skills necessary for pretest and posttest education and counseling should engage in genetic testing (29, 30). If qualified, clinicians should discuss with patients the degree to which a particular genetic risk factor correlates with the likelihood of developing disease. Evidence-based sensitivity and specificity of particular genetic
tests should be available, and the risks and benefits of testing should be made clear to patients requesting such studies. If unqualified or unsure, the clinician should refer the patient for this discussion. Testing should not be undertaken until the potential consequences of learning genetic information are fully discussed with the patient. The potential impact on the patient’s well-being; implications for family members; and the potential for adverse use of such information by employers, insurers, or other societal institutions should be fully explored and understood. Commercial mail-order and other testing do not currently address these needs nor the requirements of specificity, sensitivity, or scientific credibility (31).

The concept of “genetic predestination” may substantially alter the lives of individuals and their families with implications for employment, obtaining insurance, child-bearing, diet, and other activities. Although information about the presence of a genetic risk factor or genetic disease in a family member raises the possibility that genetically related individuals are at risk, the primary obligation of the physician is to promote the best interests of the patient. However, the physician should encourage the patient’s cooperation in contacting family members at risk or obtain the patient’s consent to inform them about genetic counseling.

As more information becomes available on genetic risk for certain diseases, physicians must be aware of the need for confidentiality concerning genetic information and should follow best practices to minimize the potential for unauthorized or inappropriate disclosure of genetic data (32). Complex ethical problems exist, such as which family member should be informed of the results of genetic tests. Physicians should be sensitive to these issues and testing should not be undertaken until they are fully discussed and their consequences are well-understood. Other concerns related to genetic privacy include discrimination; cultural considerations; the ability to safeguard genetic data; and the potential for identifying patients through unauthorized methods (33), including potential access by law enforcement agencies without first obtaining a warrant (34). Many state governments and the federal government are promulgating rules on access of employers and insurers to such information. The Genetic Information Nondiscrimination Act of 2008 was designed to prevent discrimination in health coverage and employment based on genetic information. Physicians should inform patients of genetic privacy risks and implications for themselves and family members, so that they are able to make a well-informed decision about testing and disclosure of genetic information.

**Medical Risk to Physician and Patient**

Physicians take an oath to serve the sick. Traditionally, the ethical imperative for physicians to provide care has overridden the risk to the treating physician, even during epidemics. In recent decades, with better control of such risks, physicians have practiced medicine in the absence of risk as a prominent concern. However, potential occupational exposures, such as HIV, multidrug-resistant tuberculosis, the severe acute respiratory syndrome, and viral hepatitis, necessitate reaffirmation of the ethical imperative (35).

Physicians should evaluate their risk of becoming infected with pathogens, both in their personal lives and in the workplace, and implement appropriate precautions, including following guidelines for hygiene, protective garb, and constraints for exposure, designed to decrease spread of infection. Physicians who may have been exposed to pathogens have an ethical obligation to be tested and should do so voluntarily. Infected physicians should place themselves under the guidance of their personal physician or the review of local experts to determine in a confidential manner whether practice restrictions are appropriate on the basis of the physician’s specialty, compliance with infection-control precautions, and physical and mental fitness to work. Infection does not in itself justify restrictions on the practice of an otherwise competent clinician. Physicians are expected to comply with public health and institutional policies.

Because the diseases mentioned above may be transmitted from patient to physician and pose risks to physicians’ health, some physicians may be tempted to avoid the care of infected patients. Physicians and health care organizations are obligated to provide competent and humane care to all patients, regardless of their illness. Physicians can and should expect their workplace to provide appropriate means to limit occupational exposure through rigorous infection-control methods. The denial of appropriate care to a class of patients for any reason, including disease state, is unethical (36).

Whether infected physicians should disclose their condition depends on the likelihood of risk to the patient and relevant law or regulations. Physicians should remove themselves from care if it becomes clear that the risk associated with contact or with a procedure is high despite appropriate preventive measures. Physicians are obligated to disclose their condition after the fact if a clinically significant exposure has taken place.

Physicians have several obligations concerning nosocomial risk for infection. They should help the public understand the low level of this risk and put it in the perspective of other medical risks while acknowledging public concern. Physicians provide medical care to health care workers, and part of this care is discussing with them the duty to know their risk for such diseases as HIV or viral hepatitis, to voluntarily seek testing if they are at risk, and to take reasonable steps to protect patients. The physician who provides care for a potentially infectious health care worker must determine that worker’s fitness to work. In some cases, potentially infectious health care workers cannot be persuaded to comply with accepted infection-control
guidelines. In such exceptional cases, the treating physician may need to breach confidentiality and report the situation to the appropriate authorities in order to protect patients and maintain public trust in the profession, even though such actions may have legal consequences.

**The Patient–Physician Relationship and Health Care System Catastrophes**

Large-scale health catastrophes from infectious causes (for example, influenza, the severe acute respiratory syndrome), natural disasters (for example, tsunamis, earthquakes, hurricanes), or terrorist attacks can overwhelm the capabilities of health care systems and have the potential to stress and even change the traditional norms of the patient–physician relationship. For example, physicians may unavoidably conduct triage. Furthermore, many state, national, and international bodies have issued reports on health catastrophes that include recommendations for unilateral physician decisions to withhold and withdraw mechanical ventilation from some patients who might still benefit from it, when the demand for ventilators exceeds supply (37–40). The guiding principles for health care delivery during catastrophes may shift from autonomy and beneficence to utility, fairness, and stewardship (Figure). One reports notes that “[a] public health disaster such as a pandemic, by virtue of severe resource scarcity, will impose harsh limits on decision-making autonomy for patients and providers” (37). Physicians together with public and governmental organizations should participate in the development of guidelines for the just delivery of health care in times of catastrophe, being mindful of existing health disparities that may affect populations or regions.

**Complementary and Alternative Care**

Complementary and alternative medicine (CAM), as defined by the National Center for Complementary and Alternative Medicine, “is a group of diverse medical and health care systems, practices, and products that are not generally considered part of conventional medicine” (41). Integrative medicine “combines both conventional and CAM treatments for which there is evidence of safety and effectiveness” (41). Folk healing practices are also common in many cultures (42). In 2007, 38% of U.S. adults reported using CAM in the previous year (43).

Patients may value the differing approaches of Western medicine, with its scientific basis, and CAM. A failure of conventional therapy, or cultural concerns, might lead a patient to alternative approaches to care. Requests by patients for alternative treatment require balancing the medical standard of care with a patient’s right to choose care on the basis of his or her values and preferences. Such requests warrant careful physician attention. Before advising a patient, the physician should ascertain the reason for the request. The physician should be sure that the patient understands his or her condition, standard medical treatment options, and expected outcomes. Because most patients do not affirmatively disclose their use of CAM, physicians should ask patients about their current practices (44, 45) as an essential part of a complete history.

The physician should encourage the patient who is using or requesting alternative treatment to seek literature and information from reliable sources (46). The patient should be clearly informed if the option under consideration is likely to delay access to effective treatment or is known to be harmful. The physician should be aware of the potential impact of CAM on the patient’s care. The patient’s decision to select alternative forms of treatment should not alone be cause to sever the patient–physician relationship.

**Disability Certification**

Some patients have chronic, overwhelming, or catastrophic illnesses. In these cases, society permits physicians to justify exemption from work and to legitimize other forms of financial support. As patient advocate, a physician may need to help a medically disabled patient obtain the appropriate disability status. Disability evaluation forms should be completed factually, honestly, and promptly.

Physicians may see a patient whose problems do not fit standard definitions of disability but who nevertheless seems deserving of assistance (for example, the patient may have very limited resources or poor housing). Physicians should not distort medical information or misrepresent the patient’s functional status in an attempt to help patients. Doing so jeopardizes the trustworthiness of the physician, as well as his or her ability to advocate for patients who truly meet disability or exemption criteria.

**Providing Medical Care to One’s Self; Persons With Whom the Physician has a Prior, Nonprofessional Relationship; and VIPs**

Physicians may be asked to provide medical care to a variety of people with whom the physician has a prior, nonprofessional relationship. Each of these situations raises clinical and professionalism concerns that should be considered.
Except in emergent circumstances when no other option exists, physicians ought not care for themselves. A physician cannot adequately interview, examine, or counsel herself; without which, ordering diagnostic tests, medications, or other treatments is ill- advised.

Regarding people with whom the physician has a prior, nonprofessional relationship, including family members, friends or acquaintances, colleagues, and employees, the physician’s prior emotional or social relationship complicates what would become the professional patient–physician relationship.

A physician asked to provide medical care to a person with whom the physician has a prior social or emotional relationship should first consider alternatives. The physician could serve as an advisor or medical translator and suggest questions to ask, explain medical terminology, accompany the patient to appointments, and help advocate for the patient. Alternatively, the physician could use his or her knowledge to refer the person to another physician.

Physicians should usually not enter into the dual relationship of physician–family member or physician-friend for a variety of reasons. The patient may be at risk of receiving inferior care from the physician. Problems may include effects on clinical objectivity, inadequate history-taking or physical examination, overtesting, inappropriate prescribing, incomplete counseling on sensitive issues, or failure to keep appropriate medical records. The needs of the patient may not fall within the physician’s area of expertise. The physician’s emotional proximity may result in difficulties for the patient and/or the physician. On the other hand, the patient may experience substantial benefit from having a physician-friend or physician-family member provide medical care, as may the physician. Access to the physician, the physician’s attention to detail, and physician diligence to excellence in care might be superior.

Given the complexity of the dual relationship of physician–family member or physician-friend, physicians ought to weigh such concerns and all possible alternatives and seek counsel from colleagues before taking on the care of such patients. If they do assume the care, they should do so with the same comprehensive diligence and careful documentation as exercised with other patients. Whenever physicians provide medical care, they should do so only within their realm of expertise. Medical records should be kept just as for any other patient.

Taking care of VIPs poses different challenges. The physician ought to avoid the tendency to skip over sensitive portions of the relevant medical history or physical examination. Fame or prestige ought not buy patients medical care that is not medically indicated. Patient privacy and confidentiality must be protected, as for all patients (see Confidentiality section). Finally, the social standing of a VIPought not negatively affect the physician’s responsibilities toward other patients.

**Sexual Contact Between Physician and Patient**

Issues of dependency, trust, and transference and inequalities of power lead to increased vulnerability on the part of the patient and require that a physician not engage in a sexual relationship with a patient. It is unethical for a physician to become sexually involved with a current patient even if the patient initiates or consents to the contact.

Sexual involvement between physicians and former patients also raises concern. The impact of the patient–physician relationship may be viewed very differently by physicians and former patients, and either may underestimate the influence of the past professional relationship. Many former patients continue to feel dependency and transference toward their physicians long after the professional relationship has ended. The intense trust often established between physician and patient may amplify the patient’s vulnerability in a subsequent sexual relationship. A sexual relationship with a former patient is unethical if the physician uses or exploits the trust, knowledge, emotions, or influence derived from the previous professional relationship.

A sexual relationship with a former patient is unethical because of the potential patient information must be kept to a minimum during chaperoned examinations.

Physicians who use online media, such as social networks, blogs, and video sites, should be aware of the potential to blur social and professional boundaries. They therefore must be careful to extend standards for maintaining professional relationships and confidentiality from the clinic to the online setting. Physicians must remain cognizant of the privacy settings for secure messaging and recording of patient–physician interactions as well as online networks and media and should maintain a professional demeanor in accounts that could be viewed by patients or the public.

Guidance for use of social media is noted in Box 3.
Gifts From Patients

In deciding whether to accept a gift from a patient, the physician should consider the nature of the gift and its value to the patient, the potential implications for the patient–physician relationship of accepting or refusing it, and the patient’s probable intention and expectations (56). A small gift as a token of appreciation is not ethically problematic. Favored treatment as a result of acceptance of any gift is problematic and undermines professionalism. It may also interfere with objectivity in the care of the patient (57).

Care of Patients Near the End of Life

Physicians and the medical community must be committed to the compassionate and competent provision of care to dying patients and their families (58) and effective communication with patients and families (28, 59). Patients rightfully expect their physicians to care for them as they live with eventually fatal illnesses. Good symptom control; ongoing commitment to serve the patient and family; and physical, psychological, and spiritual support are the hallmarks of high-quality end-of-life care. Care of patients near the end of life, however, has a moral, psychological, and interpersonal intensity that distinguishes it from most other clinical encounters. It is the physician’s professional obligation to develop and maintain competency in end-of-life care.

Palliative Care

Although palliative care goes beyond end-of-life care, palliative care near the end of life entails addressing physical, psychosocial, and spiritual needs and understanding that patients may at times require palliative treatment in an acute care context (60–62). To provide palliative care, the physician must be up to date on the proper use of medications and treatments, including the legality and ethical basis of using whatever doses of opioids are necessary to relieve patient suffering. The physician should seek appropriate palliative care consultation when doing so is in the patient’s best interest, know when and how to use home-based and institution-based hospice care, and be aware of the palliative care capabilities of nursing homes to which patients are referred.

Families of patients near the end of life should also be prepared for the course of illness and care options (63). Cultural differences at the end of life, including differences in beliefs, values, and health care practices, must be respected by physicians just as in other types of care (42, 64). Clinicians should also assist family members and loved ones experiencing grief after the patient’s death.

Making Decisions Near the End of Life

Informed adults with decision-making capacity have the legal and ethical right to refuse recommended life-sustaining medical treatments (65). This includes any medical intervention, including ventilators, artificial nutrition and hydration, and cardiovascular implantable electronic devices (such as pacemakers and implantable cardioverter-defibrillators) (66). The patient’s right is based on the philosophical concept of respect for autonomy, the common-law right of self-determination, and the patient’s liberty interest under the U.S. Constitution (67). This right exists, regardless of whether the patient is terminally or irreversibly ill, has dependents, or is pregnant. When a physician disagrees with a patient’s treatment decisions, the physician should respond with empathy and thoughtful exploration of all possibilities, including time-limited trials and additional consultation. If the patient’s or family’s treatment decisions violate the physician’s sense of professional integrity, referral to another qualified physician may be considered, but the patient and family should not be abandoned. Consultation with an ethics committee can be of assistance in mediating such disputes.

Patients without decision-making capacity (see the Informed Decision Making and Consent section) have the same rights concerning life-sustaining treatment decisions as mentally competent patients. Treatment should conform to what the patient would want on the basis of written or oral advance care planning. If these preferences are not known, care decisions should be based on the best evidence of what the patient would have chosen based on the patient’s values, previous choices, and beliefs (substituted judgments) or, failing that, on the best interests of the patient. However, there may be situations in which best-interest decisions should supersede substituted judgments (26). Physicians should be aware that hospital protocols and state legal requirements affecting end-of-life care vary. Patients with mental illness may pose particular challenges in understanding their wishes regarding end-of-life care. The presence of mental illness is not prima facie evidence of decisional incapacity. Psychiatric consultation should be considered to explore the patient’s ability to participate in decision making.

Advance Care Planning

Advance care planning allows a person with decision-making capacity to develop and indicate preferences for care and choose a surrogate to act on his or her behalf in the event that he or she cannot make health care decisions. It allows the patient’s values and circumstances to shape the plan with specific arrangements to ensure implementation of the plan.
Physicians should routinely raise advance planning with adult patients with decision-making capacity and encourage them to review their values and preferences with their surrogates and family members (Table 2). This is often best done in the outpatient setting before an acute crisis. These discussions let the physician know the patient’s views, enable documentation of patient wishes in the medical record, and allow the physician to reassure the patient that he or she is willing to discuss these sensitive issues and will respect patient choices. The Patient Self-Determination Act of 1990 requires hospitals, nursing homes, health maintenance organizations, and hospices that participate in Medicare and Medicaid to ask if the patient has an advance directive, to provide information about them, and to incorporate advance directives into the medical record. It does not require completion of an advance directive as a condition of care.

Written advance directives include living wills and the durable power of attorney for health care (68). The latter enables a patient to appoint a surrogate to make decisions if the patient becomes unable to do so. The surrogate is obligated to act in accordance with the patient’s previously expressed preferences or best interests. Some patients want their surrogates to strictly adhere to their expressed wishes. Others, however, want their surrogates to have flexibility in decision making (69–71). Patients should specify what authority and discretion in decision making they are giving their surrogates.

Living wills enable individuals to describe the treatment they would like to receive in the event that decision-making capacity is lost. Uncertainty about a future clinical course complicates the interpretation of living wills and emphasizes the need for physicians, patients, and surrogates to discuss patient preferences before a crisis arises. Some state laws limit the application of advance directives to terminal illness or deem advance directives not applicable for pregnant patients. Requirements for witnessing documents vary.

Advance directives should be readily accessible to health care professionals regardless of the site of care; some states have statewide systems for documenting physician orders on end-of-life care (72). When there is no advance directive and the patient’s values and preferences are unknown or unclear, decisions should be based on the patient’s best interests whenever possible, as interpreted by a guardian or a person with loving knowledge of the patient, if available. When making the decision to forgo treatment, many people give the most weight to reversibility of disease or dependence on life support, loss of capacity for social interaction, or nearness to death. Family members and clinicians should avoid projecting their own values or views about quality of life onto the incapacitated patient. Quality of life should be assessed according to the patient’s perspective (73, 74).

### Table 2. Advance Care Planning and Surrogate Decision Making

<table>
<thead>
<tr>
<th>Action</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>Raise advance care planning before an acute crisis</td>
<td>Physicians should routinely raise advance care planning with adult patients with decision-making capacity and encourage them to review their values and preferences for future care with their surrogates and family members.</td>
</tr>
<tr>
<td>Document care preferences</td>
<td>Conversations with the patient and patient views about care preferences should be documented in the medical record. Written advance directives include living wills and the durable power of attorney for health care.</td>
</tr>
<tr>
<td>Assist surrogate decision makers in fulfilling their responsibilities</td>
<td>The surrogate is obligated to act in accordance with patient’s previously expressed preferences or best interests. Some patients want their surrogates to strictly adhere to their expressed wishes. Others want their surrogates to have flexibility in decision making. Patients should specify what authority and discretion in decision making they are giving their surrogates.</td>
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### Withdrawing or Withholding Treatment

Withdrawing and withholding treatment are equivalent, ethically and legally, although state evidentiary standards for and cultural and religious beliefs about withdrawing or withholding treatment may vary. Treatments should not be withheld because of the mistaken fear that if they are started, they cannot be withdrawn. This would deny patients potentially beneficial therapies. Instead, a time-limited trial of therapy could be used to clarify the patient’s prognosis. At the end of the trial, a conference to review and revise the treatment plan should be held. Some family members may be reluctant to withdraw treatments even when they believe that the patient would not have wanted them continued. The physician should try to prevent or resolve these situations by addressing with families feelings of guilt, fear, and concern that the patient may suffer as life support is withdrawn, ensure that all appropriate measures to relieve distress are used, and explain the physician’s ethical obligation to follow the patient’s wishes.

### Artificial Nutrition and Hydration

Artificial administration of nutrition and fluids is a medical intervention subject to the same principles of decision making as other treatments. Some states require high levels of proof of the patient’s specific wishes regarding nutrition or hydration before previous statements or advance directives can be accepted as firm evidence that a patient would not want these treatments. Physicians should counsel patients desiring to forgo artificial nutrition and hydration under some circumstances to establish advance care directives with careful attention to decisions regarding artificial nutrition and hydration. Despite research to the contrary (75), concerns remain that discon-
continuing feeding tubes will cause suffering from hunger or thirst. On the other hand, imminently dying patients may develop fluid overload as their kidneys stop functioning, with peripheral and pulmonary edema; continued administration of intravenous fluids exacerbates these symptoms and may cause substantial distress. Physicians should address these issues with patients and loved ones involved in providing care.

Do-Not-Resuscitate Orders

A do-not-resuscitate order (DNR order)—or do-not-attempt-resuscitation order (DNAR order)—is a physician order to forgo basic cardiac life support in the outpatient setting and advanced cardiac life support in the inpatient setting. Intervention in the case of a cardiopulmonary arrest is inappropriate for some patients, particularly those for whom death is expected, imminent, and unavoidable. Because the onset of cardiopulmonary arrest does not permit deliberative decision making, decisions about resuscitation must be made in advance. Physicians should especially encourage patients who face serious illness or who are of advanced age (or their surrogates as appropriate) to discuss resuscitation.

A DNR order applies only to cardiopulmonary resuscitation. Discussions about this issue may reflect a revision of the larger goals and means of the care plan, and the extent to which a change is desired in treatment goals or specific interventions must be explicitly addressed for each patient. A DNR order must be written in the medical record along with notes and orders that describe all other changes in the treatment goals or plans, so that the entire health care team understands the care plan. A DNR order does not mean that the patient is necessarily ineligible for other life-prolonging measures, therapeutic and palliative. Because they are deceptive, half-hearted resuscitation efforts (“slow codes”) should not be performed (76).

A patient who is a candidate for intubation but declines will develop respiratory failure and is expected to arrest. For this reason, physicians should not write a do-not-intubate order in the absence of a DNR order. Moreover, it is important to address the patient’s or surrogate’s wishes regarding intubation and intensive care unit transfer in tandem with discussions about resuscitation.

A DNR order should not be suspended simply because of a change in the venue of care. When a patient with a preexisting DNR order is to undergo, for example, an operative procedure requiring general anesthesia, fiberoptic bronchoscopy, or gastroesophageal endoscopy, the physician should discuss the rationale for continuing or temporarily suspending the DNR order. A change in DNR status requires the consent of the patient or appropriate surrogate decision maker.

In general, any decision about advance care planning, including a decision to forgo attempts at resuscitation, applies in other care settings for that patient, and this should be routinely addressed. Many states and localities have systematic requirements for out-of-hospital implementation of DNR orders (77). Physicians should know how to effectuate the order and try to protect the patient from inappropriate resuscitation efforts. Physicians should ensure that DNR orders transfer with the patient and that the subsequent care team understands the basis for the decision.

“Futile” Treatments

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. The more common and much more difficult circumstance occurs when treatment offers some small prospect of benefit at a great burden of suffering (or financial cost—see “Resource Allocation” within in the Physician and Society section), but the patient or family nevertheless desires it. If the physician and patient (or appropriate surrogate) cannot agree on how to proceed, there is no easy, automatic solution. Consultation with learned colleagues or an ethics consultation may be helpful in ascertaining what interventions have a reasonable balance of burden and benefit. Timely transfer of care to another clinician who is willing to pursue the patient’s preference may resolve the problem. Infrequently, resort to the courts may be necessary. Some jurisdictions have specific processes and standards for allowing these unilateral decisions.

Some institutions allow physicians to unilaterally write a DNR order over patient or family objections when the patient may survive, at most, for only a brief time in the hospital. Empathy and thoughtful exploration of options for care with patients or surrogate decision makers should make such impasses rare. Full discussion about the issue should include the indications for and outcomes of cardiopulmonary resuscitation, the physical impact on the patient, the implications for clinicians, the impact (or lack thereof) of a DNR order on other care, the legal aspects of such orders, and the physician’s role as patient advocate. A physician who writes a unilateral DNR order must inform the patient or surrogate when doing so.

Determination of Death

The irreversible cessation of all functions of the entire brain is an accepted legal standard for determining death when the use of life support precludes reliance on traditional cardiopulmonary criteria. After a patient has been declared dead by brain-death criteria, medical support should ordinarily be discontinued. In some circumstances, such as the need to preserve organs for transplantation or to counsel or accommodate family beliefs or needs, physicians may temporarily support bodily functions after death has been determined. In the case of a pregnant, brain-dead
Physician-Assisted Suicide and Euthanasia

Physician-assisted suicide occurs when a physician provides a medical means for death, usually a prescription for a lethal amount of medication that the patient takes on his or her own. In euthanasia, the physician directly and intentionally administers a substance to cause death. Oregon and Washington have legalized the practice of physician-assisted suicide (78, 79). Many other states have had referenda, legislative proposals, and case law on both sides of the issues.

A decision by a patient or authorized surrogate to refuse life-sustaining treatment or an inadvertent death during an attempt to relieve suffering should be distinguished from physician-assisted suicide and euthanasia. Laws concerning or moral objections to physician-assisted suicide and euthanasia should not deter physicians from honoring a decision to withhold or withdraw medical interventions as appropriate. Fears that unwanted life-sustaining treatment will be imposed continue to motivate some patients to request assisted suicide or euthanasia.

In the clinical setting, all of these acts must be framed within the larger context of good end-of-life care. Some patients who request assisted suicide may be depressed or have uncontrolled pain. In providing comfort to a dying person, most physicians and patients should be able to address these issues. For example, regarding pain control, the physician may appropriately increase medication to relieve pain, even if this action inadvertently shortens life (80, 81). In Oregon, losing autonomy or dignity and inability to engage in enjoyable life activities were each cited as concerns in most cases (78). These concerns are less amenable to the physician’s help, although physicians should be sensitive to these aspects of suffering.

The College does not support legalization of physician-assisted suicide or euthanasia (82). After much consideration, the College concluded that making physician-assisted suicide legal raised serious ethical, clinical, and social concerns and that the practice might undermine patient trust; distract from reform in end-of-life care; and be used in vulnerable patients, including those who are poor, are disabled, or are unable to speak for themselves or minority groups who have experienced discrimination. The major emphasis of the College and its members, including those who lawfully participate in the practice, should be ensuring that all persons can count on good care through to the end of life, with prevention or relief of suffering insofar as possible, an unwavering commitment to human dignity and relief of pain and other symptoms, and support for family and friends. Physicians and patients must continue to search together for answers to the problems posed by the difficulties of living with serious illness before death, neither violating the physician’s personal and professional values, nor abandoning the patient to struggle alone.

Disorders of Consciousness

There are a variety of disorders of impaired consciousness with variable prognoses, including coma, persistent and permanent irreversible vegetative states (“wakeful unresponsiveness”), and the minimally conscious state (83). Diagnostic clarity in determining the patient’s brain state by clinicians qualified to make such assessments before making ethical judgments about appropriate care is critical (84). Goals of care as decided by the patient in advance or by an appropriate surrogate should guide decisions about treatment for these patients as for other patients without decision-making capacity.

Solid Organ Transplantation

Ideally, physicians will discuss the option of organ donation with patients during advance care planning as part of a routine office visit, before the need arises (85). All potential donors should communicate their preference for or against donation to their families as well as have it listed on such documents as driver’s licenses or organ donor cards.

Organ donation requires consideration of several issues. One set of concerns is the need to avoid even the appearance of conflict between the care of a potential donor and the needs of a potential recipient (86). The care of the potential donor must be kept separate from the care of a recipient. The potential donor’s physician should not be responsible for the care of the recipient or be involved in retrieving the organs or tissue.

Under federal regulations, all families must be presented with the option of organ donation when the death of the patient is imminent. To avoid conflicts of interest, neither physicians who will perform the transplantation nor those caring for the potential recipient should make the request. Physicians caring for the potential donor should ensure that families are treated with sensitivity and compassion. Previously expressed preferences about donation by dying or brain-dead patients should be sought and respected. Only organ procurement representatives who have completed training by an organ procurement organization may initiate the actual request (87).

Another set of issues involves the use of financial incentives to encourage organ donation. While increasing the supply of organs is a noble goal, the use of direct financial incentives raises ethical questions, including about treating humans as commodities and the potential for exploitation of families of limited means. Even the appearance of exploitation may ultimately be counterproductive to the goal of increasing the pool of organs.

In the case of brain-dead donors, once organ donation is authorized, the donor’s physician should know how to maintain the viability of organs and tissues in coordination with the procurement team. Before declaration of brain death, treatments proposed to maintain the function of
transplantable organs may be used only if they are not expected to harm the potential donor.

A particular set of issues has been raised by the advent of “donation after cardiac death” (previously known as “non–heart-beating cadaveric organ donation”). This approach allows patients who do not meet the criteria for brain death but for whom a decision has been made to discontinue life support to be considered potential organ donors. Life support is discontinued under controlled conditions. Once cardiopulmonary criteria for death are met, and a suitable period of time has elapsed that ensures clinical certitude of death but does not unduly compromise the chances of successful transplantation (generally 2 to 5 minutes), the organs are procured. This generally requires that the still-living patient be moved to the operating room (or nearby suite) in order to procure the organs as quickly after death as possible.

As in organ donation from brain-dead individuals, the care of the potential donor and the request from the family must be separated from the care of the potential recipient. The decision to discontinue life support must be kept separate from the decision to donate, and the actual request can be made only by an organ procurement representative. This process is an important safeguard in distinguishing the act of treatment refusal from organ procurement. Because these potential donors may not always die after the discontinuation of life support, palliative care interventions must be available to respond to patient distress. It is unethical, before the declaration of death, to use any treatments aimed at preserving organs for donation that may harm the still-living patient by causing pain, causing traumatic injury, or shortening the patient’s life. As long as the prospective donor is alive, the physician’s primary duty is to the donor patient’s welfare, not that of the prospective recipient.

Questions of quality and access require public dialogue in which all parties should participate. Recent advances in health insurance reform increase the need for continued attention to professional obligations of physicians to their patients and the health care system. Resource allocation decisions should always be made through an open and participatory process.

Physicians have an obligation to promote their patients’ welfare in an increasingly complex health care system. This entails forthrightly helping patients to understand clinical recommendations and make informed choices among all appropriate care options. It includes management of the conflicts of interest and multiple commitments that arise in any practice environment, especially in an era of cost concerns. It also includes stewardship of finite health care resources so that as many health care needs as possible can be met, whether in the physician’s office, in the hospital or long-term care facility, or at home.

The patient–physician relationship and the principles that govern it should be central to the delivery of care. These principles include beneficence, honesty, confidentiality, privacy, and advocacy when patient interests may be endangered by arbitrary, unjust, or inadequately individualized programs or procedures. Health care, however, does take place in a broader context beyond the patient–physician relationship. A patient’s preferences or interests may conflict with the interests or values of the physician, an institution, a payer, other members of an insurance plan who have equal claim to the same health care resources, or society.

The physician’s first and primary duty is to the patient. Physicians must base their counsel on the interests of the individual patient, regardless of the insurance or medical care delivery setting. Whether financial incentives in the fee-for-service system prompt physicians to do more rather than less or capitation arrangements encourage them to do less rather than more, physicians must not allow such considerations to affect their clinical judgment or patient counseling on treatment options, including referrals (88).

The 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 (89).

Physicians have a responsibility to practice effective and efficient health care and to use health care resources responsibly. Parsimonious care that utilizes the most efficient means to effectively diagnose a condition and treat a patient respects the need to use resources wisely and to help ensure that resources are equitably available. In making recommendations to patients, designing practice guidelines and formularies, and making decisions on medical benefits review boards, physicians’ considered judgments should reflect the best available evidence in the biomedical literature, including data on the cost-effectiveness of different clinical approaches. When patients ask, they should be
informed of the rationale that underlies the physician’s recommendation.

Guidance on stewardship of resources is noted in Box 4.

In instances of disagreement between patient and physician for any reason, the physician is obligated to explain the basis for the disagreement, to educate the patient, and to meet the patient’s needs for comfort and reassurance. Providers of health insurance are not obliged to underwrite approaches that patients may value but that are not justifiable on clinical or theoretical scientific grounds or that are relatively cost-ineffective compared with other therapies for the same condition or other therapies offered by the health plan for other conditions. However, there must be a fair appeals procedure.

The physician’s duty further requires serving as the patient’s agent within the health care arena, advocating through the necessary avenues to obtain treatment that is essential to the individual patient’s care regardless of the barriers that may discourage the physician from doing so. Moreover, physicians should advocate just as vigorously for the needs of their most vulnerable and disadvantaged patients as for the needs of their most articulate patients.

Patients may not understand or may fear conflicts of interests for physicians and the multiple commitments that can arise from cost-containment and other pressures from entities that finance health care. Physicians should disclose their potential conflicts of interest to their patients. While providers of health insurance coverage should hold physicians accountable for the quality, safety, and efficiency of care and not simply for economic performance, they also have duties to foster an ethical practice environment and should not ask physicians to participate in any arrangements that jeopardize professional and ethical standards. Physicians should enter into agreements with insurers or other organizations only if they can ensure that these agreements do not violate professional and ethical standards.

Pay-for-performance programs can help improve the quality of care, but they must be aligned with the goals of medical professionalism. The main focus of the quality movement in health care should not, however, be on “pay for” or “performance” based on limited measures. Program incentives for a few specific elements of a single disease or condition may neglect the complexity of care for the whole patient, especially patients with multiple chronic conditions. Deselection of patients and “playing to the measures” rather than focusing on the patient are also dangers. Quality programs must put the needs and interests of the patient first.

Organizations that provide health insurance coverage should not restrict the information or counsel that physicians may give patients. Physicians must provide information to the patient about all appropriate care and referral options. Providers of health insurance coverage must disclose all relevant information about benefits, including any restrictions, and about financial incentives that might negatively affect patient access to care.

When patients enroll in insurance plans, they receive a great deal of information on rules governing benefits and reimbursement. Meaningful disclosure requires explanations that are clear and easily understood. Insured patients and their families bear a responsibility for having a basic understanding of the rules of their insurance. Physicians cannot and should not be expected to advise patients on the particulars of individual insurance contracts and arrangements. Patients should, however, expect their physicians to honor the rules of the insurer unless doing so would endanger the patient’s health. Physicians should not collaborate with a patient or engage in efforts to deceive the insurer.

### Box 4. Patients first and stewardship of resources

**The physician’s first and primary duty is to the patient.**

Physicians must base their counsel on the interests of the individual patient, regardless of the insurance or medical care delivery setting.

**The 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.**

Physicians have a responsibility to practice effective and efficient health care and to use health care resources responsibly. Parsimonious care that utilizes the most efficient means to effectively diagnose a condition and treat a patient respects the need to use resources wisely and to help ensure that resources are equitably available.

Financial Arrangements

Financial relationships between patients and physicians vary from fee-for-service to government contractual arrangements and prepaid insurance. Financial arrangements and expectations should be clearly established. Fees for physician services should accurately reflect the services provided. Physicians should be aware that a beneficent intention to forgive copayments for patients who are financially stressed may nonetheless be fraud under current law.

Professional courtesy may raise ethical, practical, and legal issues. When physicians offer professional courtesy to a colleague, physician and patient should function without feelings of constraints on time or resources and without shortcut approaches. Colleague-patients who initiate questions in informal settings put the treating physician in a less-than-ideal position to provide optimal care. Both parties should avoid this inappropriate practice.

As professionals dedicated to serving the sick, all physicians should provide services to uninsured and underinsured persons. Physicians who choose to deny care solely on the basis of inability to pay should be aware that by thus limiting their patient populations, they risk compromising
their professional obligation to care for the poor and the credibility of medicine’s commitment to serving all classes of patients who are in need of medical care (91, 92). Each individual physician is obliged to do his or her fair share to ensure that all ill persons receive appropriate treatment (13) and to honor the social contract with society, which is based in part on the substantial societal support of medical education (93).

Financial Conflicts of Interest

The physician must seek to ensure that the medically appropriate level of care takes primacy over financial considerations imposed by the physician’s own practice, investments, or financial arrangements. Trust in the profession is undermined when there is even the appearance of impropriety.

Potential influences on clinical judgment cover a wide range and include financial incentives inherent in the practice environment (such as incentives to overutilize in the fee-for-service setting or underutilize under capitation arrangements) (94, 95); drug, device, and other health care company gifts; and business arrangements involving referrals. Physicians must be conscious of all potential influences, and their actions should be guided by patient best interests and appropriate utilization, not by other factors.

Physicians who have potential financial conflicts of interest, whether as researchers, speakers, consultants, investors, partners, employers, or otherwise, must not in any way compromise their objective clinical judgment or the best interests of patients or research subjects (96). Physicians must disclose their financial interests to patients, including in any medical facilities or office-based research to which they refer or recruit patients. When speaking, teaching, and authoring, physicians with ties to a particular company should disclose their interests in writing. Most journal editors require that authors and peer reviewers disclose any potential conflicts of interest. Editors themselves should be free from conflicts of interest.

Physicians should not refer patients to an outside facility in which they have invested and at which they do not directly provide care (97). Physicians may, however, invest in or own health care facilities when capital funding and necessary services that would otherwise not be made available are provided. In such situations, in addition to disclosing these interests to patients, physicians must establish safeguards against abuse, impropriety, or the appearance of impropriety.

A fee paid to one physician by another for the referral of a patient, historically known as “fee-splitting,” is unethical. It is also unethical for a physician to receive a commission or a kickback from anyone, including a company that manufactures or sells medical products or medications.

The sale of products from the physician’s office might also be considered a form of self-referral and might negatively affect the trust necessary to sustain the patient–physician relationship. Most products should not be sold in the office. The College has taken a position that asks physicians to consider seriously the moral issues involved in a decision to do so (98). Physicians should not sell products out of the office unless the products are specifically relevant to the patient’s care, offer a clear benefit based on adequate clinical evidence and research, and meet an urgent need of the patient. If geographic or time constraints make it difficult or impractical for patients to obtain a medically relevant and urgently needed product otherwise, selling a product in the office would be ethically acceptable. For example, a splint or crutches would be acceptable products, but vitamin supplements and cosmetic items are neither emergent treatments nor unlikely to be available elsewhere, and so the sale of such products is ethically suspect. Physicians should make full disclosure about their financial interests in selling acceptable products and inform patients about alternatives for purchasing the product. Charges for products sold through the office should be limited to the reasonable costs incurred in making them available. The selling of products intended to be free samples is unethical.

Physicians may invest in publicly traded securities. However, care must be taken to avoid investment decisions that may create a conflict of interest or the perception of a conflict of interest.

The acceptance by a physician of gifts, hospitality, trips, and subsidies of all types from the health care industry that might diminish, or appear to others to diminish, the objectivity of professional judgment is strongly discouraged. Even small gifts can affect clinical judgment and heighten the perception and/or reality of a conflict of interest. Physicians must gauge regularly whether any gift relationship is ethically appropriate and evaluate any potential for influence on clinical judgment. In making such evaluations, physicians should consider the following: 1) What would the public or my patients think of this arrangement?; 2) What is the purpose of the industry offer?; 3) What would my colleagues think about this arrangement?; and 4) What would I think if my own physician accepted this offer? In all instances, it is the individual responsibility of each physician to assess any potential relationship with industry to assure that it enhances patient care (96, 99). Guidance on physician-industry relations and gifts is noted in Box 5.

Physicians must critically evaluate all medical information, including that provided by detail persons, advertisements, or industry-sponsored educational programs. While providers of public and private graduate and continuing medical education may accept industry support for educational programs, they should develop and enforce strict policies maintaining complete control of program planning, content, and delivery. They should be aware of, and vigilant against, potential bias and conflicts of interest (100).

If medical professional societies accept industry support or other external funding, they also “should be aware
of potential bias and conflicts of interest and should develop and enforce explicit policies that preserve the independent judgment and professionalism of their members and maintain the ethical standards and credibility of the society” (100). At a minimum, medical societies should adhere to the Council of Medical Specialty Societies Code for Interactions with Companies (101).

**Advertising**

Advertising by physicians or health care institutions is unethical when it contains statements that are unsubstantiated, false, deceptive, or misleading, including statements that mislead by omitting necessary information.

**The Physician and Society**

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.

**Obligations of the Physician to Society**

Physicians have obligations to society that in many ways parallel their obligations to individual patients. Physicians’ conduct as professionals and as individuals should merit the respect of the community.

All physicians must fulfill the profession’s collective responsibility to advocate for the health, human rights, and well-being of the public. Physicians should protect public health by reporting disease, injury, domestic violence, abuse, or neglect to the responsible authority as required by law.

Physicians should support community health education and initiatives that provide the public with accurate information about health care and should contribute to keeping the public properly informed by commenting on medical subjects in their areas of expertise. Physicians should provide the news media with accurate information, recognizing this as an obligation to society and an extension of medical practice. However, patient confidentiality must be respected.

Physicians should help the community and policymakers recognize and address the social and environmental causes of disease, including human rights concerns, discrimination, poverty, and violence. They should work toward ensuring access to health care for all persons; act to eliminate discrimination in health care; and help correct deficiencies in the availability, accessibility, and quality of health services, including mental health services, in the community. The denial of appropriate care to a class of patients for any reason is unethical. Importantly, disparities in care as a result of personal characteristics, such as race, have received increased attention and need to be addressed (102). Physicians should also explore how their own attitudes, knowledge, and beliefs may influence their ability to fulfill these obligations.

Health and human rights are interrelated (103). When human rights are promoted, health is promoted. Violation of human rights has harmful consequences for the individual and the community. Physicians have an important role to play in promoting health and human rights and addressing social inequities. This includes caring for vulnerable populations, such as the uninsured and victims of violence or human rights abuses. Physicians have an opportunity and duty to advocate for the needs of individual patients as well as society.

Physicians should advocate for and participate in patient safety initiatives, including error, sentinel event, and “near-miss” reporting. Human errors in health care are not uncommon (104), and many result from systems problems. Physicians should initiate process improvement and work with their institutions and in all aspects of their practices in an ongoing effort to reduce errors and improve care.

**Resource Allocation**

Medical care is delivered within social and institutional systems that must take overall resources into account. Increasingly, decisions about resource allocations challenge the physician’s primary role as patient advocate. This advocacy role has always had limits. For example, a physician should not lie to third-party payers for a patient in order to ensure coverage or maximize reimbursement. Moreover, a physician is not obligated to provide all treatments and diagnostics without considering their effectiveness (105) (see also The Changing Practice Environment section). The just allocation of resources and changing reimbursement methods present the physician with ethical

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**Box 5. Physician–industry relations and gifts**

The acceptance by a physician of gifts, hospitality, trips, and subsidies of all types from the health care industry that might diminish, or appear to others to diminish, the objectivity of professional judgment is strongly discouraged.

Even small gifts can affect clinical judgment and heighten the perception and/or reality of a conflict of interest.

Physicians must gauge regularly whether any gift relationship is ethically appropriate and evaluate any potential for influence on clinical judgment. Ask:

- What would the public or my patients think of this arrangement?
- What is the purpose of the industry offer?
- What would my colleagues think about this arrangement?
- What would I think if my own physician accepted this offer?

In all instances, it is the individual responsibility of each physician to assess any potential relationship with industry to assure that it enhances patient care.
problems that cannot be ignored. Two principles are agreed on:

1. As a physician performs his or her primary role as a patient’s trusted advocate, he or she has a responsibility to use all health-related resources in a technically appropriate and efficient manner. He or she should plan work-ups carefully and avoid unnecessary testing, medications, surgery, and consultations.

2. Resource allocation decisions are most appropriately made at the policy level rather than entirely in the context of an individual patient–physician encounter. Ethical allocation policy is best achieved when all affected parties discuss what resources exist, to what extent they are limited, what costs attach to various benefits, and how to equitably balance all these factors.

Physicians, patient advocates, insurers, and payers should participate together in decisions at the policy level; should emphasize the value of health to society; should promote justice in the health care system; and should base allocations on medical need, efficacy, cost-effectiveness, and proper distribution of benefits and burdens in society.

Relation of the Physician to Government

Physicians must not be a party to and must speak out against torture or other abuses of human rights. Participation by physicians in the execution of prisoners except to certify death is unethical. Under no circumstances is it ethical for a physician to be used as an instrument of government to weaken the physical or mental resistance of a human being, nor should a physician participate in or tolerate cruel or unusual punishment or disciplinary activities beyond those permitted by the United Nations’ Standard Minimum Rules for the Treatment of Prisoners (106). Physicians must not conduct, participate in, monitor, or be present at interrogations (defined as a systematic effort to procure information useful to the purposes of the interrogator by direct questioning of a person under the control of the questioner; it is distinct from questioning to assess the medical condition or mental status of an individual) or participate in developing or evaluating interrogation strategies or techniques. A physician who becomes aware of abusive or coercive practices has a duty to report those practices to the appropriate authorities and advocate for necessary medical care. Exploiting, sharing, or using medical information from any source for interrogation purposes is unethical (107).

Limited access to health care is one of the most important characteristics of correctional systems in the United States (108). Physicians who treat prisoners as patients face special challenges in balancing the best interests of the patient with those of the correctional system. Despite these limitations, physicians should advocate for timely treatment and make independent medical judgments about what constitutes appropriate care for individual inmates.

Cross-Cultural Efficacy, Cultural Humility, and Volunteerism

Physicians should provide culturally sensitive care. Cross-cultural efficacy “implies the caregiver is effective in interactions that involve individuals of different cultures and that neither the caregiver’s nor the patient’s culture is the preferred or more accurate view” (109). Cultural humility “enhances patient care by effectively weaving an attitude of learning about cultural differences into patient encounters” (110). With the goal of public service to underserved populations, physicians are increasingly participating in volunteer missions. As cultural competence evolves into cross-cultural efficacy and cultural humility, successful volunteerism requires clear recognition of the individual’s role as visitor, educator, and healer or trainee. Needs and objectives should be mutually understood without biases and prejudices. Medically trained interpreters should be utilized as appropriate to optimize communication and avoid missing important problems. The volunteer physician should be sensitive to local mores, customs, and issues of affordability.

Continuity and sustainability should guide the volunteer physician in working with the community, local physicians, and the health system to understand the health needs of the community and help prioritize them in cultural and economic context to achieve a lasting benefit, with an understanding of short- and long-term impact. The outcomes should be desired by and the interventions acceptable to the populace.

Discrimination violates the principles of professionalism and of the College. Volunteer physicians should encourage professionalism, promote education, and support public health initiatives.

Ethics Committees and Consultants

Ethics committees and consultants contribute to achieving patient care and public health goals by facilitating resolution of conflicts in a respectful atmosphere through a fair and inclusive decision-making process, helping institutions to shape policies and practices that conform with the highest ethical standards, and assisting individual persons with handling current and future ethical problems by providing education in ethics (111).

Accrediting organizations require most health care facilities to provide ethics consultation at the request of patients, nurses, physicians, or others (112). Physicians should be aware that this resource is available. Consultation should be guided by standards, such as those developed by the American Society for Bioethics and Humanities (113). Ethics committees should be multidisciplinary and broadly representative to assure the perspectives necessary to address the complex problems with which they are confronted.

Medicine and the Law

Physicians should remember that the presence of illness does not diminish the right or expectation to be
treated equally. Stated another way, illness does not in and of itself change a patient’s legal rights or permit a physician to ignore those legal rights.

The law is society’s mechanism for establishing boundaries for conduct. Society has a right to expect that those boundaries will not be disregarded. In instances of conflict, the physician must decide whether to violate the law for the sake of what he or she considers the dictates of medical ethics. Such a violation may jeopardize the physician’s legal position or the legal rights of the patient. It should be remembered that ethical concepts are not always fully reflected in or adopted by the law. Violation of the law for purposes of complying with one’s ethical standards may have consequences for the physician and should be undertaken only after thorough consideration and, generally, after obtaining legal counsel.

**Expert Witnesses**

Physicians have specialized knowledge and expertise that may be needed in judicial or administrative processes. Often, expert testimony is necessary for a court or an administrative agency to understand the patient’s condition, treatment, and prognosis. Physicians may be reluctant to become involved in legal proceedings because the process is unfamiliar and time-consuming. Their absence may mean, however, that legal decisions are made without the benefit of all medical facts or opinions. Without the participation of physicians, the mechanisms for dispute resolution may be unsuccessful, patients may suffer, and the public at large may be affected.

Although physicians cannot be compelled to participate as expert witnesses, the profession as a whole has the ethical duty to assist patients and society in resolving disputes (114). In this role, physicians must have the appropriate expertise in the subject matter of the case and honestly and objectively interpret and represent the medical facts. Physicians should accept only noncontingent compensation for reasonable time and expenses incurred as expert witnesses.

**Strikes and Other Joint Actions by Physicians**

Changes in the practice environment sometimes adversely affect the ability of physicians to provide patients with high-quality care and can challenge the physician’s autonomy to exercise independent clinical judgment and even the ability to sustain a practice. However, physician efforts to advocate for system change should not include participation in joint actions that adversely affect access to health care or that result in anticompetitive behavior (115). Physicians should not engage in strikes, work stoppages, slowdowns, boycotts, or other organized actions that are designed, implicitly or explicitly, to limit or deny services to patients that would otherwise be available. In general, physicians should individually and collectively find advocacy alternatives, such as lobbying lawmakers and working to educate the public, patient groups, and policymakers about their concerns. Protests and marches that constitute protected free speech and political activity can be a legitimate means to seek redress, provided that they do not involve joint decisions to engage in actions that may harm patients.

**The Physician’s Relationship to Other Clinicians**

Physicians share their commitment to care for ill persons with a broad team of health professionals. The team’s ability to care effectively for the patient depends on the ability of the individuals on the team to treat each other with integrity, honesty, and respect in daily professional interactions regardless of race, religion, ethnicity, nationality, sex, sexual orientation, age, or disability. Particular attention is warranted with regard to certain types of relationships, power imbalances, and behaviors that could be abusive or disruptive or could lead to harassment, such as those between attending physician and resident, resident and medical student, or physician and nurse (116).

**Attending Physicians and Physicians-in-Training**

The very title “doctor”—from the Latin *docere*, “to teach”—means that physicians have a responsibility to share knowledge and information with colleagues and patients. This sharing includes teaching clinical skills and reporting results of scientific research to colleagues, medical students, resident physicians, and other health care providers. The duty to teach is reviewed in Box 6.

The physician has a responsibility to teach the science, art, and ethics of medicine to medical students, resident physicians, and others and to supervise physicians-in-training. Attending physicians must treat trainees and colleagues with respect, empathy, and compassion. In the teaching environment, graduated authority for patient management can be delegated to residents, with adequate supervision. All trainees should inform patients of their training status and role in the medical team. Trainees should inform the patient of their level of experience with any procedures that they are performing on the patient. Attending physicians, chiefs of service, or consultants should encourage residents to acknowledge their limitations and ask for help or supervision when concerns arise about patient care or the ability of others to perform their duties. The training environment should establish a culture of inquiry and scholarship and encourage trainees to raise ethical issues they may encounter and discuss sources of moral distress (117). Training programs should observe the requirements of regulatory bodies to avoid resident fatigue.

**Box 6. The duty to teach**

*Doctor: from the Latin *docere*, “to teach.”*

Physicians have a responsibility to share knowledge and information with colleagues, resident physicians, students, and patients.
optimize handovers or signouts, and help ensure patient safety and improve outcomes of care. While some of these requirements are more recent, the obligation to serve the patient remains the same as in the past.

It is unethical to delegate authority for patient care to anyone, including another physician, who is not appropriately qualified and experienced. On a teaching service, the ultimate responsibility for patient welfare and quality of care remains with the patient’s attending physician of record. When a patient declines to have trainees involved in her or his care, efforts should be made to discuss this with the patient, explaining the function and supervision of trainees and exploring alternative options when possible.

Prior permission from the patient’s authorized representative to perform training procedures on the newly deceased patient should be obtained in light of any known preferences of the patient regarding the handling of her or his body or the performance of such procedures and applicable laws.

Consultation and Shared Care

In almost all circumstances, patients should be encouraged to initially seek care from their principal physician. Physicians should in turn obtain competent consultation whenever they and their patients feel the need for assistance with care (118). The purpose, nature, and expectations of the consultation should be clear to all.

The consultant should respect the relationship between the patient and the principal physician, should promptly and effectively communicate recommendations to the principal physician, and should obtain concurrence of the principal physician for major procedures or additional consultants. The consultant should also share his or her findings, diagnostic assessment, and recommendations with the patient. The care of the patient and the proper records should be transferred back to the principal physician when the consultation is completed, unless another arrangement is agreed upon.

Consultants who need to take temporary charge of the patient’s care should obtain the principal physician’s cooperation and assent. The physician who does not agree with the consultant’s recommendations is free to call in another consultant. The interests of the patient should remain paramount in this process.

A complex clinical situation may call for multiple consultations. To assure a coordinated effort that is in the best interest of the patient, the principal physician should remain in charge of overall care, communicating with the patient and coordinating care on the basis of information derived from the consultations. Unless authority has been formally transferred elsewhere, the responsibility for the patient’s care lies with the principal physician.

When a hospitalized patient is not receiving care from his or her principal physician, good communication between the treating physician and principal physician is key. The principal physician should supply the inpatient physician with adequate information about current and past clinical history to allow for appropriate decision making and care. The inpatient physician should keep the principal physician informed of the patient’s clinical course and supply a timely and complete description of care. Changes in chronic medications and plans for follow-up care should be promptly communicated to the principal physician before discharge.

The patient-centered medical home model promotes whole-person, patient-centered, integrated care across the health care system (119) and has overall responsibility for ensuring the coordination of care by all involved clinicians. Achieving these goals requires the collaboration and mutual respect of subspecialists, specialists, other clinicians, and health care institutions (120) in serving the patient.

The Impaired Physician

Physicians who are impaired for any reason must refrain from assuming patient responsibilities that they may not be able to discharge safely and effectively. Whenever there is doubt, they should seek assistance in caring for their patients.

Impairment may result from use of psychoactive agents (alcohol or other substances, including prescription medications) or illness. Impairment may also be caused by a disease or profound fatigue that affects the cognitive or motor skills necessary to provide adequate care. The presence of these disorders or the fact that a physician is being treated for them does not necessarily imply impairment.

Every physician is responsible for protecting patients from an impaired physician and for assisting an impaired colleague. Fear of mistake, embarrassment, or possible litigation should not deter or delay identification of an impaired colleague (121). The identifying physician may find it helpful and prudent to seek counsel from a designated institutional official, the departmental chair, or a senior member of the staff or the community.

Although the legal responsibility to do so varies among states, there is a clear ethical responsibility to report a physician who seems to be impaired to an appropriate authority (such as a chief of service, chief of staff, institutional or medical society assistance program, or state medical board). Physicians and health care institutions should assist impaired colleagues in identifying appropriate sources of help. While undergoing therapy, the impaired physician is entitled to full confidentiality as in any other patient–physician relationship. To protect patients of the impaired physician, someone other than the physician of the impaired physician must monitor the impaired physician’s fitness to work. Serious conflicts may occur if the treating physician tries to fill both roles (122).

Peer Review

Professionalism entails membership in a self-correcting moral community. Professional peer review is critical in assuring fair assessment of physician performance for the benefit of patients. The trust that patients and the public
invest in physicians requires disclosure to the appropriate authorities and to patients at risk for immediate harm.

All physicians have a duty to participate in peer review. Fears of retaliation, ostracism by colleagues, loss of referrals, or inconvenience are not adequate reasons for refusing to participate in peer review. Society looks to physicians to establish and enforce professional standards of practice, and this obligation can be met only when all physicians participate in the process. Federal law and most states provide legal protection for physicians who participate in peer review in good faith.

It is unethical for a physician to disparage the professional competence, knowledge, qualifications, or services of another physician to a patient or a third party or to state or imply that a patient has been poorly managed or mistreated by a colleague without substantial evidence. This does not mean that a physician cannot disagree with a plan of management or recommendations made by another physician. A physician therefore has a duty to patients, the public, and the profession to report to the appropriate authority any well-formed suspicions of fraud, professional misconduct, incompetence, or abandonment of patients by another physician.

In the absence of substantial evidence of professional misconduct, negligence, or incompetence, it is unethical to use the peer review process to exclude another physician from practice, to restrict clinical privileges, or to otherwise harm the physician’s practice.

Conflicts Among Members of a Health Care Team

All health professionals share a commitment to work together to serve the patient’s interests. The best patient care is often a team effort, and mutual respect, cooperation, and communication should govern this effort. Each member of the patient care team has equal moral status. When a health professional has important ethical objections to an attending physician’s order, both should discuss the matter openly and thoroughly. Mechanisms should be available in hospitals and outpatient settings to resolve differences of opinion among members of the patient care team. Ethics committees or ethics consultants may also be appropriate resources.

Research

Medical progress and improved patient care depend on innovative and vigorous research, on honest communication of study results, and on continued evaluation of patient outcomes following implementation of research findings. Research is defined under the federal “Common Rule” as “a systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge” (123). Honesty and integrity must govern all types and stages of research, from the laboratory to randomized clinical trials, and from the initial design and grant application to publication of results and translation into practice. Institutional review boards (IRBs) must review and approve research involving human subjects to ensure consistency with ethical standards, but use of IRBs does not obviate the investigator’s responsibilities to adhere to those standards and uphold the ethical integrity of research. Investigators and their institutions, authors, and editors are individually and jointly responsible for ensuring that the obligations of honesty and integrity are met. Fraud in research must be condemned and punished. Reviewers of grant applications and journal articles must respect the confidentiality of new ideas and information; they must not use what they learn from the review process for their own purposes, and they should not misrepresent the ideas of others as their own.

Scientists have a responsibility to gather data meticulously, to keep impeccable records with appropriate levels of privacy protections, to interpret results objectively and not force them into preconceived molds or models, to submit their work for peer review, and to report knowledge. All clinical trials must be registered and reporting of methodology and outcomes must be clear, complete, and transparent (124).

Contributing to generalizable knowledge that can improve human health should be the main motivation for scientific research. Personal recognition, public acclaim, or financial gain should not be primary motivating factors, and physicians should be aware of conflicting interests when participating in or referring patients to research studies (125).

Protection of Human Subjects

The medical profession and individual researchers must assume responsibility for assuring that research is valid, has potentially important value, and is ethically conducted. Research must be thoughtfully planned to ensure a high probability of valid results, to minimize subject risk and maximize subject safety, and to achieve a benefit–risk ratio that is high enough to justify the research effort (126). Benefits and risks of research must be distributed fairly, and particular care must be taken to avoid exploitation of vulnerable populations and those in countries with limited access to health care resources (127). Research projects originating in but conducted outside of the United States must be consistent with ethical principles and practices that govern human subjects research and must adhere to regulatory standards in the United States as well as at international sites.

Functioning as both an investigator and the clinician of a patient-subject can result in conflict between what is best for the research protocol and what is in the patient’s best interests. Physician-investigators should disclose this conflict to potential research participants and should maintain patient-subject health and welfare as their primary consideration (128). Patients should be informed that the primary objective of a research protocol is to gain knowledge and that there may or may not be clinical benefit. It should also be clear to patients that participation in
research is voluntary and not a requirement for continued clinical care. The right to withdraw consent and discontinue participation at any time must be communicated. Any limitations on withdrawal of data or biological materials must be explained during the consent process.

Each research subject or an authorized representative must be fully informed of the nature and risks of the research so that he or she may give truly informed consent to participate. Physicians have an ethical obligation to ensure that the information shared during the informed consent process is appropriate and understandable to the proposed subject population. Temporary, progressive, or permanent cognitive impairment or a questionable capacity to give consent for participation in research does not preclude participation in research but does necessitate special measures (129, 130). After ensuring that ethical and legal standards of all research are met, institutions and physician-investigators should attempt to obtain the assent of the cognitively impaired individual in addition to obtaining the consent of a legally authorized representative. In some cases, the patient is able to give consent for research participation and designate a proxy in the early stages of disease (129). If there is no advance directive or proxy, the legally appointed surrogate decision maker must first consider whether the patient would have agreed to participate. Once it is determined that the patient would not object, the physician-investigator needs to instruct the surrogate about decision-making standards that are based on the patient’s best interests. Research in patients with impaired cognition or capacity still needs to meet the threshold criteria of a high probability of valid results, a benefit–risk ratio that is high enough to justify the research effort, and a fair distribution of research benefits and risks (129). Clinicians who are thinking about participating in or referring patients to research studies should be well-versed about the responsible conduct of research and protection of human subjects.

Research involving special circumstances, such as individuals requiring critical care or emergency care, also requires special measures for the protection of human subjects. While research in these contexts may contribute to improved care, investigators need to be aware that the subject may have an impaired ability to provide informed consent and that the benefits of this research may not flow to the potential subject. Special precautions should be undertaken to ensure the protection of these subjects (131). However, the extent to which precautions, such as community consultation, have actually been protective of subject and community rights and interests is unclear.

Independent review is a fundamental principle of ethical research. All proposed research, regardless of the source of support, must be assessed by an IRB to assure that the research plans are valid and reasonable, human subjects are adequately protected, the benefit–risk ratio is acceptable, the proposed research is sufficiently important and protective of human subjects in light of the local patient population, and the informed consent process and confidentiality protections are both appropriate and adequate. Physician-investigators and physicians referring patients to clinical studies have an independent, professional obligation to satisfy themselves that those studies meet ethical standards. Human subjects research ethics requirements are reviewed in Box 7.

While the formal, independent review process was designed to protect research subjects, it cannot replace mutual trust and respect between subjects and researchers. Maintaining that trust and respect requires that physician-investigators involved in designing, performing, or referring patients to research studies have primary concern for the potential subjects (132). If the risks of continued participation in a research trial become too great or cannot be justified, the physician-investigator must advise patients to withdraw. Physicians should not abdicate overall responsibility for patients they have referred to research studies and should ensure that data and safety issues are routinely monitored.

Although the responsibility for assuring reasonable protection of human research subjects resides with the investigators and the IRB, the medical profession as a whole also has responsibilities. Clinical investigation is fraught with potential conflicts. Rewards should not be linked to research outcomes and physicians participating in the conduct of clinical studies should avoid such situations. Moreover, physicians who enroll their own patients in office-based research have an ethical obligation to disclose whether they have financial or other ties to sponsors (96). Giving or accepting finder’s fees for referring patients to a research study generates an unethical conflict of interest for physicians (96). Compensation for the actual time, effort, and expense involved in research or recruiting patients is acceptable; any compensation above that level represents a profit and constitutes or can be perceived as an unethical conflict of interest.

While the Common Rule (123) and some state laws have provisions regarding privacy and confidentiality requirements for research, the HIPAA Privacy Rule (18) requires subject authorization for use or disclosure of protected health information for research. A privacy board can waive the authorization requirement or information can be used in a “limited data set” with a data use agreement or can be deidentified under HIPAA (133), although the HIPAA deidentification requirements are stricter than those under the Common Rule. Physicians who engage in research studies or who make their patient records available for research purposes should be familiar with the HIPAA requirements and each study’s procedures for protecting data confidentiality and security.

Use of Human Biological Materials in Research

Research with human biological materials has implications for the privacy of research subjects and individuals with a genetic relationship to research subjects. The poten-
tial for discrimination or other serious harm through the inappropriate or unauthorized disclosure of genetic data must be communicated during the informed consent process and steps taken to minimize this risk. Research subjects should be informed of plans to pool or otherwise share biological material. In addition, research subjects should be informed that it may not be possible to withdraw deidentified or anonymized biological data from research use.

Fully informed and transparent consent requires the disclosure of all potential uses of patient data. During the initial consent process, desired preferences of research subjects regarding sharing research results with biological relatives and future contact for notification about results or consent for additional research participation should be requested. Research should be limited to the use specified by the protocol during the informed consent process. Communication of the risks and benefits of research involving biological material allows research subjects to make a well-informed decision.

Placebo Controls

Physicians may be asked to enroll patients in placebo-controlled trials. While the World Medical Association requires that “the benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best current proven intervention” (134), in the absence of a proven intervention, the use of placebo-controlled trials may be acceptable. Placebos may also be used when compelling and scientifically sound methodological reasons require them to establish the safety and efficacy of an intervention and patients receiving placebos or no treatment will not be subject to additional risk for serious or irreversible harm (134). These ethical considerations also extend to the use of placebos in comparative effectiveness studies, which may be acceptable according to regulatory standards (135).

This view—that control group members must receive standard, proven therapies—represents a change from the gold standard of the double-blind, placebo-controlled trial. Another view is that physicians may ethically consider participating in or referring patients to placebo-controlled trials when the appropriateness of the study design has been reviewed and approved by an independent IRB (136); subjects freely consent to suspend knowledge of whether they are receiving effective treatment; the health risks and consequences of placebo or delayed treatment are minimal; the standard treatment offers no meaningful improvement to length or quality of life; or the available standard treatments are so toxic that patients routinely refuse therapy (137).

Before referring patients to a placebo-controlled study, a physician should ensure that, in addition to meeting ethical standards, the study design provides for unblinding treatment assignment to the treating physician.

### Innovative Medical Therapies

The use of innovative medical therapies falls along the continuum between established practice and research. Innovative therapies include the use of unconventional dosages of standard medications, a novel combination of currently accepted practices, new applications of standard interventions, and the use of accepted therapy or approved drugs for nonapproved indications. The primary purpose of innovative medical therapies is to benefit the individual patient. While medical innovations can yield important treatment results, they can also produce safety problems. Consequently, medical innovation should always be approached carefully. Medical therapy should be treated as research whenever data are gathered to develop new medical information and for publication. If use of the new therapy, procedure, or intervention becomes routine, it should be investigated in a clinical trial. Adverse events should be carefully monitored and reported to the U.S. Food and Drug Administration and applicable oversight bodies. When considering an innovative therapy that has no precedent, the physician should consult with peers, an IRB, or other expert group to assess the risks, potential adverse outcomes, potential consequences of forgoing a standard therapy, and whether the innovation is in the patient’s best interest (138). Informed consent is particularly important and requires that the patient understand that the recommended therapy is not standard treatment.

### Scientific Publication

Authors of research reports must be intimately acquainted with the work being reported so that they can take public responsibility for the integrity of the study and the validity of the findings. They must have substantially contributed to the research itself, and they must have been part of the decision to publish. Investigators must disclose project funding sources to potential research collaborators and publishers and must explicitly inform publishers whether they do or do not have a potential conflict of interest (see the Financial Conflicts of Interest section).
Physicians should not participate in research if the publication of negative results will be precluded.

Physician-investigators build on the published work of others and can proceed with confidence only if they can rely on the accuracy of the previously reported results on which their work is based. Registration of clinical trials in a public trials registry before patient enrollment helps address the general public and scientific community’s call for transparency in clinical research (139). All researchers have a professional responsibility to be honest in their publications. Biased reporting and selective reporting of study outcomes risks the integrity of the research and may interfere with the ability to derive evidence-based treatment outcomes (140). Researchers must describe methods accurately and in sufficient detail and assure readers that the research was carried out in accordance with ethical principles. They have an obligation to fully report observations actually made, clearly and accurately credit information drawn from the work of others, and assign authorship only to those who merit and accept it. Equally important is acknowledging and revealing the financial associations of authors and other potential conflicts of contributors in the manuscript (141).

In general, subject recruitment alone does not merit authorship. Instead, authorship means substantial contribution to the research along with compliance with current authorship guidelines (142). Ghostwriting and taking credit or payment for the authorship of another is unethical (96). Plagiarism is unethical. Incorporating the ideas of others or one’s own published ideas, either verbatim or by paraphrasing, without appropriate attribution is unethical and may have legal consequences.

**Sponsored Research**

All scientists are bound by the obligations of honesty and integrity in their research. However, in the high-stakes arena of the health care industry, industry-sponsored research is at greater risk for conflicts of interest. Scientists have a responsibility to protect human subjects, implement applicable research standards and privacy and confidentiality protections, register trials, interpret results objectively, submit their work for peer review, and disclose all conflicts of interest. With industry-sponsored research, scientists have the further obligations of ensuring that the entire data set is available and analyzed independently of the sponsor (143). Ethics issues in sponsored research are noted in Box 8. Public Announcement of Research Discoveries

In this era of rapid communication and intense media and public interest in medical news, clinical investigators or their institutions commonly make public announcements of new research developments. Because media coverage of scientific developments can be fraught with misinterpretation, unjustified extrapolation, and unwarranted conclusions, researchers should approach public pronouncements with extreme caution, using precise and measured language. Researchers should also consider notifying subjects of study findings.

In general, press or media releases should be issued and press conferences held only after the research has been published or presented in proper and complete abstract form so that study details are available to the scientific community for evaluation. Statements of scientists receive great visibility. An announcement of preliminary results, even couched in the most careful terms, is frequently reported by the media as a “breakthrough.” Spokespersons must avoid raising false public expectations or providing misleading information, both of which reduce the credibility of the scientific community as a whole.

**Conclusion**

Medicine poses challenging ethical dilemmas for patients, clinicians, and institutions. We hope that this Manual will help physicians—whether they are clinicians, educators, or researchers—and others to address these issues. The Manual is written for physicians by a physician organization as we attempt to navigate through sometimes difficult terrain. Our ultimate intent is to enhance the quality of care provided to patients. We hope the Manual will help thoughtful readers to be virtuous physicians, trusted by patients and the public.

**APPENDIX: A CASE METHOD TO ASSIST CLINICAL ETHICS DECISION MAKING**

One approach to analyzing decision making using a brief case:

1. Define the ethics problem as an “ought” or “should” question.

   **Example:** “Should we withhold a ventilator for this unconscious adult man with AIDS, as his partner requests, or use it, as his parents request?”

   **Not:** “This man with AIDS is an ethics problem.”

   **Not:** “Is it better for terminally ill patients to die with or without a ventilator?”
2a. List important facts and uncertainties that are relevant to the question. Include facts about the patient and caregivers (such as intimacy, emotional state, ethnic and cultural background, faith traditions, and legal standing).

Example: “This man and his partner have been living together for 10 years and purchased a house together. The partner has been a caregiver throughout the illness. The patient’s parents have been unaccepting of his lifestyle and orientation and have been distant from him.”

2b. Include physiologic facts.

Example: “The patient is irreversibly unconscious and incapable of making decisions; thus, he cannot now tell us who should speak on his behalf about his preferences for treatment.”

2c. Include medical uncertainties (such as prognosis and outcomes with and without treatment).

Example: “Antibiotics can be given for the current lung infection, but we do not know whether the patient can be weaned from the ventilator given the advanced disease. It seems more likely than not that he will eventually be weaned from the ventilator. The patient has an estimated life span of 3 to 9 months, but it may be much shorter or somewhat longer.”

2d. Include the benefits and harms of the treatment options.

Example: “The ventilator will prolong life, but it is a burdensome and invasive treatment and will confine the patient to a highly medicalized setting.”

3. Identify a decision maker. If the patient has decision-making capacity, the decision maker is the patient. If the patient lacks decision-making capacity, identify a proxy decision maker as specified by court appointment, state law, a durable power of attorney for health care, living will, or the persons who are best situated by virtue of their intimate, loving familiarity with the patient.

Example: “This is a 32-year-old adult who has lived away from home for 14 years and who has had only occasional contact with his parents, mainly on holidays. He does not have a living will or a durable power of attorney but has spoken often with his partner about his preferences for health care as his disease has advanced. His partner has accompanied the patient to clinic and cared for him as he has become increasingly debilitated.”

4. Give understandable, relevant, desired information to the decision maker and dispel myths and misconceptions.

Example: “The ventilator and antibiotics will prolong life and may allow for treatment of the lung infection, but they will not reverse the underlying severity of the patient’s condition. No existing treatments can affect this patient’s underlying condition. If the ventilator is started, it can be discontinued if the patient does not respond to treatment. If the ventilator is not used, medications can be given to assure that the patient is comfortable even if his lungs are failing.”

5. Solicit values of the patient that are relevant to the question. These include the patient’s values about life; place in the life cycle; relation to community, health care, and health care institutions; goals for health care (for example, palliation, enhancement of function or independence, prolongation of life, or palliation without prolongation of life); conditions that would change goals; and specific preferences about health care or proxy decision makers that are relevant to this situation.

Example: “This patient made many statements to his partner about wanting exclusively palliative care at this time and specifically declined further anti-HIV therapies, as noted in the medical record. He stated that he wanted no life-prolonging treatments of any kind if he could not communicate with his partner, which his present unconscious state prevents him from doing.”

6. Identify health professional values. Values include health-promoting goals (such as prolonging life, alleviating pain, promoting health, curing disease, rehabilitating an injury, preventing harm, providing comfort, empowering patients to make choices, and advocating for patients). Values that pertain to patient–physician communication (truth-telling, confidentiality, nondiscrimination, requirement for informed consent, and tolerance of the diversity of values) are also included, as well as some values that extend outside of the patient–physician relationship (such as protection of third parties, promotion of public health, and respect for the law).

Example: “Although the physician may feel that a ventilator is indicated for this person with respiratory failure, this patient has articulated different goals for health care. The physician is obliged to respect the diversity of values and the requirement for informed consent and respect the patient’s goals and preferences.”

7. Propose and critique solutions, including multiple options for treatment and alternative providers.

Example: “The physician could provide palliative care to a person who has respiratory failure who elects not to receive a ventilator or seek to expeditiously transfer the patient to someone who can provide such care (the latter course would disrupt a relationship between this physician and patient). The physician, in protecting the interests and values of this patient who cannot speak on his own behalf, must serve as the patient’s advocate to the parents of the patient.”

8. Identify and remove or address constraints on solutions (such as reimbursement, unavailability of services, laws, or legal myths).

Example: “The parents in this case asserted that the doctor had to obey them because they were family members. A check with the hospital attorney showed that this was not true in this state.”

From the American College of Physicians, Philadelphia, Pennsylvania.
developed this sixth edition. It updates the 2005 fifth edition, which served as the starting point for line-by-line review and debate by Committee members and staff following literature reviews and an environmental assessment to determine the scope of issues, what new topics to include, and other changes. The Committee met 13 times in person, by conference call, and by Webinar, reaching consensus on issues through facilitated discussion. A draft Manual then underwent external peer review and review by College councils and leadership. After review and revisions based on those comments, the Manual was approved by the Committee and reviewed and approved by the Board of Regents. The Ethics Manual is official ACP policy. ACP members pledge “to uphold the ethics of medicine as exemplified by the standards and traditions of this College,” and we hope the Manual is a resource to all physicians and to others, as well.

Acknowledgment: The College and the ACP Ethics, Professionalism, and Human Rights Committee thank former Committee members who made contributions to the development of this Manual through their work on previous editions. They thank reviewers of this edition of the Manual: Rebecca Andrews, MD; Clifton R. Cleaveland, MD; Charles Cutler, MD; Serle M. Epstein, MD; David A. Fleming, MD; Angela C. Johnson, MD; Edwin P. Maynard, MD; David W. Potts, MD; William A. Reynolds, MD; James R. Webster, MD, MS; and Steven E. Weinberger, MD. They also thank staff to the Committee and the ACP Center for Ethics and Professionalism who worked on the Manual: Michael S. Barr, MD, MBA; Eileen M. D’Amico; Carol R. Dembe, MD, JD; Sheryl Mitnick, MPH, RN; and Lois Snyder, JD.

Financial Support: Financial support for the development of the Manual came exclusively from the ACP operating budget.

Potential Conflicts of Interest: Ms. Snyder: Other relationships: Member of Society of General Internal Medicine Ethics Committee. Dr. Hood: Employment: ACP (president-elect, 2010–2012); Grants/grants pending: American Medical Group Association Hypertension Learning Foundation; Payment for lectures including service on speakers bureaus: American Society of Nephrology; Stock/options: mutual funds. Dr. Kutty: Employment: The Medical College of Wisconsin; Royalties: Wolters Kluwer; Stock/options: Medtronic. Dr. Fins: Support for travel to meetings for the study or other purposes: ACP; Board membership: ACP Foundation; Employment: Weill Cornell; Grants/grants pending: RWF; Payment for lectures including service on speakers bureaus: various entities; Royalties: Jones and Bartlett; Payment for development of educational presentations: Weill Cornell. Dr. López: Grant: NIH, HRSA, Komen; Consulting fee or honorarium: GlaxoSmithKline; Grants/grants pending: American Cancer Society, NIH, Komen. Dr. Braddock: Board membership: Foundation for Informed Medical Decision Making. Dr. Calvano: Travel/accommodations/meeting expenses unrelated to activities listed: ACP. Dr. Faber-Langendoen: Support for travel to meetings for the study or other purposes: ACP; Employment: SUNY Upstate Medical University; Travel/accommodations/meeting expenses unrelated to activities listed: ACP. Dr. Herrin: Payment for lectures including service on speakers bureaus: Gentech Speakers Bureau. Dr. Mir: Employment: NSLUHS. Dr. Moreno: Support for travel to meetings for the study or other purposes: ACP; Other relationships: Governor, American College of Legal Medicine (February 2011–present); member and pro bono consultant, Physicians for Human Rights (1997–present); member of Board of Directors and President Elect, Texas Chapter of the ACP and ACP Services; pro bono advisor, Center for Survivors of Torture. Mr. Pasha: Support for travel to meetings for the study or other purposes: ACP. Dr. Turner: Employment: Annals of Internal Medicine Executive Deputy Editor, November 2009–November 2010. Disclosures can also be viewed at www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M11-1111.

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OBJECTIVES
These activities have been developed for internists to facilitate the highest quality professional work in clinical applications, teaching, consultation, or research. Upon completion of a CME activity, participants should be able to demonstrate an increase in the skills and knowledge required to maintain competence, strengthen their habits of critical inquiry and balanced judgment, and contribute to better patient care.

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Christine Laine, MD, MPH, Editor in Chief, reports that she has no financial relationships or interests to disclose.

Darren B. Taichman, PhD, Executive Deputy Editor, reports that he has received research support from a grant to the University of Pennsylvania from Actelion.

Cynthia D. Mulrow, MD, MSc, Senior Deputy Editor, reports that she has no financial relationships or interests to disclose.

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Deborah Cotton, MD, MPH, Deputy Editor, reports that she has no financial relationships or interest to disclose.

Sankey V. Williams, MD, Deputy Editor, reports that he has no financial relationships or interests to disclose.


Funding source: American College of Physicians.

Potential conflicts of interest: Ms. Snyder: Other relationships: Member of Society of General Internal Medicine Ethics Committee. Dr. Hood: Employment: ACP (president-elect 2010-2012); Grants/grants pending: American Medical Group Association Hypertension Learning Foundation; Payment for lectures including service on speakers bureaus: American Society of Nephrology; Stock/stock options: mutual funds. Dr. Kutty: Employment: The Medical College of Wisconsin; Royalties: Wolters Kluwer; Stock/stock options: Medtronic. Dr. Fins: Support for travel to meetings for the study or other purposes: ACP; Board membership: ACP Foundation; Employment: Weill Cornell; Grants/grants pending: RWF; Payment for lectures including service on speakers bureaus: various entities; Royalties: Jones and Bartlett; Payment for development of educational presentations: Weill Cornell. Dr. López: Grant: NIH, HRSA, Komen; Consulting fee or honorarium: GlaxoSmithKline; Grants/grants pending: American Cancer Society, NIH, Komen. Dr. Braddock: Board membership: Foundation for Informed Medical Decision Making. Dr. Calvano: Travel/accommodations/meeting expenses unrelated to activities listed: ACP. Dr. Faber-Langendoen: Support for travel to meetings for the study or other purposes: ACP; Employment: SUNY Upstate Medical University; Travel/accommodations/meeting expenses unrelated to activities listed: ACP. Dr. Herrin: Payment for lectures including service on speakers bureaus: Gentech Speakers Bureau. Dr. Mir: Employment: NSLUHS. Dr. Moreno: Support for travel to meetings for the study or other purposes: ACP; Other relationships: Governor, American College of Legal Medicine (February 2011-present); member and pro bono consultant, Physicians for Human Rights (1997-present); member of Board of Directors and President Elect, Texas Chapter of the ACP and ACP Services; pro bono advisor, Center for Survivors of Torture. Mr. Pasha: Support for travel to meetings for the study or other purposes: ACP. Dr. Turner: Employment: Annals of Internal Medicine Executive Deputy Editor, November 2009 to November 2010. Disclosures can also be viewed at www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M11-1111.

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1. A 54-year-old woman with advanced rheumatoid arthritis lives in an assisted living facility because of severe functional impairment and uses a motorized wheelchair. She has a daughter who lives in a different city. She is hospitalized for drug-induced pancreatitis; when she does not improve after a week of bowel rest, she refuses jejunal nutrition or further intravenous fluids and asks for referral to hospice, saying she is tired of living with her pain and functional limitations and is ready to die.

Which of the following should be done next?
A. Start the patient on an antidepressant.
B. Assess the extent to which the patient’s pain is controlled.
C. Discuss this decision with her daughter.
D. Override the patient’s refusal.

2. A 68-year-old homeless man with chronic obstructive pulmonary disease and heart failure presents to the emergency department with pneumonia. He has been admitted to the hospital numerous times for respiratory decompensation and generally signs out against medical advice as soon as his symptoms resolve. He is readmitted, intubated, placed on mechanical ventilation, and vasopressors, and antibiotics are initiated. Over the next few days, he develops acute kidney failure. He is confused and unable to speak for himself. Six months ago he wrote an advance directive specifying his treatment wishes and designating his only family member, a distant cousin he has not seen in 20 years, as his health care agent. In the advance directive, the patients indicated that he did not want any “machines” to keep him alive. The health care agent believes everything should be done to save the patient’s life. No outpatient dialysis facility in the community is willing to dialyze cognitively impaired patients long-term.

Which of the following provides the most ethically sound basis for determining whether dialysis ought to be started?
A. The health care agent’s request.
B. The patient’s history of refusing medical advice.
C. The patient’s advance directive.
D. The lack of an outpatient dialysis facility.

3. Which of the following best describes ethically sound practice in the procurement of organs using “donation after cardiac death” procedures?
A. The physician caring for the prospective donor is responsible for obtaining consent for donation and procuring the organs to facilitate continuity of care.
B. The major determinant for the appropriate interval between donor pulselessness and declaring death should be maximizing organ viability in the recipient.
C. Invasive procedures on the dying patient to promote organ viability in the recipient are justified as long as the donor patient is certain to die regardless.
D. Until the donor dies, the primary ethical responsibility of the donor’s physician is to the donor’s welfare.

4. Physicians must routinely gauge whether any gift relationship with the health care industry is ethically appropriate and evaluate any potential for influence on clinical judgment. Which of the following is the least important criterion in judging the ethical appropriateness of accepting a gift from industry?
A. The perception of the public and patients.
B. The purpose of the industry offer.
C. The perception of colleagues.
D. The dollar value of the gift.

5. “Pay-for-performance” programs can help improve the quality of health care. You are debating participating in a program in your area. Which program should you avoid because it does not align with the goals of medical professionalism?
A. A program that addresses the complexity of care for the whole patient.
B. A program that discourages deselection of patients or categories of patients.
C. A program that focuses on linking compensation to performance based on limited measures of care.
D. A program that ensures there are no incentives to “game the system.”

6. Physicians have certain obligations in relation to government. Regarding interrogations of prisoners by government agents, such as the military, the police or other security officials, physicians:
A. Must not conduct or participate in but may be present at interrogations.
B. Must report abusive or coercive practices to the appropriate authorities.
C. May participate in developing humane interrogation strategies.
D. May use medical information available from other sources for interrogation purposes.

7. The physicians in a group practice are very concerned about malpractice liability issues in their state. A full-day event is being held at the state capital in support of a tort reform bill. The physicians are debating whether and how they can participate, including closing the practice that day. They are aware of the ethical prohibition that physicians:
A. May use medical information available from other sources for interrogation purposes.
B. Must report abusive or coercive practices to the appropriate authorities.
C. May participate in developing humane interrogation strategies.
D. May use medical information available from other sources for interrogation purposes.
cians advocating for system change should not participate in joint actions that adversely affect access to health care. But they are wondering what would be allowable. They can attend the event if:

A. It is a protest and provisions are made for the care of their patients.
B. It is a work stoppage or slowdown that limits services to patients.
C. It results in anticompetitive behavior.
D. It is a strike.

8. Resource allocation issues challenge the physician’s role as trusted advocate to the individual patient in the face of the interests of the community or of society. Which of the following should guide physician behavior regarding resource allocation?

A. Bend the truth to ensure the patient receives coverage.
B. Provide all tests or treatments a patient (or a patient’s family) wants.
C. Use all health resources in a technically appropriate and efficient manner.
D. Ration care.