# AMA CODE OF MEDICAL ETHICS

## AMA PRINCIPLES OF MEDICAL ETHICS*

*Preamble*

The medical profession has long subscribed to a body of ethical statements developed primarily for the benefit of the patient. As a member of this profession, a physician must recognize responsibility to patients first and foremost, as well as to society, to other health professionals, and to self. The following Principles adopted by the American Medical Association are not laws, but standards of conduct that define the essentials of honorable behavior for the physician.

*Principles of medical ethics*

I. A physician shall be dedicated to providing competent medical care, with compassion and respect for human dignity and rights.

II. A physician shall uphold the standards of professionalism, be honest in all professional interactions, and strive to report physicians deficient in character or competence, or engaging in fraud or deception, to appropriate entities.

III. A physician shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient.

IV. A physician shall respect the rights of patients, colleagues, and other health professionals, and shall safeguard patient confidences and privacy within the constraints of the law.

V. A physician shall continue to study, apply, and advance scientific knowledge, maintain a commitment to medical education, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talents of other health professionals when indicated.

VI. A physician shall, in the provision of appropriate patient care, except in emergencies, be free to choose whom to serve, with whom to associate, and the environment in which to provide medical care.

VII. A physician shall recognize a responsibility to participate in activities contributing to the improvement of the community and the betterment of public health.

VIII. A physician shall, while caring for a patient, regard responsibility to the patient as paramount.

IX. A physician shall support access to medical care for all people.

* Revised June 2001.

## CHAPTER 1: OPINIONS ON PATIENT-PHYSICIAN RELATIONSHIPS

The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.


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### *1.1.1 Patient-Physician Relationships*

The practice of medicine, and its embodiment in the clinical encounter between a patient and a physician, is fundamentally a moral activity that arises from the imperative to care for patients and to alleviate suffering. The relationship between a patient and a physician is based on trust, which gives rise to physicians' ethical responsibility to place patients' welfare above the physician's own self-interest or obligations to others, to use sound medical judgment on patients' behalf, and to advocate for their patients' welfare.

A patient-physician relationship exists when a physician serves a patient's medical needs. Generally, the relationship is entered into by mutual consent between physician and patient (or surrogate).

However, in certain circumstances a limited patient-physician relationship may be created without the patient's (or surrogate's) explicit agreement. Such circumstances include:

(a) When a physician provides emergency care or provides care at the request of the patient's treating physician. In these circumstances, the patient's (or surrogate's) agreement to the relationship is implicit.

(b) When a physician provides medically appropriate care for a prisoner under court order, in keeping with ethics guidance on court-initiated treatment.

(c) When a physician examines a patient in the context of an independent medical examination, in keeping with ethics guidance. In such situations, a limited patient-physician relationship exists.

*AMA Principles of Medical Ethics: I,II,IV,VIII*

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### *1.1.2 Prospective Patients*

As professionals dedicated to protecting the well-being of patients, physicians have an ethical obligation to provide care in cases of medical emergency. Physicians must also uphold ethical responsibilities not to discriminate against a prospective patient on the basis of race, gender, sexual orientation or gender identity, or other personal or social characteristics that are not clinically relevant to the individual's care. Nor may physicians decline a patient based solely on the individual's infectious disease status. Physicians should not decline patients for whom they have accepted a contractual obligation to provide care.

However, physicians are not ethically required to accept all prospective patients. Physicians should be thoughtful in exercising their right to choose whom to serve.

A physician may decline to establish a patient-physician relationship with a prospective patient, or provide specific care to an existing patient, in certain limited circumstances:

(a) The patient requests care that is beyond the physician's competence or scope of practice; is known to be scientifically invalid, has no medical indication, or cannot reasonably be expected to achieve the intended clinical benefit; or is incompatible with the physician's deeply held personal, religious, or moral beliefs in keeping with ethics guidance on exercise of conscience.

(b) The physician lacks the resources needed to provide safe, competent, respectful care for the individual. Physicians may not decline to accept a patient for reasons that would constitute discrimination against a class or category of patients

(c) Meeting the medical needs of the prospective patient could seriously compromise the physician's ability to provide the care needed by his or her other patients. The greater the prospective patient's medical need, however, the stronger is the physician's obligation to provide care, in keeping with the professional obligation to promote access to care.

(d) The individual is abusive or threatens the physician, staff, or other patients, unless the physician is legally required to provide emergency medical care. Physicians should be aware of the possibility that an underlying medical condition may contribute to this behavior.

*AMA Principles of Medical Ethics: I,VI,VIII,X*

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### *1.1.3 Patient Rights*

The health and well-being of patients depends on a collaborative effort between patient and physician in a mutually respectful alliance. Patients contribute to this alliance when they fulfill responsibilities they have, to seek care and to be candid with their physicians.

Physicians can best contribute to a mutually respectful alliance with patients by serving as their patients' advocates and by respecting patients' rights. These include the right:

(a) To courtesy, respect, dignity, and timely, responsive attention to his or her needs.

(b) To receive information from their physicians and to have opportunity to discuss the benefits, risks, and costs of appropriate treatment alternatives, including the risks, benefits and costs of forgoing treatment. Patients should be able to expect that their physicians will provide guidance about what they consider the optimal course of action for the patient based on the physician's objective professional judgment.

(c) To ask questions about their health status or recommended treatment when they do not fully understand what has been described and to have their questions answered.

(d) To make decisions about the care the physician recommends and to have those decisions respected. A patient who has decision-making capacity may accept or refuse any recommended medical intervention.

(e) To have the physician and other staff respect the patient's privacy and confidentiality.

(f) To obtain copies or summaries of their medical records.

(g) To obtain a second opinion.

(h) To be advised of any conflicts of interest their physician may have in respect to their care.

(i) To continuity of care. Patients should be able to expect that their physician will cooperate in coordinating medically indicated care with other health care professionals, and that the physician will not discontinue treating them when further treatment is medically indicated without giving them sufficient notice and reasonable assistance in making alternative arrangements for care.

*AMA Principles of Medical Ethics: I,IV,V,VIII,IX*

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### *1.1.4 Patient Responsibilities*

Successful medical care requires ongoing collaboration between patients and physicians. Their partnership requires both individuals to take an active role in the healing process.

Autonomous, competent patients control the decisions that direct their health care. With that exercise of self-governance and choice comes a number of responsibilities. Patients contribute to the collaborative effort when they:

(a) Are truthful and forthcoming with their physicians and strive to express their concerns clearly. Physicians likewise should encourage patients to raise questions or concerns.

(b) Provide as complete a medical history as they can, including providing information about past illnesses, medications, hospitalizations, family history of illness, and other matters relating to present health.

(c) Cooperate with agreed-on treatment plans. Since adhering to treatment is often essential to public and individual safety, patients should disclose whether they have or have not followed the agreed-on plan and indicate when they would like to reconsider the plan.

(d) Accept care from medical students, residents, and other trainees under appropriate supervision. Participation in medical education is to the mutual benefit of patients and the health care system; nonetheless, patients' (or surrogates') refusal of care by a trainee should be respected in keeping with ethics guidance.

(e) Meet their financial responsibilities with regard to medical care or discuss financial hardships with their physicians. Patients should be aware of costs associated with using a limited resource like health care and try to use medical resources judiciously.

(f) Recognize that a healthy lifestyle can often prevent or mitigate illness and take responsibility to follow preventive measures and adopt health-enhancing behaviors.

(g) Be aware of and refrain from behavior that unreasonably places the health of others at risk. They should ask about what they can do to prevent transmission of infectious disease.

(h) Refrain from being disruptive in the clinical setting.

(i) Not knowingly initiate or participate in medical fraud.

(j) Report illegal or unethical behavior by physicians or other health care professionals to the appropriate medical societies, licensing boards, or law enforcement authorities.

*AMA Principles of Medical Ethics: I,IV,VI*

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### *1.1.5 Terminating a Patient-Physician Relationship*

Physicians' fiduciary responsibility to patients entails an obligation to support continuity of care for their patients. At the beginning of patient-physician relationship, the physician should alert the patient to any foreseeable impediments to continuity of care.

When considering withdrawing from a case, physicians must:

(a) Notify the patient (or authorized decision maker) long enough in advance to permit the patient to secure another physician.

(b) Facilitate transfer of care when appropriate.

*AMA Principles of Medical Ethics: I,VI*

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### *1.1.6 Quality*

As professionals dedicated to promoting the well-being of patients, physicians individually and collectively share the obligation to ensure that the care patients receive is safe, effective, patient centered, timely, efficient, and equitable.

While responsibility for quality of care does not rest solely with physicians, their role is essential. Individually and collectively, physicians should actively engage in efforts to improve the quality of health care by:

(a) Keeping current with best care practices and maintaining professional competence.

(b) Holding themselves accountable to patients, families, and fellow health care professionals for communicating effectively and coordinating care appropriately.

(c) Monitoring the quality of care they deliver as individual practitioners—e.g., through personal case review and critical self-reflection, peer review, and use of other quality improvement tools.

(d) Demonstrating commitment to develop, implement, and disseminate appropriate, well-defined quality and performance improvement measures in their daily practice.

(e) Participating in educational, certification, and quality improvement activities that are well designed and consistent with the core values of the medical profession.

*AMA Principles of Medical Ethics: I,V,VII,VIII*

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### *1.1.7 Physician Exercise of Conscience*

Physicians are expected to uphold the ethical norms of their profession, including fidelity to patients and respect for patient self-determination. Yet physicians are not defined solely by their profession. They are moral agents in their own right and, like their patients, are informed by and committed to diverse cultural, religious, and philosophical traditions and beliefs. For some physicians, their professional calling is imbued with their foundational beliefs as persons, and at times the expectation that physicians will put patients' needs and preferences first may be in tension with the need to sustain moral integrity and continuity across both personal and professional life.

Preserving opportunity for physicians to act (or to refrain from acting) in accordance with the dictates of conscience in their professional practice is important for preserving the integrity of the medical profession as well as the integrity of the individual physician, on which patients and the public rely. Thus physicians should have considerable latitude to practice in accord with well-considered, deeply held beliefs that are central to their self-identities.

Physicians' freedom to act according to conscience is not unlimited, however. Physicians are expected to provide care in emergencies, honor patients' informed decisions to refuse life-sustaining treatment, and respect basic civil liberties and not discriminate against individuals in deciding whether to enter into a professional relationship with a new patient.

In other circumstances, physicians may be able to act (or refrain from acting) in accordance with the dictates of their conscience without violating their professional obligations. Several factors impinge on the decision to act according to conscience. Physicians have stronger obligations to patients with whom they have a patient-physician relationship, especially one of long standing; when there is imminent risk of foreseeable harm to the patient or delay in access to treatment would significantly adversely affect the patient's physical or emotional well-being; and when the patient is not reasonably able to access needed treatment from another qualified physician.

In following conscience, physicians should:

(a) Thoughtfully consider whether and how significantly an action (or declining to act) will undermine the physician's personal integrity, create emotional or moral distress for the physician, or compromise the physician's ability to provide care for the individual and other patients.

(b) Before entering into a patient-physician relationship, make clear any specific interventions or services the physician cannot in good conscience provide because they are contrary to the physician's deeply held personal beliefs, focusing on interventions or services a patient might otherwise reasonably expect the practice to offer.

(c) Take care that their actions do not discriminate against or unduly burden individual patients or populations of patients and do not adversely affect patient or public trust.

(d) Be mindful of the burden their actions may place on fellow professionals.

(e) Uphold standards of informed consent and inform the patient about all relevant options for treatment, including options to which the physician morally objects.

(f) In general, physicians should refer a patient to another physician or institution to provide treatment the physician declines to offer. When a deeply held, well-considered personal belief leads a physician also to decline to refer, the physician should offer impartial guidance to patients about how to inform themselves regarding access to desired services.

(g) Continue to provide other ongoing care for the patient or formally terminate the patient-physician relationship in keeping with ethics guidance.

*AMA Principles of Medical Ethics: I,II,IV,VI,VIII,IX*

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### *1.1.8 Required Reporting of Adverse Events*

Physicians' primary ethical obligation to promote the well-being of individual patients encompasses an obligation to collaborate in a discharge plan that is safe for the patient. As advocates for their patients, physicians should resist any discharge requests that are likely to compromise a patient's safety. The discharge plan should be developed without regard to socioeconomic status, immigration status, or other clinically irrelevant considerations. Physicians also have a long-standing obligation to be prudent stewards of the shared societal resources with which they are entrusted. That obligation may require physicians to balance advocating on behalf of an individual patient with recognizing the needs of other patients.

To facilitate a patient's safe discharge from an inpatient unit, physicians should:

(a) Determine that the patient is medically stable and ready for discharge from the treating facility.

(b) Collaborate with those health care professionals and others who can facilitate a patient discharge to establish that a plan is in place for medically needed care that considers the patient's particular needs and preferences.

If a medically stable patient refuses discharge, physicians should support the patient's right to seek further review, including consultation with an ethics committee or other appropriate institutional resource.

*AMA Principles of Medical Ethics: I,II,VIII*

### *1.2.1 Treating Self or Family*

Treating oneself or a member of one's own family poses several challenges for physicians, including concerns about professional objectivity, patient autonomy, and informed consent.

When the patient is an immediate family member, the physician's personal feelings may unduly influence his or her professional medical judgment. Or the physician may fail to probe sensitive areas when taking the medical history or to perform intimate parts of the physical examination. Physicians may feel obligated to provide care for family members despite feeling uncomfortable doing so. They may also be inclined to treat problems that are beyond their expertise or training.

Similarly, patients may feel uncomfortable receiving care from a family member. A patient may be reluctant to disclose sensitive information or undergo an intimate examination when the physician is an immediate family member. This discomfort may particularly be the case when the patient is a minor child, who may not feel free to refuse care from a parent.

In general, physicians should not treat themselves or members of their own families. However, it may be acceptable to do so in limited circumstances:

(a) In emergency settings or isolated settings where there is no other qualified physician available. In such situations, physicians should not hesitate to treat themselves or family members until another physician becomes available.

(b) For short-term, minor problems.

When treating self or family members, physicians have a further responsibility to:

(c) Document treatment or care provided and convey relevant information to the patient's primary care physician.

(d) Recognize that if tensions develop in the professional relationship with a family member, perhaps as a result of a negative medical outcome, such difficulties may be carried over into the family member's personal relationship with the physician.

(e) Avoid providing sensitive or intimate care especially for a minor patient who is uncomfortable being treated by a family member.

(f) Recognize that family members may be reluctant to state their preference for another physician or decline a recommendation for fear of offending the physician.

*AMA Principles of Medical Ethics: I,II,IV*

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### *1.2.2 Discrimination and Disruptive Behavior by Patients*

The relationship between patients and physicians is based on trust and should serve to promote patients' well-being while respecting the dignity and rights of both patients and physicians.

Disrespectful, derogatory, or prejudiced language or conduct, or prejudiced requests for accommodation of personal preferences on the part of either patients or physicians can undermine trust and compromise

the integrity of the patient-physician relationship. It can make individuals who themselves experience (or are members of populations that have experienced) prejudice reluctant to seek care as patients or to provide care as health care professionals, and create an environment that strains relationships among patients, physicians, and the health care team.

Trust can be established and maintained only when there is mutual respect. Therefore, in their interactions with patients, physicians should:

(a) Recognize that disrespectful, derogatory, or prejudiced language or conduct can cause psychological harm to those who are targeted.

(b) Always treat patients with compassion and respect.

(c) Explore the reasons for which a patient behaves in disrespectful, derogatory, or prejudiced ways insofar as possible. Physicians should identify, appreciate, and address potentially treatable clinical conditions or personal experiences that influence patient behavior. Regardless of cause, when a patient's behavior threatens the safety of health care personnel or other patients, steps should be taken to de-escalate or remove the threat.

(d) Prioritize the goals of care when deciding whether to decline or accommodate a patient's request for an alternative physician. Physicians should recognize that some requests for a concordant physician may be clinically useful or promote improved outcomes.

(e) Within the limits of ethics guidance, trainees should not be expected to forgo valuable learning opportunities solely to accommodate prejudiced requests.

(f) Make patients aware that they are able to seek care from other sources if they persist in opposing treatment from the physician assigned. If patients require immediate care, inform them that, unless they exercise their right to leave, care will be provided by appropriately qualified staff independent of their expressed preference.

(g) Terminate the patient-physician relationship only when the patient will not modify disrespectful, derogatory or prejudiced behavior that is within the patient's control, in keeping with ethics guidance.

Physicians, especially those in leadership roles, should encourage the institutions with which they are affiliated to:

(h) Be mindful of the messages the institution conveys within and outside its walls by how it responds to prejudiced behavior by patients.

(i) Educate staff, patients, and the community about the institution's expectations for behavior.

(j) Promote a safe and respectful working environment and formally set clear expectations for how disrespectful, derogatory, or prejudiced behavior by patients will be managed.

(k) Clearly and openly support physicians, trainees, and facility personnel who experience prejudiced behavior and discrimination by patients, including allowing physicians, trainees, and facility personnel to decline to care for those patients, without penalty, who have exhibited discriminatory behavior specifically toward them.

(l) Collect data regarding incidents of discrimination by patients and their effects on physicians and facility personnel on an ongoing basis and seek to improve how incidents are addressed to better meet the needs of patients, physicians, other facility personnel, and the community.

*AMA Principles of Medical Ethics: I,II,VI,IX*

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### *1.2.3 Consultation, Referral, and Second Opinions*

Physicians' fiduciary obligation to promote patients' best interests and welfare can include consulting other physicians for advice in the care of the patient or referring patients to other professionals to provide care.

When physicians seek or provide consultation about a patient's care or refer a patient for health care services, including diagnostic laboratory services, they should:

(a) Base the decision or recommendation on the patient's medical needs, as they would for any treatment recommendation, and consult or refer the patient to only health care professionals who have appropriate knowledge and skills and are licensed to provide the services needed.

(b) Share patients' health information in keeping with ethics guidance on confidentiality.

(c) Assure the patient that he or she may seek a second opinion or choose someone else to provide a recommended consultation or service. Physicians should urge patients to familiarize themselves with any restrictions associated with their individual health plan that may bear on their decision, such as additional out-of-pocket costs to the patient for referrals or care outside a designated panel of providers.

(d) Explain the rationale for the consultation, opinion, or findings and recommendations clearly to the patient.

(e) Respect the terms of any contractual relationships they may have with health care organizations or payers that affect referrals and consultation.

Physicians may not terminate a patient-physician relationship solely because the patient seeks recommendations or care from a health care professional whom the physician has not recommended.

*AMA Principles of Medical Ethics: IV,V,VI*

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### *1.2.4 Use of Chaperones*

Efforts to provide a comfortable and considerate atmosphere for the patient and the physician are part of respecting patients' dignity. These efforts may include providing appropriate gowns, private facilities for undressing, sensitive use of draping, and clearly explaining various components of the physical examination. They also include having chaperones available. Having chaperones present can also help prevent misunderstandings between patient and physician.

Physicians should:

(a) Adopt a policy that patients are free to request a chaperone and ensure that the policy is communicated to patients.

(b) Always honor a patient's request to have a chaperone.

(c) Have an authorized member of the health care team serve as a chaperone. Physicians should establish clear expectations that chaperones will uphold professional standards of privacy and confidentiality.

(d) In general, use a chaperone even when a patient's trusted companion is present.

(e) Provide opportunity for private conversation with the patient without the chaperone present. Physicians should minimize inquiries or history taking of a sensitive nature during a chaperoned examination.

*AMA Principles of Medical Ethics: I,IV*

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### *1.2.5 Sports Medicine*

Many professional and amateur athletic activities, including contact sports, can put participants at risk of injury. Physicians can provide valuable information to help sports participants, dancers, and others make informed decisions about whether to initiate or continue participating in such activities.

Physicians who serve in a medical capacity at athletic, sporting, or other physically demanding events should protect the health and safety of participants.

In this capacity, physicians should:

(a) Base their judgment about an individual's participation solely on medical considerations.

(b) Not allow the desires of spectators, promoters of the event, or even the injured individual to govern a decision about whether to remove the participant from the event.

*AMA Principles of Medical Ethics: I,VII*

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### *1.2.6 Work-Related and Independent Medical Examinations*

Physicians who are employed by businesses or insurance companies, or who provide medical examinations within their realm of specialty as independent contractors, to assess individuals' health or disability face a conflict of duties. They have responsibilities both to the patient and to the employer or third party.

Such industry-employed physicians or independent medical examiners establish limited patient-physician relationships. Their relationships with patients are confined to the isolated examination; they do not monitor patients' health over time, treat them, or carry out many other duties fulfilled by physicians in the traditional fiduciary role.

In keeping with their core obligations as medical professionals, physicians who practice as industry-employed physicians or independent medical examiners should:

(a) Disclose the nature of the relationship with the employer or third party and that the physician is acting as an agent of the employer or third party before gathering health information from the patient.

(b) Explain that the physician's role in this context is to assess the patient's health or disability independently and objectively. The physician should further explain the differences between this practice and the traditional fiduciary role of a physician.

(c) Protect patients' personal health information in keeping with professional standards of confidentiality.

(d) Inform the patient about important incidental findings the physician discovers during the examination. When appropriate, the physician should suggest the patient seek care from a qualified physician and, if requested, provide reasonable assistance in securing follow-up care.

*AMA Principles of Medical Ethics: I*

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### *1.2.7 Use of Restraints*

All individuals have a fundamental right to be free from unreasonable bodily restraint. At times, however, health conditions may result in behavior that puts patients at risk of harming themselves. In such situations, it may be ethically justifiable for physicians to order the use of chemical or physical restraint to protect the patient.

Except in emergencies, patients should be restrained only on a physician's explicit order. Patients should never be restrained punitively, for convenience, or as an alternate to reasonable staffing.

Physicians who order chemical or physical restraints should:

(a) Use best professional judgment to determine whether restraint is clinically indicated for the individual patient.

(b) Obtain the patient's informed consent to the use of restraint, or the consent of the patient's surrogate when the patient lacks decision-making capacity. Physicians should explain to the patient or surrogate:

(i) why restraint is recommended;

(ii) what type of restraint will be used;

(iii) length of time for which restraint is intended to be used.

(c) Regularly review the need for restraint and document the review and resulting decision in the patient's medical record.

In certain limited situations, when a patient poses a significant danger to self or others, it may be appropriate to restrain the patient involuntarily. In such situations, the least restrictive restraint reasonable should be implemented and the restraint should be removed promptly when no longer needed.

*AMA Principles of Medical Ethics: I,IV*

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### *1.2.8 Gifts from Patients*

Patients offer gifts to a physician for many reasons. Some gifts are offered as an expression of gratitude

or a reflection of the patient's cultural tradition. Accepting gifts offered for these reasons can enhance the patient-physician relationship.

Other gifts may signal psychological needs that require the physician's attention. Some patients may offer gifts or cash to secure or influence care or to secure preferential treatment. Such gifts can undermine physicians' obligation to provide services fairly to all patients; accepting them is likely to damage the patient-physician relationship.

The interaction of these factors is complex and physicians should consider them sensitively before accepting or declining a gift.

Physicians to whom a patient offers a gift should:

(a) Be sensitive to the gift's value relative to the patient's or physician's means. Physicians should decline gifts that are disproportionately or inappropriately large, or when the physician would be uncomfortable to have colleagues know the gift had been accepted.

(b) Not allow the gift or offer of a gift to influence the patient's medical care.

(c) Decline a bequest from a patient if the physician has reason to believe accepting the gift would present an emotional or financial hardship to the patient's family.

(d) Physicians may wish to suggest that the patient or family make a charitable contribution in lieu of the bequest, in keeping with ethics guidance.

*AMA Principles of Medical Ethics: I,II*

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### *1.2.9 Use of Remote Sensing and Monitoring Devices*

Sensing and monitoring devices can benefit patients by allowing physicians and other health care professionals to obtain timely information about the patient's vital signs or health status without requiring an in-person, face-to-face encounter. Implantable devices can also enable physicians to identify patients rapidly and expedite access to patients' medical records. Devices that transmit patient information wirelessly to remote receiving stations can offer convenience for both patients and physicians, enhance the efficiency and quality of care, and promote increased access to care, but also raise concerns about safety and the confidentiality of patient information.

Individually, physicians who employ remote sensing and monitoring devices in providing patient care should:

(a) Determine whether using one or more such devices is appropriate in light of individual patients' medical needs and circumstances, including patients' ability to use the chosen device appropriately.

(b) Explain how the device(s) will be used in the patient's care and what will be expected of the patient in using the technology, and disclose any limitations, risks, or medical uncertainties associated with the device(s) and data transmission.

(c) Obtain the patient's or surrogate's informed consent before implementing the device in treatment.

Collectively, physicians should:

(d) Support research into the safety, efficacy, and possible non-medical uses of remote sensing and monitoring devices, including devices intended to transmit biometric data and implantable radio frequency ID devices.

(e) Advocate for appropriate oversight of remote sensing and monitoring devices.

*AMA Principles of Medical Ethics: I,III,V*

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### *1.2.10 Political Action by Physicians*

Like all Americans, physicians enjoy the right to advocate for change in law and policy, in the public arena, and within their institutions. Indeed, physicians have an ethical responsibility to seek change when they believe the requirements of law or policy are contrary to the best interests of patients. However, they have a responsibility to do so in ways that are not disruptive to patient care.

Physicians who participate in advocacy activities should:

(a) Ensure that the health of patients is not jeopardized and that patient care is not compromised.

(b) Avoid using disruptive means to press for reform. Strikes and other collection actions may reduce access to care, eliminate or delay needed care, and interfere with continuity of care and should not be used as a bargaining tactic. In rare circumstances, briefly limiting personal availability may be appropriate as a means of calling attention to the need for changes in patient care. Physicians should be aware that some actions may put them or their organizations at risk of violating antitrust laws or laws pertaining to medical licensure or malpractice.

(c) Avoid forming workplace alliances, such as unions, with workers who do not share physicians' primary and overriding commitment to patients.

(d) Refrain from using undue influence or pressure colleagues to participate in advocacy activities and should not punish colleagues, overtly or covertly, for deciding not to participate.

*AMA Principles of Medical Ethics: I,III,VI*

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### *1.2.11 Ethically Sound Innovation in Medical Practice*

Innovation in medicine can range from improving an existing intervention, to introducing an innovation in one's own clinical practice for the first time, to using an existing intervention in a novel way or translating knowledge from one clinical context into another. Innovation shares features with both research and patient care, but is distinct from both.

When physicians participate in developing and disseminating innovative practices, they act in accord with professional responsibilities to advance medical knowledge, improve quality of care, and promote the well-being of individual patients and the larger community. Similarly, these responsibilities are honored when physicians enhance their own practices by expanding the range of techniques and interventions they offer to patients.

Individually, physicians who are involved in designing, developing, disseminating, or adopting innovative modalities should:

(a) Innovate on the basis of sound scientific evidence and appropriate clinical expertise.

(b) Seek input from colleagues or other medical professionals in advance or as early as possible in the course of innovation.

(c) Design innovations so as to minimize risks to individual patients and maximize the likelihood of application and benefit for populations of patients.

(d) Be sensitive to the cost implications of innovation.

(e) Be aware of influences that may drive the creation and adoption of innovative practices for reasons other than patient or public benefit.

When they offer existing innovative diagnostic or therapeutic services to individual patients, physicians must:

(f) Base recommendations on patients' medical needs.

(g) Refrain from offering such services until they have acquired appropriate knowledge and skills.

(h) Recognize that in this context informed decision making requires the physician to disclose:

(i) how a recommended diagnostic or therapeutic service differs from the standard therapeutic approach if one exists;

(ii) why the physician is recommending the innovative modality;

(iii) what the known or anticipated risks, benefits, and burdens of the recommended therapy and alternatives are;

(iv) what experience the professional community in general and the physician individually has had to date with the innovative therapy;

(v) what conflicts of interest the physician may have with respect to the recommended therapy.

(i) Discontinue any innovative therapies that are not benefiting the patient.

(j) Be transparent and share findings from their use of innovative therapies with peers in some manner. To promote patient safety and quality, physicians should share both immediate or delayed positive and negative outcomes.

To promote responsible innovation, the medical profession should:

(k) Require that physicians who adopt innovative treatment or diagnostic techniques into their practice have appropriate knowledge and skills.

(l) Provide meaningful professional oversight of innovation in patient care.

(m) Encourage physician-innovators to collect and share information about the resources needed to implement their innovative therapies effectively.

*AMA Principles of Medical Ethics: V,VIII*

### *1.2.12 Ethical Practice in Telemedicine*

Innovation in technology, including information technology, is redefining how people perceive time and distance. It is reshaping how individuals interact with and relate to others, including when, where, and how patients and physicians engage with one another.

Telehealth and telemedicine span a continuum of technologies that offer new ways to deliver care. Yet as in any mode of care, patients need to be able to trust that physicians will place patient welfare above other interests, provide competent care, provide the information patients need to make well-considered decisions about care, respect patient privacy and confidentiality, and take steps to ensure continuity of care. Although physicians' fundamental ethical responsibilities do not change, the continuum of possible patient-physician interactions in telehealth/telemedicine give rise to differing levels of accountability for physicians.

All physicians who participate in telehealth/telemedicine have an ethical responsibility to uphold fundamental fiduciary obligations by disclosing any financial or other interests the physician has in the telehealth/telemedicine application or service and taking steps to manage or eliminate conflicts of interests. Whenever they provide health information, including health content for websites or mobile health applications, physicians must ensure that the information they provide or that is attributed to them is objective and accurate.

Similarly, all physicians who participate in telehealth/telemedicine must assure themselves that telemedicine services have appropriate protocols to prevent unauthorized access and to protect the security and integrity of patient information at the patient end of the electronic encounter, during transmission, and among all health care professionals and other personnel who participate in the telehealth/telemedicine service consistent with their individual roles.

Physicians who respond to individual health queries or provide personalized health advice electronically through a telehealth service in addition should:

(a) Inform users about the limitations of the relationship and services provided.

(b) Advise site users about how to arrange for needed care when follow-up care is indicated.

(c) Encourage users who have primary care physicians to inform their primary physicians about the online health consultation, even if in-person care is not immediately needed.

Physicians who provide clinical services through telehealth/telemedicine must uphold the standards of professionalism expected in in-person interactions, follow appropriate ethical guidelines of relevant specialty societies and adhere to applicable law governing the practice of telemedicine. In the context of telehealth/telemedicine they further should:

(d) Be proficient in the use of the relevant technologies and comfortable interacting with patients and/or surrogates electronically.

(e) Recognize the limitations of the relevant technologies and take appropriate steps to overcome those limitations. Physicians must ensure that they have the information they need to make well-grounded clinical recommendations when they cannot personally conduct a physical examination, such as by having another health care professional at the patient's site conduct the exam or obtaining vital information through remote technologies.

(f) Be prudent in carrying out a diagnostic evaluation or prescribing medication by:

(i) establishing the patient's identity;

(ii) confirming that telehealth/telemedicine services are appropriate for that patient's individual situation and medical needs;

(iii) evaluating the indication, appropriateness and safety of any prescription in keeping with best practice guidelines and any formulary limitations that apply to the electronic interaction; and

(iv) documenting the clinical evaluation and prescription.

(g) When the physician would otherwise be expected to obtain informed consent, tailor the informed consent process to provide information patients (or their surrogates) need about the distinctive features of telehealth/telemedicine, in addition to information about medical issues and treatment options. Patients and surrogates should have a basic understanding of how telemedicine technologies will be used in care, the limitations of those technologies, the credentials of health care professionals involved, and what will be expected of patients for using these technologies.

(h) As in any patient-physician interaction, take steps to promote continuity of care, giving consideration to how information can be preserved and accessible for future episodes of care in keeping with patients' preferences (or the decisions of their surrogates) and how follow-up care can be provided when needed. Physicians should assure themselves how information will be conveyed to the patient's primary care physician when the patient has a primary care physician and to other physicians currently caring for the patient.

Collectively, through their professional organizations and health care institutions, physicians should:

(i) Support ongoing refinement of telehealth/telemedicine technologies, and the development and implementation of clinical and technical standards to ensure the safety and quality of care.

(j) Advocate for policies and initiatives to promote access to telehealth/telemedicine services for all patients who could benefit from receiving care electronically.

(k) Routinely monitor the telehealth/telemedicine landscape to:

(i) identify and address adverse consequences as technologies and activities evolve; and

(ii) identify and encourage dissemination of both positive and negative outcomes.

*AMA Principles of Medical Ethics: I,IV,VI,IX*

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### *1.2.13 Medical Tourism*

Medical tourists travel to address what they deem to be unmet personal medical needs, prompted by issues of cost, timely access to services, higher quality of care or perceived superior services, or to access services that are not available in their country of residence. In many instances, patients travel on their own initiative, with or without consulting their physician, and with or without utilizing the services of commercial medical tourism companies. The care medical tourists seek may be elective procedures, medically necessary standard care, or care that is unapproved or legally or ethically prohibited in their home system.

Many medical tourists receive excellent care, but issues of safety and quality can loom large. Substandard surgical care, poor infection control, inadequate screening of blood products, and falsified or outdated medications in lower income settings of care can pose greater risks than patients would face at home. Medical tourists also face heightened travel-related risks. Patients who develop complications may need extensive follow-up care when they return home. They may pose public health risks to their home communities as well.

Medical tourism can leave home country physicians in problematic positions: Faced with the reality that medical tourists often need follow-up when they return, even if only to monitor the course of an uneventful recovery; confronted with the fact that returning medical tourists often do not have records of the procedures they underwent and the medications they received, or contact information for the foreign health care professionals who provided services, asked to make right what went wrong when patients experience complications as a result of medical travel, often having not been informed about, let alone part of the patient's decision to seek health care abroad.

Physicians need to be aware of the implications of medical tourism for individual patients and the community.

Collectively, through their specialty societies and other professional organizations, physicians should:

(a) Support collection of and access to outcomes data from medical tourists to enhance informed decision making.

(b) Advocate for education for health care professionals about medical tourism.

(c) Advocate for appropriate oversight of medical tourism and companies that facilitate it to protect patient safety and promote high quality care.

(d) Advocate against policies that would require patients to accept care abroad as a condition of access to needed services.

Individually, physicians should:

(e) Be alert to indications that a patient may be contemplating seeking care abroad and explore with the patient the individual's concerns and wishes about care.

(f) Seek to familiarize themselves with issues in medical tourism to enable them to support informed decision making when patients approach them about getting care abroad.

(g) Help patients understand the special nature of risk and limited likelihood of benefit when they desire an unapproved therapy. Physicians should help patients frame realistic goals for care and encourage a plan of care based on scientifically recognized interventions.

(h) Advise patients who inform them in advance of a decision to seek care abroad whether the physician is or is not willing to provide follow-up care for the procedure(s), and refer the patient to other options for care.

(i) Offer their best professional guidance about a patient's decision to become a medical tourist, just as they would any other decision about care. This includes being candid when they deem a decision to obtain specific care abroad not to be in the patient's best interests. Physicians should encourage patients who seek unapproved therapy to enroll in an appropriate clinical trial.

(j) Physicians should respond compassionately when a patient who has undergone treatment abroad without the physician's prior knowledge seeks nonemergent follow-up care. Those who are reluctant to provide such care should carefully consider:

(i) the nature and duration of the patient-physician relationship;

(ii) the likely impact on the individual patient's well-being;

(iii) the burden declining to provide follow-up care may impose on fellow professionals;

(iv) the likely impact on the health and resources of the community.

Physicians who are unable or unwilling to provide care in these circumstances have a responsibility to refer the patient to appropriate services.

*AMA Principles of Medical Ethics: IV,V,VI*

## CHAPTER 2: OPINIONS ON CONSENT, COMMUNICATION & DECISION MAKING

The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.

*2.1 Informed Consent & Shared Decision Making*


2.1.1 Informed Consent
2.1.2 Decisions for Adult Patients Who Lack Capacity
2.1.3 Withholding Information from Patients
2.1.4 Use of Placebo in Clinical Practice
2.1.5 Reporting Clinical Test Results
2.1.6 Substitution of Surgeon


*2.2 Decisions for Minors*


2.2.1 Pediatric Decision Making
2.2.2 Confidential Health Care for Minors
2.2.3 Mandatory Parental Consent to Abortion
2.2.4 Treatment Decisions for Seriously Ill Newborns
2.2.5 Genetic Testing of Children


*2.3 Communication with Patients*


2.3.1 Electronic Communication with Patients
2.3.2 Professionalism in the Use of Social Media
2.3.3 Informing Families of a Patient's Death
2.3.4 Political Communications
2.3.5 Soliciting Charitable Contributions from Patients
2.3.6 Surgical Co-Management


### *2.1.1 Informed Consent*

Informed consent to medical treatment is fundamental in both ethics and law. Patients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care. Successful communication in the patient-physician relationship fosters trust and supports shared decision making.

The process of informed consent occurs when communication between a patient and physician results in the patient's authorization or agreement to undergo a specific medical intervention. In seeking a patient's informed consent (or the consent of the patient's surrogate if the patient lacks decision-making capacity or declines to participate in making decisions), physicians should:

(a) Assess the patient's ability to understand relevant medical information and the implications of treatment alternatives and to make an independent, voluntary decision.

(b) Present relevant information accurately and sensitively, in keeping with the patient's preferences for receiving medical information. The physician should include information about:

(i) the diagnosis (when known);

(ii) the nature and purpose of recommended interventions;

(iii) the burdens, risks, and expected benefits of all options, including forgoing treatment.

(c) Document the informed consent conversation and the patient's (or surrogate's) decision in the medical record in some manner. When the patient/surrogate has provided specific written consent, the consent form should be included in the record.

In emergencies, when a decision must be made urgently, the patient is not able to participate in decision making, and the patient's surrogate is not available, physicians may initiate treatment without prior informed consent. In such situations, the physician should inform the patient/surrogate at the earliest opportunity and obtain consent for ongoing treatment in keeping with these guidelines.

*AMA Principles of Medical Ethics: I,II,V,VIII*

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### *2.1.2 Decisions for Adult Patients Who Lack Capacity*

Respect for patient autonomy is central to professional ethics and physicians should involve patients in health care decisions commensurate with the patient's decision-making capacity. Even when a medical condition or disorder impairs a patient's decision-making capacity, the patient may still be able to participate in some aspects of decision making. Physicians should engage patients whose capacity is impaired in decisions involving their own care to the greatest extent possible, including when the patient has previously designated a surrogate to make decisions on his or her behalf.

When a patient lacks decision-making capacity, the physician has an ethical responsibility to:

(a) Identify an appropriate surrogate to make decisions on the patient's behalf:

(i) the person the patient designated as surrogate through a durable power of attorney for health care or other mechanism; or

(ii) a family member or other intimate associate, in keeping with applicable law and policy if the patient has not previously designated a surrogate.

(b) Recognize that the patient's surrogate is entitled to the same respect as the patient.

(c) Provide advice, guidance, and support to the surrogate.

(d) Assist the surrogate to make decisions in keeping with the standard of substituted judgment, basing decisions on:

(i) the patient's preferences (if any) as expressed in an advance directive or as documented in the medical record;

(ii) the patient's views about life and how it should be lived;

(iii) how the patient constructed his or her life story; and

(iv) the patient's attitudes toward sickness, suffering, and certain medical procedures.

(e) Assist the surrogate to make decisions in keeping with the best interest standard when the patient's preferences and values are not known and cannot reasonably be inferred, such as when the patient has not previously expressed preferences or has never had decision-making capacity. Best interest decisions should be based on:

(i) the pain and suffering associated with the intervention;

(ii) the degree of and potential for benefit;

(iii) impairments that may result from the intervention;

(iv) quality of life as experienced by the patient.

(f) Consult an ethics committee or other institutional resource when:

(i) no surrogate is available or there is ongoing disagreement about who is the appropriate surrogate;

(ii) ongoing disagreement about a treatment decision cannot be resolved; or

(iii) the physician judges that the surrogate's decision:

a. is clearly not what the patient would have decided when the patient's preferences are known or can be inferred;

b. could not reasonably be judged to be in the patient's best interest; or

c. primarily serves the interests of the surrogate or other third party rather than the patient.

*AMA Principles of Medical Ethics: I,III,VIII*

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### *2.1.3 Withholding Information from Patients*

Truthful and open communication between physician and patient is essential for trust in the relationship and for respect for autonomy. Withholding pertinent medical information from patients in the belief that disclosure is medically contraindicated creates a conflict between the physician's obligations to promote patient welfare and to respect patient autonomy.

Except in emergency situations in which a patient is incapable of making an informed decision, withholding information without the patient's knowledge or consent is ethically unacceptable. When information has been withheld in such circumstances, physicians' should convey that information once the emergency situation has been resolved, in keeping with relevant guidelines below.

The obligation to communicate truthfully about the patient's medical condition does not mean that the physician must communicate information to the patient immediately or all at once. Information may be conveyed over time in keeping with the patient's preferences and ability to comprehend the information. Physicians should always communicate sensitively and respectfully with patients.

With respect to disclosing or withholding information, physicians should:

(a) Encourage the patient to specify preferences regarding communication of medical information, preferably before the information becomes available.

(b) Honor a patient's request not to receive certain medical information or to convey the information to a designated surrogate, provided these requests appear to represent the patient's genuine wishes.

(c) Assess the amount of information the patient is capable of receiving at a given time, and tailor disclosure to meet the patient's needs and expectations in keeping with the individual's preferences.

(d) Consult with the patient's family, the physician's colleagues, or an ethics committee or other institutional resource for help in assessing the relative benefits and harms associated with delaying disclosure.

(e) Monitor the patient carefully and offer full disclosure when the patient is able to decide whether to receive the information. This should be done according to a definite plan, so that disclosure is not permanently delayed.

(f) Disclose medical errors if they have occurred in the patient's care, in keeping with ethics guidance.

*AMA Principles of Medical Ethics: I,III,V,VIII*

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### *2.1.4 Use of Placebo in Clinical Practice*

A placebo is a substance provided to a patient that the physician believes has no specific pharmacological effect on the condition being treated. The use of placebo, when consistent with good medical care, is distinct from interventions that lack scientific foundation.

A placebo may still be effective if the patient knows it will be used but cannot identify it and does not know the precise timing of its use. In the clinical setting, the use of a placebo without the patient's knowledge may undermine trust, compromise the patient-physician relationship, and result in medical harm to the patient.

Physicians may use placebos for diagnosis or treatment only if they:

(a) Enlist the patient's cooperation. The physician should explain that it can be possible to achieve a better understanding of the medical condition by evaluating the effects of different medications, including the placebo.

(b) Obtain the patient's general consent to administer a placebo. The physician does not need to identify precisely when the placebo will be administered. In this way, the physician respects the patient autonomy and fosters a trusting relationship, while the patient may still benefit from the placebo effect.

(c) Avoid giving a placebo merely to mollify a difficult patient. Giving a placebo for such reasons places the convenience of the physician above the welfare of the patient. Physicians can produce a placebo-like effect through the skillful use of reassurance and encouragement, thereby building respect and trust, promoting the patient-physician relationship, and improving health outcomes.

*AMA Principles of Medical Ethics: I,III,V,VIII*

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### *2.1.5 Reporting Clinical Test Results*

Patients should be able to be confident that they will receive the results of clinical tests in a timely fashion. Physicians have a corresponding obligation to be considerate of patient concerns and anxieties and ensure that patients receive test results within a reasonable time frame.

When and how clinical test results are conveyed to patients can vary considerably in different practice environments and for different clinical tests. In some instances results are conveyed by the patient's treating physician, in others by other practice staff, or directly by the laboratory or other entity.

To ensure that test results are communicated appropriately to patients, physicians should adopt, or advocate for, policies and procedures to ensure that:

(a) The patient (or surrogate decision maker if the patient lacks decision-making capacity) is informed about when he or she can reasonably expect to learn the results of clinical tests and how those results will be conveyed.

(b) The patient/surrogate is instructed what to do if he or she does not receive results in the expected time frame.

(c) Test results are conveyed sensitively, in a way that is understandable to the patient/surrogate, and the patient/surrogate receives information needed to make well-considered decisions about medical treatment and give informed consent to future treatment.

(d) Patient confidentiality is protected regardless of how clinical test results are conveyed.

(e) The ordering physician is notified before the disclosure takes place and has access to the results as they will be conveyed to the patient/surrogate, if results are to be conveyed directly to the patient/surrogate by a third party.

*AMA Principles of Medical Ethics: II,IV,V*

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### *2.1.6 Substitution of Surgeon*

Patients are entitled to choose their own physicians, which includes being permitted to accept or refuse having an intervention performed by a substitute. A surgeon who allows a substitute to conduct a medical procedure on his or her patient without the patient's knowledge or consent risks compromising the trust-based relationship of patient and physician.

When one or more other appropriately trained health care professionals will participate in performing a surgical intervention, the surgeon has an ethical responsibility to:

(a) Notify the patient (or surrogate if the patient lacks decision-making capacity) that others will participate, including whether they will do so under the physician's personal supervision or not.

(b) Obtain the patient's or surrogate's informed consent for the intervention, in keeping with ethical and legal guidelines.

*AMA Principles of Medical Ethics: I,II,IV,V*

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### *2.2.1 Pediatric Decision Making*

As the persons best positioned to understand their child's unique needs and interests, parents (or guardians) are asked to fill the dual responsibility of protecting their children and, at the same time, empowering them and promoting development of children's capacity to become independent decision makers. In giving or withholding permission for medical treatment for their

children, parents/guardians are expected to safeguard their children's physical health and well-being and to nurture their children's developing personhood and autonomy.

But parents' authority as decision makers does not mean children should have no role in the decision-making process. Respect and shared decision making remain important in the context of decisions for minors. Thus, physicians should evaluate minor patients to determine if they can understand the risks and benefits of proposed treatment and tailor disclosure accordingly. The more mature a minor patient is, the better able to understand what a decision will mean, and the more clearly the child can communicate preferences, the stronger the ethical obligation to seek minor patients' assent to treatment. Except when immediate intervention is essential to preserve life or avert serious, irreversible harm, physicians and parents/guardians should respect a child's refusal to assent, and when circumstances permit should explore the child's reason for dissent.

For health care decisions involving minor patients, physicians should:

(a) Develop an individualized plan of care that will best serve the patient, basing treatment recommendations on the best available evidence and in general preferring alternatives that will not foreclose important future choices by the adolescent and adult the patient will become. Where there are questions about the efficacy or long-term impact of treatment alternatives, physicians should encourage ongoing collection of data to help clarify value to patients of different approaches to care.

(b) Work with parents/guardians to simplify complex treatment regimens whenever possible and educate parents/guardians in ways to avoid behaviors that will put the child or others at risk.

(c) Provide a supportive environment and encourage parents/guardians to discuss the child's health status with the patient, offering to facilitate the parent-child conversation for reluctant parents. Physicians should offer education and support to minimize the psychosocial impact of socially or culturally sensitive care, including putting the patient and parents/guardians in contact with others who have dealt with similar decisions and have volunteered their support as peers.

(d) When decisions involve life-sustaining treatment for a terminally ill child, ensure that patients have an opportunity to be involved in decision making in keeping with their ability to understand decisions and their desire to participate. Physicians should ensure that the patient and parents/guardians understand the prognosis (with and without treatment). They should discuss the option of initiating therapy with the intention of evaluating its clinical effectiveness for the patient after a specified time to determine whether it has led to improvement and confirm that if the intervention has not achieved agreed-on goals it may be discontinued.

(g) When it is not clear whether a specific intervention promotes the patient's interests, respect the decision of the patient (if the patient has capacity and is able to express a preference) and parents/guardians.

(h) When there is ongoing disagreement about patient's best interest or treatment recommendations, seek consultation with an ethics committee or other institutional resource.

### *2.2.2 Confidential Health Care for Minors*

Physicians who treat minors have an ethical duty to promote the developing autonomy of minor patients by involving children in making decisions about their health care to a degree commensurate with the child's abilities. A minor's decision-making capacity depends on many factors, including not only chronological age, but also emotional maturity and the individual's medical experience. Physicians also have a responsibility to protect the confidentiality of minor patients, within certain limits.

In some jurisdictions, the law permits minors who are not emancipated to request and receive confidential services relating to contraception, or to pregnancy testing, prenatal care, and delivery services. Similarly, jurisdictions may permit unemancipated minors to request and receive confidential care to prevent, diagnose, or treat sexually transmitted disease, substance use disorders, or mental illness.

When an unemancipated minor requests confidential care and the law does not grant the minor decision-making authority for that care, physicians should:

(a) Inform the patient (and parent or guardian, if present) about circumstances in which the physician is obligated to inform the minor's parent/guardian, including situations when:

    (i) involving the patient's parent/guardian is necessary to avert life- or health- threatening harm to the patient;

    (ii) involving the patient's parent/guardian is necessary to avert serious harm to others;

    (iii) the threat to the patient's health is significant and the physician has no reason to believe that parental involvement will be detrimental to the patient's well- being.

(b) Explore the minor patient's reasons for not involving his or her parents (or guardian) and try to correct misconceptions that may be motivating the patient's reluctance to involve parents.

(c) Encourage the minor patient to involve his or her parents and offer to facilitate conversation between the patient and the parents.

(d) Inform the patient that despite the physician's respect for confidentiality the minor patient's parents/guardians may learn about the request for treatment or testing through other means (e.g., insurance statements).

(e) Protect the confidentiality of information disclosed by the patient during an exam or interview or in counseling unless the patient consents to disclosure or disclosure is required to protect the interests of others, in keeping with ethical and legal guidelines.

(f) Take steps to facilitate a minor patient's decision about health care services when the patient remains unwilling to involve parents or guardians, so long as the patient has appropriate decision-making capacity in the specific circumstances and the physician believes the decision is in the patient's best interest. Physicians should be aware that states provide mechanisms for unemancipated minors to receive care without parental involvement under conditions that vary from state to state.

(g) Consult experts when the patient's decision-making capacity is uncertain.

(h) Inform or refer the patient to alternative confidential services when available if the physician is unwilling to provide services without parental involvement.

*AMA Principles of Medical Ethics: IV*

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### *2.2.3 Mandatory Parental Consent to Abortion*

In many jurisdictions, unemancipated minors are not permitted to request or receive abortion services without their parents' knowledge and consent. Physicians should ascertain the law in their state on parental involvement to ensure that their practices are consistent with their legal obligations. In many places, the issue of confidentiality for minors who seek an abortion implicates competing ethical concerns apart from the abortion issue itself.

When an unemancipated minor requests abortion services, physicians should:

(a) Strongly encourage the patient to discuss the pregnancy with her parents (or guardian).

(b) Explore the minor patient's reasons for not involving her parents (or guardian) and try to correct misconceptions that may be motivating the patient's reluctance to involve parents. If the patient is unwilling to involve her parents, encourage her to seek the advice and counsel of adults in whom she has confidence, including professional counselors, relatives, friends, teachers, or the clergy.

(c) Explain to the minor patient under what circumstances the minor's confidentiality will be abrogated, including:

  (i) life-threatening emergency; or

  (ii) when parental notification is required by applicable law.

(d) Try to ensure that the minor patient carefully considers the issues involved and makes an informed decision.

(e) Not feel or be compelled to require a minor patient to involve her parents before she decides whether to undergo an abortion.

*AMA Principles of Medical Ethics: III,IV*

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### *2.2.4 Treatment Decisions for Seriously Ill Newborns*

Making treatment decisions for seriously ill newborns is emotionally and ethically challenging for both parents and health care professionals. Decisions must take into account the newborn's medical needs; the interests, needs, and resources of the family; and available treatment options. Decision makers must also assess whether the choice made for the newborn will abrogate a choice the future individual would want to make for him- or herself, i.e., whether the choice will undermine the child's right to an "open future." Providing information and other resources to support parents or guardians when they must make decisions about their child's care and future is a key responsibility for physicians and other health care professionals.

Decisions not to initiate care or to discontinue an intervention can be emotionally wrenching in any circumstance, but may be particularly so for a seriously ill newborn. Physicians are in a position to help

parents, families, and fellow professionals understand that there is no ethical difference between withholding and withdrawing treatment—when an intervention no longer helps to achieve the goals of care or promote the quality of life desired for the patient, it is ethically appropriate to withdraw it.

To help parents formulate goals for their newborn's care and make decisions about life-sustaining treatment on their child's behalf, physicians should:

(a) Inform the parents about available therapeutic options, the nature of available interventions, and their child's expected prognosis with and without treatment.

(b) Help the parents formulate goals for care that will promote their child's best interests in light of:

    (i) the chance that the intervention will achieve the intended clinical benefit;

    (ii) the risks involved with treatment and nontreatment;

    (iii) the degree to which treatment can be expected to extend life;

    (iv) the pain and discomfort associated with the intervention; and

    (v) the quality of life the child can be expected to have with and without treatment.

(c) Discuss the option of initiating an intervention with the intention of evaluating its clinical effectiveness after a given amount of time to determine whether the intervention has led to improvement. Confirm that if the intervention has not achieved agreed-on goals, it may be withdrawn. Physicians should recognize, and help parents appreciate, that it is not necessary to have prognostic certainty to withdraw life-sustaining treatment, since prognostic certainty is often unattainable and may unnecessarily prolong the infant's suffering.

(d) Initiate life-sustaining and life-enhancing treatment when the child's prognosis is largely uncertain.

(e) Adhere to good clinical practice for palliative care when life-sustaining treatment is withheld or withdrawn.

(f) Provide access to counseling services or other resources to facilitate decision making and to enable parents opportunity to talk with others who have had to make similar decisions.

(g) Seek consultation through an ethics committee or other institutional resource when disagreement about the appropriate course of action persists.

*AMA Principles of Medical Ethics: I,III,IV,V*

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### *2.2.5 Genetic Testing of Children*

In genetics, the ability to diagnose disease or identify predisposition to disease often precedes the ability to prevent, treat, or ameliorate the condition in question. Genetic diagnosis can carry both benefits and risks for the patient, as well as implications for others to whom the patient is biologically related. Thus, decisions to carry out genetic testing can be challenging for any patient.

Genetic testing of children implicates important concerns about the minor patient's present and future autonomy and best interests. Decisions to test must balance multiple considerations, including likely benefits, the risks of knowing genetic status (including abrogating the child's opportunity to make the

choice about knowing genetic status him- or herself as an adult), features unique to the condition(s) being tested for (such as age of onset), and the availability of effective preventive, therapeutic, or palliative interventions.

With respect to genetic testing of a minor patient, including genetic testing of children being considered for adoption, physicians should:

(a) Offer diagnostic testing when the child is at risk for a condition for which effective measures to prevent, treat, or ameliorate it are available. As for any medical intervention, the physician should seek the informed consent of the minor patient's parents (or guardian) and engage the patient in decision making at a developmentally appropriate level, in keeping with ethics guidance.

(b) In general, respect the decision of the patient's parents/guardian about testing when the child is at risk for a condition with pediatric onset for which no effective measures to prevent, treat, or ameliorate the condition are available.

(c) Attempt to persuade reluctant parents/guardians to consent to testing when there are effective measures to prevent, treat, or ameliorate the condition and, in the physician's judgment, delaying testing would result in irreversible harm to the child.

(d) Regardless of the source of the testing, help the patient /parent/guardian access appropriate counseling.

(e) Refrain from offering, providing, or recommending a genetic test:

    (i) when parents/guardians request testing for a child who is at risk for a condition with adult onset for which no effective measures to prevent, treat, or ameliorate the condition are available. Physicians should inform the parents/guardian about the test and why it is not recommended. When a minor patient seeks genetic testing for such a condition, physicians should condition testing on the patient's developmental status and ability to understand the implications of testing, in keeping with ethics guidance on decisions for minor patients;

    (ii) when parents/guardians request testing to determine the child's carrier status for a recessive genetic condition and there are no other health implications for the child. Physicians may provide testing when reproductive decisions need to be made on behalf of or by a minor patient, in keeping with ethics guidance;

    (iii) for the benefit of a family member, unless testing will prevent substantial harm to the individual;

    (iv) when testing will not serve the child's health interests.

(f) Seek consultation from an ethics committee or other institutional resource when disagreements about genetic testing persist. If parents unreasonably request or refuse testing of their child, the physician should take steps to change or, if necessary, use legal means to override the parents' choice.

(g) Encourage parents to share genetic information with the child in a manner appropriate to the child's stage of development.

(h) Ensure that parents/guardians are aware of findings that are not immediately relevant but will need to be shared later so that the information can be conveyed to the child when it becomes relevant.

### *2.3.1 Electronic Communication with Patients*

Electronic communication, such as email or text messaging, can be a useful tool in the practice of medicine and can facilitate communication within a patient-physician relationship. However, these channels can raise special concerns about privacy and confidentiality, particularly when sensitive information is to be communicated. When physicians engage in electronic communication they hold the same ethical responsibilities to patients as they do during other clinical encounters. Any method of communication, virtual, telephonic, or in person, should be appropriate to the patient's clinical need and to the information being conveyed.

Email correspondence should not be used to establish a patient-physician relationship. Rather email should supplement other, more personal encounters.

Physicians who choose to communicate electronically with patients should:

(a) Uphold professional standards of confidentiality and protection of privacy, security, and integrity of patient information.

(b) Notify the patient of the inherent limitations of electronic communication, including possible breach of privacy or confidentiality, difficulty in validating the identity of the parties, and possible delays in response. Such disclaimers do not absolve physicians of responsibility to protect the patient's interests. Patients should have the opportunity to accept or decline electronic communication before privileged information is transmitted. The patient's decision to accept or decline email communication containing privileged information should be documented in the medical record.

(c) Advise the patient of the limitations of these channels when a patient initiates electronic communication.

(d) Obtain the patient's consent to continue electronic communication when a patient initiates electronic communication.

(e) Present medical information in a manner that meets professional standards. Diagnostic or therapeutic services must conform to accepted clinical standards.

(f) Be aware of relevant laws that determine when a patient-physician relationship has been established.

*AMA Principles of Medical Ethics: I,IV,VI,VII*

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### *2.3.2 Professionalism in the Use of Social Media*

The Internet has created the ability for medical students and physicians to communicate and share information quickly and to reach millions of people easily. Participating in social networking and other similar Internet opportunities can support physicians' personal expression, enable individual physicians to have a professional presence online, foster collegiality and camaraderie within the profession, and provide opportunity to widely disseminate public health messages and other health communications. Social networks, blogs, and other forms of communication online also create new challenges to the patient-physician relationship.

Physicians and trainees have an ethical responsibility to weigh a number of considerations when maintaining a presence online:

(a) They should be cognizant of standards of patient privacy and confidentiality that must be maintained in all environments, including online, and must refrain from posting identifiable patient information online.

(b) When using social media for educational purposes or to exchange information professionally with other physicians, follow ethics guidance regarding confidentiality, privacy and informed consent.

(c) When using the Internet for social networking, they should use privacy settings to safeguard personal information and content to the extent possible but should realize that privacy settings are not absolute and that once on the Internet, content is likely there permanently. Thus, physicians should routinely monitor their own Internet presence to ensure that the personal and professional information on their own sites and, to the extent possible, content posted about them by others, is accurate and appropriate.

(d) If they interact with patients on the Internet, they must maintain appropriate boundaries of the patient-physician relationship in accordance with professional ethics guidance, just as they would in any other context.

(e) To maintain appropriate professional boundaries, they should consider separating personal and professional content online.

(f) When they see content posted by colleagues that appears unprofessional they have a responsibility to bring that content to the attention of the individual, so that he or she can remove it and/or take other appropriate actions. If the behavior significantly violates professional norms and the individual does not take appropriate action to resolve the situation, the physician should report the matter to appropriate authorities.

(g) They must recognize that actions online and content posted may negatively affect their reputations among patients and colleagues, may have consequences for their medical careers (particularly for physicians-in-training and medical students), and can undermine public trust in the medical profession.

*AMA Principles of Medical Ethics: I,II,IV*

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### *2.3.3 Informing Families of a Patient's Death*

Informing a patient's family that the patient has died is a duty that is fundamental to the patient-physician relationship. When communicating this event, physicians should give foremost attention to the family's emotional needs and the integrity of the patient-physician relationship.

The following guidelines apply to communicating news of a patient's death:

(a) Any physician informing a patient's family about the patient's death has a responsibility to:

  (i) communicate this information compassionately;

  (ii) disclose the death in a timely manner.

(b) Ordinarily, the treating physician should take responsibility for informing the family. However, it may be appropriate to delegate the task of informing the family to another physician if the other

physician has a previous close personal relationship with the patient or family and the appropriate skill.

(c) Medical students should not be asked to inform family members of a patient's death. Medical students should be trained in communication skills relating to death and dying, and should be encouraged to accompany attending physicians when news of a patient's death is conveyed to family members.

*AMA Principles of Medical Ethics: I,IV*

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### *2.3.4 Political Communications*

Physicians enjoy the rights and privileges of free speech shared by all Americans. It is laudable for physicians to run for political office; to lobby for political positions, parties, or candidates; and in every other way to exercise the full scope of their political rights as citizens. Physicians may exercise these rights individually or through involvement with professional societies and political action committees or other organizations.

When physicians wish to express their personal political views to a patient or a patient's family, the physician must be sensitive to the imbalance of power in the patient- physician relationship, as well as to the patient's vulnerability and desire for privacy. Physicians should refrain from initiating political conversations during the clinical encounter.

Physicians must not allow differences with the patient or family about political matters to interfere with the delivery of professional care.

When expressing political views to a patient or a patient's family, physicians should:

(a) Judge both the intrusiveness of the discussion and the patient's level of comfort before initiating such a discussion.

(b) Discuss political matters only in contexts where conversation with the patient or family about social, civic, or recreational matters is acceptable.

(c) Refrain from conversation about political matters when the patient or family is emotionally pressured by significant medical circumstances.

(d) Work towards and advocate for the reform and proper administration of laws related to health care. Physicians should stay well informed of current political questions regarding needed and proposed reforms.

(e) Stay well informed about needed or proposed policies concerning health care access and quality, medical research, and promoting public health so as to be able to advocate for patients' needs.

*AMA Principles of Medical Ethics: I,VII*

### *2.3.5 Soliciting Charitable Contributions from Patients*

Charitable contributions play an important role in supporting and improving a community's health, and physicians are encouraged to participate in fundraising and other solicitation activities.

To sustain the trust that is the foundation of the patient-physician relationship and to reassure patients that their welfare is the physician's primary priority, physicians who participate in fundraising should:

(a) Assure patients that they need not contribute in order to continue receiving quality care.

(b) Refrain from directly soliciting contributions from their own patients, especially during clinical encounters.

(c) Solicit contributions by making information available, for example, in their office reception areas or by speaking at fundraising events.

(d) Protect patient privacy and confidentiality by not acknowledging that a patient is under the physician's care when approached by fundraising personnel without the prior consent of the patient.

(e) Obtain permission from the patient before releasing information for purposes of fundraising when the nature of the physician's practice could make it possible to identify the medical services provided or the patient's diagnosis.

(f) Refer patients or families who wish to make charitable contributions to appropriate information or fundraising personnel.

(g) Be sensitive to the likelihood that they may be perceived to be acting in their professional role when participating in fundraising activities as a member of the general community.

*AMA Principles of Medical Ethics: IV,VII,VIII*

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### *2.3.6 Surgical Co-Management*

Surgical co-management refers to the practice of allotting specific responsibilities of patient care to designated clinicians. Such arrangements should be made only to ensure the highest quality of care.

When engaging in this practice, physicians should:

(a) Allocate responsibilities among physicians and other clinicians according to each individual's expertise and qualifications.

(b) Work with the patient and family to designate one physician to be responsible for ensuring that care is delivered in a coordinated and appropriate manner.

(c) Participate in the provision of care by communicating with the coordinating physician and encouraging other members of the care team to do the same.

(d) Obtain patient consent for the surgical co-management arrangement of care, including disclosing significant aspects of the arrangement such as qualifications of clinicians, services each clinician will provide, and billing arrangement.

(e) Obtain informed consent for medical services in keeping with ethics guidance, including provision of all relevant medical facts.

(f) Employ appropriate safeguards to protect patient confidentiality.

(g) Ensure that surgical co-management arrangements are in keeping with ethical and legal restrictions.

(h) Engage another caregiver based on that caregiver's skill and ability to meet the patient's needs, not in the expectation of reciprocal referrals or other self-serving reasons, in keeping with ethics guidance on consultation and referrals.

(i) Refrain from participating in unethical or illegal financial agreements, such as fee-splitting.

*AMA Principles of Medical Ethics: I,II,IV,V,VI*

## CHAPTER 3: OPINIONS ON PRIVACY, CONFIDENTIALITY & MEDICAL RECORDS

The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.

*3.1 Privacy*


3.1.1 Privacy in Health Care
3.1.2 Patient Privacy & Outside Observers to the Clinical Encounter
3.1.3 Audio or Visual Recording of Patients for Education in Health Care
3.1.4 Audio or Visual Recording of Patients for Public Education
3.1.5 Professionalism in Relationships with Media


*3.2 Confidentiality*


3.2.1 Confidentiality
3.2.2 Confidentiality Post Mortem
3.2.3 Industry-Employed Physicians & Independent Medical Examiners
3.2.4 Access to Medical Records by Data Collection Companies


*3.3 Medical Records*


3.3.1 Management of Medical Records
3.3.2 Confidentiality & Electronic Medical Records
3.3.3 Breach of Security in Electronic Medical Records


### *3.1.1 Privacy in Health Care*

Protecting information gathered in association with the care of the patient is a core value in health care. However, respecting patient privacy in other forms is also fundamental, as an expression of respect for patient autonomy and a prerequisite for trust.

Patient privacy encompasses a number of aspects, including personal space (physical privacy), personal data (informational privacy), personal choices including cultural and religious affiliations (decisional privacy), and personal relationships with family members and other intimates (associational privacy).

Physicians must seek to protect patient privacy in all settings to the greatest extent possible and should:

(a) Minimize intrusion on privacy when the patient's privacy must be balanced against other factors.

(b) Inform the patient when there has been a significant infringement on privacy of which the patient would otherwise not be aware.

(c) Be mindful that individual patients may have special concerns about privacy in any or all of these areas.

*AMA Principles of Medical Ethics: I,IV*

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### *3.1.2 Patient Privacy & Outside Observers to the Clinical Encounter*

Individuals legitimately present during patient-physician encounters include those directly involved in the patient's care, and can include other members of the health care team or employees of pharmaceutical or

medical device companies when they are present to provide technical assistance, in keeping with ethics guidance.

When individuals who are not involved in providing care seek to observe patient-physician encounters, e.g., for educational purposes, physicians should safeguard patient privacy by permitting such observers to be present during a clinical encounter only when:

(a) The patient has explicitly agreed to the presence of the observer(s). Outside observers should not be permitted when the patient lacks decision-making capacity, except in rare circumstances and with the consent of the parent, legal guardian, or authorized decision maker.

(b) The presence of the observer will not compromise care.

(c) The observer understands and has agreed to adhere to standards of medical privacy and confidentiality.

Under no circumstances should physicians accept payment from outside observers to allow those observers to be present during a clinical encounter.

*AMA Principles of Medical Ethics: I,IV,VIII*

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### *3.1.3 Audio or Visual Recording Patients for Education in Health Care*

Audio or visual recording of patients can be a valuable tool for educating health care professionals, but physicians must balance educational goals with patient privacy and confidentiality. The intended audience is bound by professional standards of respect for patient autonomy, privacy, and confidentiality, but physicians also have an obligation to ensure that content is accurate and complete and that the process and product of recording uphold standards of professional conduct.

To safeguard patient interests in the context of recording for purposes of educating health care professionals, physicians should:

(a) Ensure that all nonclinical personnel present during recording understand and agree to adhere to medical standards of privacy and confidentiality.

(b) Restrict participation to patients who have decision-making capacity. Recording should not be permitted when the patient lacks decision-making capacity except in rare circumstances and with the consent of the parent, legal guardian, or authorized decision maker.

(c) Inform the patient (or authorized decision maker, in the rare circumstances when recording is authorized for minors or patients who lack decision-making capacity):

  (i) about the purpose of recording, the intended audience(s), and the expected distribution;

  (ii) about the potential benefits and harms (such as breach of privacy or confidentiality) of participating;

  (iii) that participation is voluntary and that a decision not to participate (or to withdraw) will not affect the patient's care;

  (iv) that the patient may withdraw consent at any time and if so, what will be done with the recording;

(v) that use of the recording will be limited to those involved in health care education, unless the patient specifically permits use by others.

(d) Ensure that the patient has had opportunity to discuss concerns before and after recording.

(e) Obtain consent from a patient (or the authorized decision maker):

(i) prior to recording whenever possible; or

(ii) before use for educational purposes when consent could not be obtained prior to recording.

(f) Respect the decision of a patient to withdraw consent.

(g) Seek assent from the patient for participation in addition to consent by the patient's parent or guardian when participation by a minor patient is unavoidable.

(h) Be aware that the act of recording may affect patient behavior during a clinical encounter and thereby affect the film's educational content and value.

(i) Be aware that the information contained in educational recordings should be held to the same protections as any other record of patient information. Recordings should be securely stored and properly destroyed, in keeping with ethics guidance for managing medical records.

(j) Be aware that recording creates a permanent record of personal patient information and may be considered part of the medical record and subject to laws governing medical records.

*AMA Principles of Medical Ethics: I,IV,V,VIII*

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### *3.1.4 Audio or Visual Recording of Patients for Public Education*

Audio and/or visual recording of patient care for public broadcast is one way to help educate the public about health care. However, no matter what medium is used, such recording poses challenges for protecting patient autonomy, privacy, and confidentiality. Filming cannot benefit a patient medically and may cause harm. As advocates for their patients, physicians have an obligation to protect patient interests and ensure that professional standards are upheld. Physicians also have a responsibility to ensure that information conveyed to the public is complete and accurate (including the risks, benefits, and alternatives of treatments).

Physicians involved in recording patients for public broadcast should:

(a) Participate in institutional review of requests to record patient interactions.

(b) Require that persons present for recording purposes who are not members of the health care team:

(i) minimize third-party exposure to the patient's care; and

(ii) adhere to medical standards of privacy and confidentiality.

(c) Encourage recording personnel to engage medical specialty societies or other sources of independent expert review in assessing the accuracy of the product.

(d) Refuse to participate in programs that foster misperceptions or are otherwise misleading.

(e) Restrict participation to patients who have decision-making capacity. Recording should not be permitted when the patient lacks decision-making capacity except in rare circumstances and with the consent of the parent, legal guardian, or authorized decision maker.

(f) Inform a patient (or authorized decision maker) who is to be recorded:

(i) about the purpose for which patient encounters with physicians or other health care professionals will be recorded;

(ii) about the intended audience(s);

(iii) that the patient may withdraw consent at any time prior to recording and up to an agreed on time before the completed recording is publicly broadcast, and if so, what will be done with the recording;

(iv) that at any time the patient has the right to have recording stopped and recording personnel removed from the area;

(v) whether the patient will be allowed to review the recording before broadcast and the degree to which the patient may edit the final product; and

(vi) whether the physician was compensated for his participation and the terms of that compensation.

(g) Ensure that the patient has had the opportunity to address concerns before and after recording.

(h) Ensure that the patient's consent is obtained by a disinterested third party not involved with the production team to avoid potential conflict of interest.

(i) Request that recording be stopped and recording personnel removed if the physician (or other person involved in the patient's care) perceives that recording may jeopardize patient care.

(j) Ensure that the care they provide and the advice they give to patients regarding participation in recording is not influenced by potential financial gain or promotional benefit to themselves, their patients, or the health care institution.

(k) Remind patients and colleagues that recording creates a permanent record and may in some instances be considered part of the medical record.

*AMA Principles of Medical Ethics: I,IV,VII,VIII*

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### *3.1.5 Professionalism in Relationships with Media*

Ensuring that the public is informed promptly and accurately about medical issues is a valuable objective. However, media requests for information about patients can pose concerns about patient privacy and confidentiality, among other issues.

Physicians who speak on health-related matters on behalf of organizations should be aware of to institutional guidelines for communicating with media, where they exist. To safeguard patient interests when working with representative of the media, all physicians should:

(a) Obtain consent from the patient or the patient's authorized representative before releasing information.

(b) Release only information specifically authorized by the patient or patient's representative or that is part of the public record.

(c) Ensure that no statement regarding diagnosis or prognosis is made except by or on behalf of the attending physician.

(d) Refer any questions regarding criminal activities or other police matters to the proper authorities.

*AMA Principles of Medical Ethics: IV*

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### *3.2.1 Confidentiality*

Patients need to be able to trust that physicians will protect information shared in confidence. They should feel free to fully disclose sensitive personal information to enable their physician to most effectively provide needed services. Physicians in turn have an ethical obligation to preserve the confidentiality of information gathered in association with the care of the patient.

In general, patients are entitled to decide whether and to whom their personal health information is disclosed. However, specific consent is not required in all situations.

When disclosing patients' personal health information, physicians should:

(a) Restrict disclosure to the minimum necessary information; and

(b) Notify the patient of the disclosure, when feasible.

Physicians may disclose personal health information without the specific consent of the patient (or authorized surrogate when the patient lacks decision-making capacity):

(c) To other health care personnel for purposes of providing care or for health care operations; or

(d) To appropriate authorities when disclosure is required by law.

(e) To other third parties situated to mitigate the threat when in the physician's judgment there is a reasonable probability that:

  (i) the patient will seriously harm him/herself; or

  (ii) the patient will inflict serious physical harm on an identifiable individual or individuals.

For any other disclosures, physicians should obtain the consent of the patient (or authorized surrogate) before disclosing personal health information.

*AMA Principles of Medical Ethics: III,IV,VII,VIII*

### *3.2.2 Confidentiality Post Mortem*

In general, patients are entitled to the same respect for the confidentiality of their personal information after death as they were in life. Physicians have a corresponding obligation to protect patient information, including information obtained post mortem. However, the obligation to safeguard confidentiality post mortem is subject to certain exceptions that are ethically and legally justifiable because of overriding societal concerns.

Physicians may disclose autopsy results to the surrogate or other decision maker who gave consent for the procedure.

Otherwise, physicians may disclose a deceased patient's personal health information only:

(a) In accord with the patient's explicit prior consent or directive. Physicians should respect the individual's specific preferences regarding disclosure; or

(b) When required by law; or

(c) When in the physician's judgment disclosure will avert harm to, or benefit, identifiable individuals or the community; or

(d) For purposes of medical research or education if personal identifiers have been removed.

In all circumstances, physicians should:

(e) Consider the effect disclosure is likely to have on the patient's reputation.

(f) Restrict disclosure to the minimum necessary information.

When disclosing a deceased patient's health information would result in personal gain for the physician (financial or otherwise), the physician must seek specific consent to the disclosure from the patient's authorized decision maker.

*AMA Principles of Medical Ethics: IV*

### *3.2.3 Industry-Employed Physicians & Independent Medical Examiners*

Physicians may obtain personal information about patients outside an ongoing patient-physician relationship. For example, physicians may assess an individual's health or disability on behalf of an employer, insurer, or other third party. Or they may obtain information in providing care specifically for a work-related illness or injury. In all these situations, physicians have a responsibility to protect the confidentiality of patient information.

When conducting third-party assessments or treating work-related medical conditions, physicians may disclose information to a third party:

(a) With written or documented consent of the individual (or authorized surrogate); or

(b) As required by law, including workmen's compensation law where applicable.

When disclosing information to third parties, physicians should:

(c) Restrict disclosure to the minimum necessary information for the intended purpose.

(d) Ensure that individually identifying information is removed before releasing aggregate data or statistical health information about the pertinent population.

*AMA Principles of Medical Ethics: IV*

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### *3.2.4 Access to Medical Records by Data Collection Companies*

Information contained in patients' medical records about physicians' prescribing practices or other treatment decisions can serve many valuable purposes, such as improving quality of care. However, ethical concerns arise when access to such information is sought for marketing purposes on behalf of commercial entities that have financial interests in physicians' treatment recommendations, such as pharmaceutical or medical device companies.

Information gathered and recorded in association with the care of a patient is confidential. Patients are entitled to expect that the sensitive personal information they divulge will be used solely to enable their physician to most effectively provide needed services. Disclosing information to third parties for commercial purposes without consent undermines trust, violates principles of informed consent and confidentiality, and may harm the integrity of the patient-physician relationship.

Physicians who propose to permit third-party access to specific patient information for commercial purposes should:

(a) Only provide data that has been de-identified.

(b) Fully inform each patient whose record would be involved (or the patient's authorized surrogate when the individual lacks decision-making capacity) about the purpose(s) for which access would be granted.

Physicians who propose to permit third parties to access the patient's full medical record should:

(c) Obtain the consent of the patient (or authorized surrogate) to permit access to the patient's medical record.

(d) Prohibit access to or decline to provide information from individual medical records for which consent has not been given.

(e) Decline incentives that constitute ethically inappropriate gifts, in keeping with ethics guidance.

*AMA Principles of Medical Ethics: I,II,IV*

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### *3.3.1 Management of Medical Records*

Medical records serve important patient interests for present health care and future needs, as well as insurance, employment, and other purposes.

In keeping with the professional responsibility to safeguard the confidentiality of patients' personal information, physicians have an ethical obligation to manage medical records appropriately.

This obligation encompasses not only managing the records of current patients, but also retaining old records against possible future need, and providing copies or transferring records to a third party as requested by the patient or the patient's authorized representative when the physician leaves a practice, sells his or her practice, retires, or dies.

To manage medical records responsibly, physicians (or the individual responsible for the practice's medical records) should:

(a) Ensure that the practice or institution has and enforces clear policy prohibiting access to patients' medical records by unauthorized staff.

(b) Use medical considerations to determine how long to keep records, retaining information that another physician seeing the patient for the first time could reasonably be expected to need or want to know unless otherwise required by law, including:

  (i) immunization records, which should be kept indefinitely;

  (ii) records of significant health events or conditions and interventions that could be expected to have a bearing on the patient's future health care needs, such as records of chemotherapy.

(c) Make the medical record available:

  (i) as requested or authorized by the patient (or the patient's authorized representative);

  (ii) to the succeeding physician or other authorized person when the physician discontinues his or her practice (whether through departure, sale of the practice, retirement, or death);

  (iii) as otherwise required by law.

(d) Never refuse to transfer the record on request by the patient or the patient's authorized representative, for any reason.

(e) Charge a reasonable fee (if any) for the cost of transferring the record.

(f) Appropriately store records not transferred to the patient's current physician.

(g) Notify the patient about how to access the stored record and for how long the record will be available.

(h) Ensure that records that are to be discarded are destroyed to protect confidentiality.

*AMA Principles of Medical Ethics: IV,V*

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### *3.3.2 Confidentiality & Electronic Medical Records*

Information gathered and recorded in association with the care of a patient is confidential, regardless of the form in which it is collected or stored.

Physicians who collect or store patient information electronically, whether on stand-alone systems in their own practice or through contracts with service providers, must:

(a) Choose a system that conforms to acceptable industry practices and standards with respect to:

(i) restriction of data entry and access to authorized personnel;

(ii) capacity to routinely monitor/audit access to records;

(iii) measures to ensure data security and integrity; and

(iv) policies and practices to address record retrieval, data sharing, third-party access and release of information, and disposition of records (when outdated or on termination of the service relationship) in keeping with ethics guidance.

(b) Describe how the confidentiality and integrity of information is protected if the patient requests.

(c) Release patient information only in keeping with ethics guidance for confidentiality.

*AMA Principles of Medical Ethics: V*

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### *3.3.3 Breach of Security in Electronic Medical Records*

When used with appropriate attention to security, electronic medical records (EMRs) promise numerous benefits for quality clinical care and health-related research. However, when a security breach occurs, patients may face physical, emotional, and dignitary harms.

Dedication to upholding trust in the patient-physician relationship, to preventing harms to patients, and to respecting patients' privacy and autonomy create responsibilities for individual physicians, medical practices, and health care institutions when patient information is inappropriately disclosed.

The degree to which an individual physician has an ethical responsibility to address inappropriate disclosure depends in part on his or her awareness of the breach, relationship to the patient(s) affected, administrative authority with respect to the records, and authority to act on behalf of the practice or institution.

When there is reason to believe that patients' confidentiality has been compromised by a breach of the electronic medical record, physicians should:

(a) Ensure that patients are promptly informed about the breach and potential for harm, either by disclosing directly (when the physician has administrative responsibility for the EMR), participating in efforts by the practice or health care institution to disclose, or ensuring that the practice or institution takes appropriate action to disclose.

(b) Follow all applicable state and federal laws regarding disclosure.

Physicians have a responsibility to follow ethically appropriate procedures for disclosure, which should at minimum include:

(c) Carrying out the disclosure confidentially and within a time frame that provides patients ample opportunity to take steps to minimize potential adverse consequences.

(d) Describing what information was breached; how the breach happened; what the consequences may be; what corrective actions have been taken by the physician, practice, or institution; and what steps patients themselves might take to minimize adverse consequences.

(e) Supporting responses to security breaches that place the interests of patients above those of the physician, medical practice, or institution.

(f) Providing information to patients to enable them to mitigate potential adverse consequences of inappropriate disclosure of their personal health information to the extent possible.

*AMA Principles of Medical Ethics: IV,VIII*

## CHAPTER 4: OPINIONS ON GENETICS & REPRODUCTIVE MEDICINE

The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.

*4.1 Genetics*


4.1.1 Genetic Testing & Counseling
4.1.2 Genetic Testing for Reproductive Decision Making
4.1.3 Third-Party Access to Genetic Information
4.1.4 Forensic Genetics


*4.2 Reproductive Medicine*


4.2.1 Assisted Reproductive Technology
4.2.2 Gamete Donation
4.2.3 Therapeutic Donor Insemination
4.2.4 Third-Party Reproduction
4.2.5 Storage & Use of Human Embryos
4.2.6 Cloning for Reproduction
4.2.7 Abortion


### *4.1.1 Genetic Testing & Counseling*

Genetic testing can provide valuable information to support informed decision making about personal health risks and care options as well as reproductive choices. The fact that genetic information carries implications for others to whom the individual is biologically related raises ethical challenges of balancing confidentiality against the well-being of others.

Because genetic contribution to disease can be complex and highly variable, interpreting findings and helping patients understand the implications for their health and health care requires special skill and attention.

Genetic testing is most appropriate when the results of testing will have meaningful impact on the patient's care. Physicians should not encourage testing unless there is effective therapy available to prevent or ameliorate the condition tested for. Whether a genetic test is performed to help diagnose an existing health condition, or to predict future health risks, or to provide information for managing a disease, it is important that the patient receives appropriate counseling.

Physicians who order genetic tests (individually or as part of a multi-test panel or large-scale sequencing) or who offer clinical genetic services should:

(a) Have appropriate knowledge and expertise to counsel patients about heritable conditions, risks for disease, and implications for health management, and to interpret findings of individual genetic tests or collaborate with other health care professionals who can provide these services, such as licensed genetic counselors.

(b) Adhere to standards of nondirective counseling and avoid imposing their personal moral values or judgment on the patient.

(c) Discuss with the patient:

(i) what can and cannot be learned from the proposed genetic test(s) and reasons for and against testing, including the possibility of incidental findings. Physicians should ascertain whether the patient wishes to be informed about findings unrelated to the goal of testing;

(ii) medical and psychological implications for the individual's biological relatives;

(iii) circumstances under which the physician will expect the patient to notify biological relatives of test findings; and

(iv) that the physician will be available to assist in communicating with relatives.

(d) Obtain the individual's informed consent for the specific test or tests to be performed.

(e) Ensure that appropriate measures are taken to protect the confidentiality of the patient's and their biological relatives' genetic information.

*AMA Principles of Medical Ethics: II,IV,V,VI*

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### *4.1.2 Genetic Testing for Reproductive Decision Making*

Genetic testing can provide information to help prospective parents make informed decisions about childbearing.

Genetic testing to inform reproductive decisions was once recommended only for women/couples whose family history or medical record indicated elevated risk for a limited set of genetically mediated conditions. As procreation among individuals of diverse ancestries becomes more common and tests for more conditions become more accurate and less costly, the relevance of broad preconception, pre-implantation, or prenatal genetic screening grows stronger. Physicians may ethically provide genetic testing to inform reproductive decision making when the patient requests, but may also wish to offer broad screening to all persons who are considering having a child.

Physicians who provide reproductive health care that includes genetic testing should:

(a) Adhere to standards of nondirective counseling and avoid imposing their personal moral values or judgment on the patient.

(b) Discuss reasons for and against genetic testing and ethically inappropriate uses of genetic testing, such as to identify non-disease-related characteristics or traits.

(c) Obtain the individual's informed consent to the specific test or tests to be performed. Physicians should ascertain whether the person wishes to be informed about incidental findings.

(d) Inform the individual about any abnormal findings for the tests ordered and discuss the severity of the associated health condition, likelihood of clinical manifestation (penetrance), age at onset, and other factors relevant to a decision about childbearing.

(e) Respect an individual's decision to terminate or continue a pregnancy when testing reveals a genetic abnormality in the fetus, in accordance with applicable law.

(f) Refer the individual to another qualified physician when personal moral values prohibit the physician from providing lawful abortion services when this is a service that the person desires, in keeping with ethics guidance.

*AMA Principles of Medical Ethics: II,IV,V,VI*

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### *4.1.3 Third-Party Access to Genetic Information*

The rapid pace of development and dissemination of genetic testing has made it possible to generate information about individuals across a wide and growing spectrum of genetic variations associated with disease risk. The prospect of access to and use of such information by third parties who have a stake in an individual's health raises ethical concerns about confidentiality and potentially inappropriate use of genetic information.

Patients who undergo genetic testing have a right to have their information kept in confidence, and a variety of state and federal laws prohibit discrimination by employers, insurers, and other third parties based on genetic information they obtain about an individual.

Physicians who provide and interpret genetic tests, or who maintain patient records that include the findings of genetic tests, have professional ethical obligations to:

(a) Maintain the confidentiality of the patient's health information, including genetic information.

(b) Release a patient's genetic information to third parties only with the patient's informed consent.

(c) Decline to participate in genetic testing at the request of third parties (for example, for purposes of establishing health care or other benefits or coverage for the individual) except when at the patient's request and with their informed consent.

*AMA Principles of Medical Ethics: IV*

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### *4.1.4 Forensic Genetics*

With the exception of genetic information (or material) collected under the jurisdiction of a coroner, medical examiner, or other medical legal officer, the release of genetic information from a physician's records without the patient's informed consent constitutes a breach of confidentiality. However, under limited circumstances with overriding legal and social considerations, all physicians may disclose such information to the criminal justice system.

Physicians from whom genetic information is sought for purposes of criminal justice:

(a) May ethically carry out DNA analysis on stored tissue samples or release genetic information without the consent of a living or deceased patient (or the patient's authorized surrogate) in response to a warrant or court order.

(b) Should release only the minimum information necessary for the specific purpose.

(c) Should not be required to provide genetic information when:

(i) a suspect whose location is known refuses to provide a tissue sample for genetic analysis; or

(ii) a tissue sample for the suspect can be obtained from other sources (such as the body of a deceased suspect).

(d) Should decline to participate in the use of information from a genetic database created exclusively for criminal justice for any purpose other than identification.

*AMA Principles of Medical Ethics: III,IV*

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### *4.2.1 Assisted Reproductive Technology*

Assisted reproduction offers hope to patients who want children but are unable to have a child without medical assistance. In many cases, patients who seek assistance have been repeatedly frustrated in their attempts to have a child and are psychologically very vulnerable. Patients whose health insurance does not cover assisted reproductive services may also be financially vulnerable. Candor and respect are thus essential for ethical practice.

"Assisted reproductive technology" is understood as all treatments or procedures that include the handling of human oocytes or embryos. It encompasses an increasingly complex range of interventions—such as therapeutic donor insemination, ovarian stimulation, ova and sperm retrieval, in vitro fertilization, gamete intrafallopian transfer—and may involve multiple participants.

Physicians should increase their awareness of infertility treatments and options for their patients. Physicians who offer assisted reproductive services should:

(a) Value the well-being of the patient and potential offspring as paramount.

(b) Ensure that all advertising for services and promotional materials are accurate and not misleading.

(c) Provide patients with all of the information they need to make an informed decision, including investigational techniques to be used (if any); risks, benefits, and limitations of treatment options and alternatives, for the patient and potential offspring; accurate, clinic-specific success rates; and costs.

(d) Provide patients with psychological assessment, support and counseling or a referral to such services.

(e) Base fees on the value of the service provided. Physicians may enter into agreements with patients to refund all or a portion of fees if the patient does not conceive where such agreements are legally permitted.

(f) Not discriminate against patients who have difficult-to-treat conditions, whose infertility has multiple causes, or on the basis of race, socioeconomic status, or sexual orientation or gender identity.

(g) Participate in the development of peer-established guidelines and self-regulation.

*AMA Principles of Medical Ethics: I,V,VII*

### *4.2.2 Gamete Donation*

Donating eggs or sperm for others to use in reproduction can enable individuals who would not otherwise be able to do so to have children. However, gamete donation also raises ethical concerns about the privacy of donors and the nature of relationships among donors and children born through use of their gametes by means of assisted reproductive technologies.

Physicians who participate in gamete retrieval and storage should:

(a) Inform prospective donors of sperm or ova:

(i) about the clinical risks of gamete donation, including the near and long-term risks and the discomforts of ovarian hyperstimulation and egg retrieval as appropriate;

(ii) about the need for full medical disclosure and that prospective donors will be tested for infectious disease agents and genetic disorders;

(iii) whether and how the donor will be informed if testing indicates the presence of infectious disease or genetic disorder;

(iv) that all information collected, including test results, will be stored indefinitely;

(v) what additional personal information will be collected about the donor;

(vi) under what circumstances and with whom personal information, including identifying information, will be shared for clinical purposes;

(vii) how donated gametes will be stored and policies and procedures governing the use of stored gametes;

(viii) whether and how the donor will be compensated;

(ix) the fact that state law will govern the relationship between the donor and any resulting child (or children).

(b) Exclude prospective donors for whom testing reveals the presence of infectious disease agents.

(c) Obtain the prospective donor's consent for gamete retrieval.

(d) Discuss, document and respect the prospective donor's preferences for how gametes may be used, including whether they may be donated for research purposes.

(e) Discuss, document, and respect the prospective donor's preferences regarding release of identifying information to any child (or children) resulting from use of the donated gametes.

(f) Adhere to good clinical practices, including ensuring that identifying information is maintained indefinitely so that:

(i) donors can be notified in the event a child born through use of his/her gametes subsequently tests positive for infectious disease or genetic disorder that may have been transmitted by the donor;

(ii) the number of pregnancies resulting from a single gamete donor is limited.

*AMA Principles of Medical Ethics: I,V*

### *4.2.3 Therapeutic Donor Insemination*

Therapeutic donor insemination using sperm from a woman's partner or a third-party donor can enable a woman or couple who might not otherwise be able to do so to fulfill the important life choice of becoming a parent (or parents).

However, the procedure also raises ethical considerations about safety for the woman and potential offspring, donor privacy, and the disposition of frozen semen, as well as the use of screening to select the sex of a resulting embryo.

Physicians who choose to provide artificial insemination should:

(a) Provide therapeutic donor insemination in a nondiscriminatory manner. Physicians should not withhold or refuse services on the basis of nonclinical considerations, such as a patient's marital status.

(b) Obtain informed consent for therapeutic donor insemination, after informing the patient (and partner, if appropriate):

  (i) about the risks, benefits, likelihood of success, and costs of the intervention;

  (ii) about the need to screen donated semen for infectious disease agents and genetic disorders when an individual proposes to donate sperm specifically for the patient's use in therapeutic donor insemination;

  (iii) about the need to address in advance what will be done with frozen sperm (if any) from a known donor in the event the donor dies;

  (iv) that state law will govern the status, obligations, and rights of the sperm donor, known or anonymous, in relation to a resulting child.

(c) When sperm is collected specifically for use by an identified patient, obtain informed consent from the prospective donor, after informing the individual:

  (i) about the need to test donated semen for infectious disease agents and genetic disorders;

  (ii) whether and how the donor will be informed in the event the semen tests positive for infectious disease or genetic disorder;

  (iii) that state law will govern the status, obligations, and rights of the donor in relation to a resulting child.

(d) Counsel patients who choose to be inseminated with sperm from an anonymous donor to involve their partner (if any) in the decision.

(e) Provide sex selection of sperm only for purposes of avoiding a sex-linked inheritable disorder. Physicians should not participate in sex selection of sperm for reasons of gender preference.

*AMA Principles of Medical Ethics: I,V*

### *4.2.4 Third-Party Reproduction*

Third-party reproduction is a form of assisted reproduction in which a woman agrees to bear a child on behalf of and relinquish the child to an individual or couple who intend to rear the child. Such arrangements can promote fundamental human values by enabling individuals or couples who are otherwise unable to do so to fulfill deeply held desires to raise a child. Gestational carriers in their turn can take satisfaction in expressing altruism by helping others fulfill such desires.

Third-party reproduction may involve therapeutic donor insemination or use of assisted reproductive technologies, such as in vitro fertilization and embryo transfer. The biological and social relationships among participants in these arrangements can form a complex matrix of roles among gestational carrier, gamete donor(s), and rearing parent(s).

Third-party reproduction can alter social understandings of parenthood and family structure. They can also raise concerns about the voluntariness of the gestational carrier's participation and about possible psychosocial harms to those involved, such as distress on the part of the gestational carrier at relinquishing the child or on the part of the child at learning of the circumstances of his or her birth. Third-party reproduction can also carry potential to depersonalize carriers, exploit economically disadvantaged women, and commodify human gametes and children. These concerns may be especially challenging when carriers or gamete donors are compensated financially for their services. Finally, third-party reproduction can raise concerns about dual loyalties or conflict of interest if a physician establishes patient-physician relationships with multiple parties to the arrangement.

Individual physicians who care for patients in the context of third-party reproduction should:

(a) Establish a patient-physician relationship with only one party (gestational carriers, gamete donor[s] or intended rearing parent[s]) to avoid situations of dual loyalty or conflict of interest.

(b) Ensure that the patient undergoes appropriate medical screening and psychological assessment.

(c) Encourage the parties to agree in advance on the terms of the agreement, including identifying possible contingencies and deciding how they will be handled.

(d) Inform the patient about the risks of third-party reproduction for that individual (those including individuals), possible psychological harms to the individual(s), the resulting child, and other relationships.

(e) Satisfy themselves that the patient's decision to participate in third-party reproduction is free of coercion before agreeing to provide assisted reproductive services.

Collectively, the profession should advocate for public policy that will help ensure that the practice of third-party reproduction does not exploit disadvantaged women or commodify human gametes or children.

*AMA Principles of Medical Ethics: I,II,IV*

### *4.2.5 Storage & Use of Human Embryos*

Embryos created during cycles of in vitro fertilization (IVF) that are not intended for immediate transfer are often frozen for future use. The primary goal is to minimize risk and burden by minimizing the number of cycles of ovarian stimulation and egg retrieval that an IVF patient undergoes.

While embryos are usually frozen with the expectation that they will be used for reproductive purposes by the prospective parent(s) for whom they were created, frozen embryos may also offer hope to other prospective parent(s) who would otherwise not be able to have a child. Frozen embryos also offer the prospect of advancing scientific knowledge when made available for research purposes. In all of these possible scenarios, ethical concerns arise regarding who has authority to make decisions about stored embryos and what kinds of choices they may ethically make. Decision-making authority with respect to stored embryos varies depending on the relationships between the prospective rearing parent(s) and any individual(s) who may provide gametes. At stake are individuals' interests in procreating.

When gametes are provided by the prospective rearing parent(s) or a known donor, physicians who provide clinical services that include creation and storage of embryos have an ethical responsibility to proactively discuss with the parties whether, when, and under what circumstances stored embryos may be:

(a) Used by a surviving party for purposes of reproduction in the event of the death of a partner or gamete donor.

(b) Made available to other patients for purposes of reproduction.

(c) Made available to investigators for research purposes, in keeping with ethics guidance and on the understanding that embryo(s) used for research will not subsequently be used for reproduction.

(d) Allowed to thaw and deteriorate.

(e) Otherwise disposed of.

Under no circumstances should physicians participate in the sale of stored embryos.

*AMA Principles of Medical Ethics: I,III,IV,V*

### *4.2.6 Cloning for Reproduction*

Somatic cell nuclear transfer (SCNT) is the process in which the nucleus of a somatic cell of an organism is transferred into an enucleated oocyte. Cloning for reproduction, that is, the application of SCNT to create a human embryo that shares all of its nuclear genes with the donor of the human somatic cell, has been debated as having possible clinical benefit. It has been suggested that reproductive cloning might be ethically acceptable to assist individuals or couples to reproduce and to create a compatible tissue donor.

Misconceptions often surround proposals for reproductive cloning, including the mistaken notion that one's genotype determines one's individuality and using SCNT to create a human embryo would replicate a person (the donor of the somatic cell).

The possible use of SCNT in reproductive medicine also poses risks of unknown physical harms from the technology itself, including concerns about long-term safety, and the possibility that SCNT will be associated with genetic anomalies or have other unforeseen medical consequences. Reproductive cloning also carries the risk of psychosocial harm, including violations of privacy and autonomy and the possibility of compromising the cloned child's right to an open future by creating enormous pressures to live up to expectations based on the life of the somatic cell donor.

Reproductive cloning may have adverse effects on familial and societal relations and on the gene pool in altering reproductive patterns and the resulting genetic characteristics of a population, including posing harms to future generations if deleterious genetic mutations are introduced. Moreover, reproductive cloning has the potential to be used in a eugenic or discriminatory fashion—practices that are incompatible with the ethical norms of medicine.

In light of the physical risks of SCNT, ongoing moral debate about the status of the human embryo, and concerns about the impact of reproductive cloning on cloned children, families and communities, reproductive cloning is not endorsed by the medical profession or by society.

Should reproductive cloning at some point be introduced into medical practice, physicians must be aware that cloning techniques must not be used without the informed consent of the somatic cell donor, the oocyte donor, and the prospective rearing parent(s), in keeping with ethics guidance for assisted reproduction.

Further, any child produced by reproductive cloning would be entitled to the same rights, freedoms, and protections as every other individual in society, irrespective of the fact that the child's nuclear genes derive from a single individual.

As professionals dedicated to protecting the well-being of patients, physicians should not participate in using SCNT to produce children. Because SCNT technology is not limited to any single country, physicians should help establish international guidelines governing its uses before experimentally proven techniques are introduced into clinical practice.

*AMA Principles of Medical Ethics: V*

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### *4.2.7 Abortion*

The Principles of Medical Ethics of the AMA do not prohibit a physician from performing an abortion in accordance with good medical practice and under circumstances that do not violate the law.

*AMA Principles of Medical Ethics: III,IV*

## CHAPTER 5: OPINIONS ON CARING FOR PATIENTS AT THE END OF LIFE

The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.


5.1 Advance Care Planning
5.2 Advance Directives
5.3 Withholding or Withdrawing Life-Sustaining Treatment
5.4 Orders Not to Attempt Resuscitation (DNAR)
5.5 Medically Ineffective Interventions
5.6 Sedation to Unconsciousness in End-of-Life Care
5.7 Physician-Assisted Suicide
5.8 Euthanasia


### *5.1 Advance Care Planning*

The process of advance care planning is widely recognized as a way to support patient self-determination, facilitate decision making, and promote better care at the end of life. Although often thought of primarily for terminally ill patients or those with chronic medical conditions, advance care planning is valuable for everyone, regardless of age or current health status. Planning in advance for decisions about care in the event of a life-threatening illness or injury gives individuals the opportunity to reflect on and express the values they want to have govern their care, to articulate the factors that are important to them for quality of life, and to make clear any preferences they have with respect to specific interventions. Importantly, these discussions also give individuals the opportunity to identify who they would want to make decisions for them should they not have decision-making capacity.

Proactively discussing with patients what they would or would not want if recovery from illness or injury is improbable also gives physicians opportunity to address patients' concerns and expectations and clarify misunderstandings individuals may have about specific medical conditions or interventions. Encouraging patients to share their views with their families or other intimates and record them in advance directives, and to name a surrogate decision maker, helps to ensure that patients' own values, goals, and preferences will inform care decisions even when they cannot speak for themselves.

Physicians must recognize, however that patients and families approach decision making in many different ways, informed by culture, faith traditions, and life experience, and should be sensitive to each patient's individual situations and preferences when broaching discussion of planning for care at the end of life.

Physicians should routinely engage their patients in advance care planning in keeping with the following guidelines:

(a) Regularly encourage all patients, regardless of age or health status, to:

(i) think about their values and perspectives on quality of life and articulate what goals they would have for care if they faced a life-threatening illness or injury, including any preferences they may have about specific medical interventions (such as pain management, medically administered nutrition and hydration, mechanical ventilation, use of antibiotics, dialysis, or cardiopulmonary resuscitation);

(ii) identify someone they would want to have make decisions on their behalf if they did not have decision-making capacity;

(iii) make their views known to their designated surrogate and to (other) family members or intimates.

(b) Be prepared to answer questions about advance care planning, to help patients formulate their views, and to help them articulate their preferences for care (including their wishes regarding time-limited trials of interventions and surrogate decision maker). Physicians should also be prepared to refer patients to additional resources for further information and guidance if appropriate.

(c) Explain how advance directives, as written articulations of patients' preferences, are used as tools to help guide treatment decisions in collaboration with patients themselves when they have decision-making capacity, or with surrogates when they do not, and explain the surrogate's responsibilities in decision making. Involve the patient's surrogate in this conversation whenever possible.

(d) Incorporate notes from the advance care planning discussion into the medical record. Patient values, preferences for treatment, and designation of surrogate decision maker should be included in the notes to be used as guidance when the patient is unable to express his or her own decisions. If the patient has an advance directive document or written designation of proxy, include a copy (or note the existence of the directive) in the medical record and encourage the patient to give a copy to his or her surrogate and others to help ensure it will be available when needed.

(e) Periodically review with the patient his or her goals, preferences, and chosen decision maker, which often change over time or with changes in health status. Update the patient's medical records accordingly when preferences have changed to ensure that these continue to reflect the individual's current wishes. If applicable, assist the patient with updating his or her advance directive or designation of proxy forms. Involve the patient's surrogate in these reviews whenever possible.

*AMA Principles of Medical Ethics: I,IV*

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***5.2 Advance Directives***

Respect for autonomy and fidelity to the patient are widely acknowledged as core values in the professional ethics of medicine. For patients who lack decision-making capacity, these values are fulfilled through third-party decision making and the use of advance directives. Advance directives also support continuity of care for patients when they transition across care settings, physicians, or health care teams.

Advance directives, whether oral or written, advisory or a formal statutory document, are tools that give patients of all ages and health status the opportunity to express their values, goals for care, and treatment preferences to guide future decisions about health care. Advance directives also allow patients to identify whom they want to make decisions on their behalf when they cannot do so themselves. They enable physicians and surrogates to make good-faith efforts to respect the patient's goals and implement the patient's preferences when the patient does not have decision-making capacity.

An advance directive never takes precedence over the contemporaneous wishes of a patient who has decision-making capacity.

In emergency situations when a patient is not able to participate in treatment decisions and there is no surrogate or advance directive available to guide decisions, physicians should provide medically appropriate interventions when urgently needed to meet the patient's immediate clinical needs. Interventions may be withdrawn at a later time in keeping with the patient's preferences when they become known and in accordance with ethics guidance for withdrawing treatment.

Before initiating or continuing treatment, including, but not limited to, life-sustaining interventions, the physician should:

(a) Assess the patient's decision-making capacity in the current clinical circumstances.

(b) Ascertain whether the patient has an advance directive and if so, whether it accurately reflects his/her current values and preferences. Determine whether the patient's current clinical circumstances meet relevant thresholds set out in the directive.

(c) Ascertain whether the patient has named a health care proxy (e.g., orally or through a formal legal document). If the patient has not, ask who the patient would want to have make decisions should he or she become unable to do so.

(d) Document the conversation, including the patient's goals for care, and specific preferences regarding interventions and surrogate decision maker, in the medical record; incorporate any written directives (as available) into the medical record to ensure they are accessible to the health care team.

(e) When treatment decisions must be made by the patient's surrogate, help the surrogate understand how to carry out the patient's wishes in keeping with the advance directive (when available), including whether the directive applies in the patient's current clinical circumstances and what medically appropriate interventions are available to achieve the patient's goals for care. When conflicts arise between the advance directive and the wishes of the patient's surrogate, the attending physician should seek assistance from an ethics committee or other appropriate institutional resource.

(f) When a patient who lacks decision-making capacity has no advance directive and there is no surrogate available and willing to make treatment decisions on the patient's behalf, or no surrogate can be identified, the attending physician should seek assistance from an ethics committee or other appropriate resource in ascertaining the patient's best interest.

(g) Document physician orders to implement treatment decisions in the medical record, including both orders for specific, ongoing interventions (e.g., palliative interventions) and orders to forgo specific interventions (e.g., orders not to attempt resuscitation, not to intubate, not to provide antibiotics or dialysis).

*AMA Principles of Medical Ethics: I,IV*

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### *5.3 Withholding or Withdrawing Life-Sustaining Treatment*

Decisions to withhold or withdraw life-sustaining interventions can be ethically and emotionally challenging to all involved. However, a patient who has decision-making capacity appropriate to the decision at hand has the right to decline any medical intervention or ask that an intervention be stopped, even when that decision is expected to lead to his or her death and regardless of whether or not the individual is terminally ill. When a patient lacks appropriate capacity, the patient's surrogate may decline an intervention or ask that an intervention be stopped in keeping with ethics guidance for surrogate decision making.

While there may be an emotional difference between not initiating an intervention at all and discontinuing it later in the course of care, there is no ethical difference between withholding and withdrawing treatment. When an intervention no longer helps to achieve the patient's goals for care or desired quality of life, it is ethically appropriate for physicians to withdraw it.

Physicians should elicit patient goals of care and preferences regarding life-sustaining interventions early in the course of care, including the patient's surrogate in that discussion whenever possible. When facing decisions about withholding or withdrawing life- sustaining treatment the physician should:

(a) Review with the patient the individual's advance directive, if there is one. Otherwise, elicit the patient's values, goals for care, and treatment preferences. Include the patient's surrogate in the conversation if possible, even when the patient retains decision-making capacity.

(b) Document the patient's preferences and identify the patient's surrogate in the medical record and ensure that the record includes the patient's written advance directive or durable power of attorney for health care (DPAHC), where applicable.

(c) Support the decision-making process by providing all relevant medical information to the patient and/or surrogate.

(d) Discuss with the patient and/or surrogate the option of initiating an intervention with the intention of evaluating its clinical effectiveness after a given amount of time to determine if it has led to improvement. Confirm that if the intervention has not achieved agreed-on goals, it may be withdrawn.

(e) Reassure the patient and/or surrogate that all other medically appropriate care will be provided, including aggressive palliative care, appropriate symptom management if that is what the patient wishes.

(f) Explain that the surrogate should make decisions to withhold or withdraw life-sustaining interventions when the patient lacks decision-making capacity and there is a surrogate available and willing to make decisions on the patient's behalf, in keeping with ethics guidance for substituted judgment or best interests as appropriate.

(g) Seek consultation through an ethics committee or other appropriate resource in keeping with ethics guidance when:

    (i) the patient or surrogate and the health care team cannot reach agreement about a decision to withhold or withdraw life-sustaining treatment;

    (ii) there is no surrogate available and willing to make decisions on behalf of a patient who does not have decision-making capacity or no surrogate can be identified;

    (iii) in the physician's best professional judgment a decision by the patient's surrogate clearly violates the patient's previously expressed values, goals for care, or treatment preferences, or is not in the patient's medical interest.

(h) Ensure that relevant standards for good clinical practice and palliative care are followed when implementing any decision to withdraw a life-sustaining intervention.

*AMA Principles of Medical Ethics: I,III,IV,V*

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***5.4 Orders Not to Attempt Resuscitation (DNAR)***

The ethical obligation to respect patient autonomy and self-determination requires that the physician respect decisions to refuse care, even when such decisions will result in the patient's death. Whether a

patient declines or accepts medically appropriate resuscitative interventions, physicians should not permit their personal value judgments to obstruct implementation of the patient's decision.

Orders not to attempt resuscitation (DNAR orders) direct the health care team to withhold resuscitative measures in accord with a patient's wishes. DNAR orders can be appropriate for any patient medically at risk of cardiopulmonary arrest, regardless of the patient's age or whether or not the patient is terminally ill. DNAR orders apply in any care setting, in or out of hospital, within the constraints of applicable law.

In the event a patient suffers a cardiopulmonary arrest when there is no DNAR order in the medical record, resuscitation should be attempted if it is medically appropriate. If it is found after the code is initiated that the patient would not have wanted resuscitation, the attending physician should order that resuscitative efforts be stopped.

Physicians should address the potential need for resuscitation early in the patient's course of care, while the patient has decision-making capacity, and should encourage the patient to include his or her chosen surrogate in the conversation. Before entering a DNAR order in the medical record, the physician should:

(a) Candidly describe the procedures involved in resuscitation, the likelihood of medical benefit in the patient's clinical circumstances, and the likelihood of achieving the patient's desired goals for care or quality of life to address any misconceptions the patient may have about probable outcomes of resuscitation.

(b) Ascertain the patient's wishes with respect to resuscitation—directly from the patient when the individual has decision-making capacity, or from the surrogate when the patient lacks capacity. If the patient has an advance directive, the physician should review the directive with the patient and confirm that the preferences set out in the directive about resuscitation are current and valid. The DNAR order should be tailored to reflect the particular patient's preferences and clinical circumstances.

(c) Reinforce with the patient, loved ones, and the health care team that DNAR orders apply only to resuscitative interventions as they relate to the patient's goals for care. Other medically appropriate interventions, such as antibiotics, dialysis, or appropriate symptom management will be provided or withheld in accordance with the patient's wishes.

(d) Revisit and revise decisions about resuscitation—with appropriate documentation in the medical record—as the patient's clinical circumstances change. Confirm whether the patient wants the DNAR order to remain in effect when obtaining consent for surgical or other interventions that carry a known risk for cardiopulmonary arrest and adhere to those wishes.

(e) Document in the medical record the patient's clinical status, prognosis, current decision-making capacity, and preferences with respect to resuscitation, as well as the physician's medical judgment about the appropriateness of resuscitation.

When the patient cannot express preferences regarding resuscitation or does not have decision-making capacity and has not previously indicated his or her preferences, the physician has an ethical responsibility to:

(f) Candidly and compassionately discuss these issues with the patient's authorized surrogate and document the surrogate's decision in the medical record.

(g) Revisit with the surrogate decisions about resuscitation as the patient's clinical circumstances change, revising the decision as needed and updating the medical record accordingly.

(h) Seek consultation with an ethics committee or other appropriate institutional resource if disagreement about a DNAR order that cannot be resolved at the bedside.

When the patient's preferences cannot be determined and the individual has no surrogate, the physician should consult with an ethics committee or other appropriate institutional resource before entering an order not to attempt resuscitation.

*AMA Principles of Medical Ethics: I,IV,VIII*

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### *5.5 Medically Ineffective Interventions*

At times patients (or their surrogates) request interventions that the physician judges not to be medically appropriate. Such requests are particularly challenging when the patient is terminally ill or suffers from an acute condition with an uncertain prognosis and therapeutic options range from aggressive, potentially burdensome life-extending intervention to comfort measures only. Requests for interventions that are not medically appropriate challenge the physician to balance obligations to respect patient autonomy and not to abandon the patient with obligations to be compassionate, yet candid, and to preserve the integrity of medical judgment.

Physicians should only recommend and provide interventions that are medically appropriate—i.e., scientifically grounded—and that reflect the physician's considered medical judgment about the risks and likely benefits of available options in light of the patient's goals for care. Physicians are not required to offer or to provide interventions that, in their best medical judgment, cannot reasonably be expected to yield the intended clinical benefit or achieve agreed-on goals for care. Respecting patient autonomy does not mean that patients should receive specific interventions simply because they (or their surrogates) request them.

Many health care institutions have promoted policies regarding so-called "futile" care. However, physicians must remember that it is not possible to offer a single, universal definition of futility." The meaning of the term "futile" depends on the values and goals of a particular patient in specific clinical circumstances.

As clinicians, when a patient (or surrogate on behalf of a patient who lacks decision-making capacity) request care that the physician or other members of the health care team judge not to be medically appropriate, physicians should:

(a) Discuss with the patient the individual's goals for care, including desired quality of life, and seek to clarify misunderstandings. Include the patient's surrogate in the conversation if possible, even when the patient retains decision-making capacity.

(b) Reassure the patient (and/or surrogate) that medically appropriate interventions, including appropriate symptom management, will be provided unless the patient declines particular interventions (or the surrogate does so on behalf of a patient who lacks capacity).

(c) Negotiate a mutually agreed-on plan of care consistent with the patient's goals and with sound clinical judgment.

(d) Seek assistance from an ethics committee or other appropriate institutional resource if the patient (or surrogate) continues to request care that the physician judges not to be medically appropriate, respecting the patient's right to appeal when review does not support the request.

(e) Seek to transfer care to another physician or another institution willing to provide the desired care in the rare event that disagreement cannot be resolved through available mechanisms, in keeping with ethics guidance. If transfer is not possible, the physician is under no ethical obligation to offer the intervention.

As leaders within their institutions, physicians should encourage the development of institutional policy that:

(f) Acknowledges the need to make context sensitive judgments about care for individual patients.

(g) Supports physicians in exercising their best professional judgment.

(h) Takes into account community and institutional standards for care.

(i) Uses scientifically sound measures of function or outcome.

(j) Ensures consistency and due process in the event of disagreement over whether an intervention should be provided.

*AMA Principles of Medical Ethics: I,IV,V*

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***5.6 Sedation to Unconsciousness in End-of-Life Care***

The duty to relieve pain and suffering is central to the physician's role as healer and is an obligation physicians have to their patients. When a terminally ill patient experiences severe pain or other distressing clinical symptoms that do not respond to aggressive, symptom-specific palliation it can be appropriate to offer sedation to unconsciousness as an intervention of last resort.

Sedation to unconsciousness must never be used to intentionally cause a patient's death.

When considering whether to offer palliative sedation to unconsciousness, physicians should:

(a) Restrict palliative sedation to unconsciousness to patients in the final stages of terminal illness.

(b) Consult with a multi-disciplinary team (if available), including an expert in the field of palliative care, to ensure that symptom-specific treatments have been sufficiently employed and that palliative sedation to unconsciousness is now the most appropriate course of treatment.

(c) Document the rationale for all symptom management interventions in the medical record.

(d) Obtain the informed consent of the patient (or authorized surrogate when the patient lacks decision-making capacity).

(e) Discuss with the patient (or surrogate) the plan of care relative to:

  (i) degree and length of sedation;

  (ii) specific expectations for continuing, withdrawing, or withholding future life-sustaining treatments.

(f) Monitor care once palliative sedation to unconsciousness is initiated.

Physicians may offer palliative sedation to unconsciousness to address refractory clinical symptoms, not to respond to existential suffering arising from such issues as death anxiety, isolation, or loss of control. Existential suffering should be addressed through appropriate social, psychological or spiritual support.

*AMA Principles of Medical Ethics: I,VII*

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*Thoughtful, morally admirable individuals hold diverging, yet equally deeply held, and well-considered perspectives about physician-assisted suicide. Nonetheless, at the core of public and professional debate about physician-assisted suicide is the aspiration that every patient come to the end of life as free as possible from suffering that does not serve the patient's deepest self-defining beliefs. Supporters and opponents share a fundamental commitment to values of care, compassion, respect, and dignity; they diverge in drawing different moral conclusions from those underlying values in equally good faith.*

*Guidance in the AMA* Code of Medical Ethics *encompasses the irreducible moral tension at stake for physicians with respect to participating in assisted suicide. Opinion E-5.7 powerfully expresses the perspective of those who oppose physician-assisted suicide. Opinion 1.1.7 articulates the thoughtful moral basis for those who support assisted suicide.*

***5.7 Physician-Assisted Suicide***

Physician-assisted suicide occurs when a physician facilitates a patient's death by providing the necessary means and/or information to enable the patient to perform the life-ending act (e.g., the physician provides sleeping pills and information about the lethal dose, while aware that the patient may commit suicide).

It is understandable, though tragic, that some patients in extreme duress—such as those suffering from a terminal, painful, debilitating illness—may come to decide that death is preferable to life. However, permitting physicians to engage in assisted suicide would ultimately cause more harm than good.

Physician-assisted suicide is fundamentally incompatible with the physician's role as healer, would be difficult or impossible to control, and would pose serious societal risks.

Instead of engaging in assisted suicide, physicians must aggressively respond to the needs of patients at the end of life. Physicians:

(a) Should not abandon a patient once it is determined that cure is impossible.

(b) Must respect patient autonomy.

(c) Must provide good communication and emotional support.

(d) Must provide appropriate comfort care and adequate pain control.

*AMA Principles of Medical Ethics: I, IV*

***1.1.7 Physician Exercise of Conscience***

Physicians are expected to uphold the ethical norms of their profession, including fidelity to patients and respect for patient self-determination. Yet physicians are not defined solely by their profession. They are moral agents in their own right and, like their patients, are informed by and committed to diverse cultural, religious, and philosophical traditions and beliefs. For some physicians, their professional

calling is imbued with their foundational beliefs as persons, and at times the expectation that physicians will put patients' needs and preferences first may be in tension with the need to sustain moral integrity and continuity across both personal and professional life.

Preserving opportunity for physicians to act (or to refrain from acting) in accordance with the dictates of conscience in their professional practice is important for preserving the integrity of the medical profession as well as the integrity of the individual physician, on which patients and the public rely. Thus physicians should have considerable latitude to practice in accord with well-considered, deeply held beliefs that are central to their self-identities.

Physicians' freedom to act according to conscience is not unlimited, however. Physicians are expected to provide care in emergencies, honor patients' informed decisions to refuse life-sustaining treatment, and respect basic civil liberties and not discriminate against individuals in deciding whether to enter into a professional relationship with a new patient.

In other circumstances, physicians may be able to act (or refrain from acting) in accordance with the dictates of their conscience without violating their professional obligations. Several factors impinge on the decision to act according to conscience. Physicians have stronger obligations to patients with whom they have a patient-physician relationship, especially one of long standing; when there is imminent risk of foreseeable harm to the patient or delay in access to treatment would significantly adversely affect the patient's physical or emotional well-being; and when the patient is not reasonably able to access needed treatment from another qualified physician.

In following conscience, physicians should:

(a) Thoughtfully consider whether and how significantly an action (or declining to act) will undermine the physician's personal integrity, create emotional or moral distress for the physician, or compromise the physician's ability to provide care for the individual and other patients.

(b) Before entering into a patient-physician relationship, make clear any specific interventions or services the physician cannot in good conscience provide because they are contrary to the physician's deeply held personal beliefs, focusing on interventions or services a patient might otherwise reasonably expect the practice to offer.

(c) Take care that their actions do not discriminate against or unduly burden individual patients or populations of patients and do not adversely affect patient or public trust.

(d) Be mindful of the burden their actions may place on fellow professionals.

(e) Uphold standards of informed consent and inform the patient about all relevant options for treatment, including options to which the physician morally objects.

(f) In general, physicians should refer a patient to another physician or institution to provide treatment the physician declines to offer. When a deeply held, well-considered personal belief leads a physician also to decline to refer, the physician should offer impartial guidance to patients about how to inform themselves regarding access to desired services.

(g) Continue to provide other ongoing care for the patient or formally terminate the patient-physician relationship in keeping with ethics guidance.

*AMA Principles of Medical Ethics: I, II, IV, VI, VIII, IX*

### *5.8 Euthanasia*

Euthanasia is the administration of a lethal agent by another person to a patient for the purpose of relieving the patient's intolerable and incurable suffering.

It is understandable, though tragic, that some patients in extreme duress—such as those suffering from a terminal, painful, debilitating illness—may come to decide that death is preferable to life.

However, permitting physicians to engage in euthanasia would ultimately cause more harm than good.

Euthanasia is fundamentally incompatible with the physician's role as healer, would be difficult or impossible to control, and would pose serious societal risks. Euthanasia could readily be extended to incompetent patients and other vulnerable populations.

The involvement of physicians in euthanasia heightens the significance of its ethical prohibition. The physician who performs euthanasia assumes unique responsibility for the act of ending the patient's life.

Instead of engaging in euthanasia, physicians must aggressively respond to the needs of patients at the end of life. Physicians:

(a) Should not abandon a patient once it is determined that a cure is impossible.

(b) Must respect patient autonomy.

(c) Must provide good communication and emotional support.

(d) Must provide appropriate comfort care and adequate pain control.

*AMA Principles of Medical Ethics: I,IV*

## CHAPTER 6: OPINIONS ON ORGAN PROCUREMENT & TRANSPLANTATION

The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.

*6.1 Organ Procurement*

6.1.1 Transplantation of Organs from Living Donors
6.1.2 Organ Donation after Cardiac Death
6.1.3 Studying Financial Incentives for Cadaveric Organ Donation
6.1.4 Presumed Consent & Mandated Choice for Organs from Deceased Donors
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*6.2 Organ Transplantation*

6.2.1 Guidelines for Organ Transplantation
6.2.2 Directed Donation of Organs for Transplantation

*6.3 Special Issues in Organ Procurement & Transplantation*

6.3.1 Xenotransplantation

### *6.1.1 Transplantation of Organs from Living Donors*

Donation of nonvital organs and tissue from living donors can increase the supply of organs available for transplantation, to the benefit of patients with end-stage organ failure. Enabling individuals to donate nonvital organs is in keeping with the goals of treating illness and relieving suffering so long as the benefits to both donor and recipient outweigh the risks to both.

Living donors expose themselves to harm to benefit others; novel variants of living organ donation call for special safeguards for both donors and recipients.

Physicians who participate in donation of nonvital organs and tissues by a living individual should:

(a) Ensure that the prospective donor is assigned an advocacy team, including a physician, dedicated to protecting the donor's well-being.

(b) Avoid conflicts of interest by ensuring that the health care team treating the prospective donor is as independent as possible from the health care team treating the prospective transplant recipient.
(c) Carefully evaluate prospective donors to identify serious risks to the individual's life or health, including psychosocial factors that would disqualify the individual from donating; address the individual's specific needs; and explore the individual's motivations to donate.

(d) Secure agreement from all parties to the prospective donation in advance so that, should the donor withdraw, his or her reasons for doing so will be kept confidential.

(e) Determine that the prospective living donor has decision-making capacity and adequately understands the implications of donating a nonvital organ, and that the decision to donate is voluntary.

(f) In general, decline proposed living organ donations from unemancipated minors or legally incompetent adults, who are not able to understand the implications of a living donation or give voluntary consent to donation.

(g) In exceptional circumstances, enable donation of a nonvital organ or tissue from a minor who has substantial decision-making capacity when:

(i) the minor agrees to the donation;

(ii) the minor's legal guardians consent to the donation;

(iii) the intended recipient is someone to whom the minor has an emotional connection.

(h) Seek advice from another adult trusted by the prospective minor donor when circumstances warrant, or from an independent body such as an ethics committee, pastoral service, or other institutional resource.

(i) Inform the prospective donor:

(i) about the donation procedure and possible risks and complications for the donor;

(ii) about the possible risks and complications for the transplant recipient;

(iii) about the nature of the commitment the donor is making and the implications for other parties;

(iv) that the prospective donor may withdraw at any time before undergoing the intervention to remove the organ or collect tissue, whether the context is paired, domino, or chain donation; and

(v) that if the donor withdraws, the health care team will report simply that the individual was not a suitable candidate for donation.

(j) Obtain the prospective donor's separate consent for donation and for the specific intervention(s) to remove the organ or collect tissue.

(k) Ensure that living donors do not receive payment of any kind for any of their solid organs. Donors should be compensated fairly for the expenses of travel, lodging, meals, lost wages, and medical care associated with the donation only.

(l) Permit living donors to designate a recipient, whether related to the donor or not.

(m) Decline to facilitate a living donation to a known recipient if the transplantation cannot reasonably be expected to yield the intended clinical benefit or achieve agreed on goals for the intended recipient.

(n) Permit living donors to designate a stranger as the intended recipient if doing so produces a net gain in the organ pool without unreasonably disadvantaging others on the waiting list. Variations on donation to a stranger include:

(i) prospective donors who respond to public solicitations for organs or who wish to participate in a paired donation ("organ swap," as when donor-recipient pairs Y and Z with incompatible blood types are recombined to make compatible pairs: donor-Y with recipient-Z and donor-Z with recipient-Y);

(ii) domino paired donation;

(iii) nonsimultaneous extended altruistic donation ("chain donation").

(o) When the living donor does not designate a recipient, allocate organs according to the algorithm that governs the distribution of deceased donor organs.

(p) Protect the privacy and confidentiality of donors and recipients, which may be difficult in novel donation arrangements that involve many patients and in which donation-transplant cycles may be extended over time (as in domino or chain donation).

(q) Monitor prospective donors and recipients in proposed nontraditional donation arrangements for signs of psychological distress during screening and after the transplant is complete.

(r) Support the development and maintenance of a national database of living donor outcomes to support better understanding of associated harms and benefits and enhance the safety of living donation.

*AMA Principles of Medical Ethics: I,V,VII,VIII*

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### *6.1.2 Organ Donation after Cardiac Death*

Increasing the supply of organs available for transplant serves the interests of patients and the public and is in keeping with physicians' ethical obligation to contribute to the health of the public and to support access to medical care. Physicians should support innovative approaches to increasing the supply of organs for transplantation, but must balance this obligation with their duty to protect the interests of their individual patients.

Organ donation after cardiac death is one approach being undertaken to make greater numbers of transplantable organs available. In what is known as "controlled" donation after cardiac death, a patient who has decided to forgo life-sustaining treatment (or the patient's authorized surrogate when the patient lacks decision-making capacity) may be offered the opportunity to discontinue life support under conditions that would permit the patient to become an organ donor by allowing organs to be removed promptly after death is pronounced. Organ retrieval under this protocol thus differs from usual procedures for cadaveric donation when the patient has died as a result of catastrophic illness or injury.

Donation after cardiac death raises a number of special ethical concerns, including how and when death is declared, potential conflicts of interest for physicians in managing the withdrawal of life support for a patient whose organs are to be retrieved for transplantation, and the use of a surrogate decision maker.

In light of these concerns, physicians who participate in retrieving organs under a protocol of donation after cardiac death should observe the following safeguards:

(a) Promote the development of and adhere to clinical criteria for identifying prospective donors whose organs are reasonably likely to be suitable for transplantation.

(b) Promote the development of and adhere to clear and specific institutional policies governing donation after cardiac death.

(c) Avoid actual or perceived conflicts of interest by:

  (i) ensuring that the health care professionals who provide care at the end of life are distinct from those who will participate in retrieving organs for transplant;

(ii) ensuring that no member of the transplant team has any role in the decision to withdraw treatment or the pronouncement of death.

(d) Ensure that the decision to withdraw life-sustaining treatment is made prior to and independent of any offer of opportunity to donate organs (unless organ donation is spontaneously broached by the patient or surrogate).

(e) Obtain informed consent for organ donation from the patient (or surrogate), including consent specifically to the use of interventions intended not to benefit the patient but to preserve organs in order to improve the opportunity for successful transplantation.

(f) Ensure that relevant standards for good clinical practice and palliative care are followed when implementing the decision to withdraw a life-sustaining intervention.

*AMA Principles of Medical Ethics: I,III,V*

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### *6.1.3 Studying Financial Incentives for Cadaveric Organ Donation*

Physicians' ethical obligations to contribute to the health of the public and to support access to medical care extend to participating in efforts to increase the supply of organs for transplantation. However, offering financial incentives for donation raises ethical concerns about potential coercion, the voluntariness of decisions to donate, and possible adverse consequences, including reducing the rate of altruistic organ donation and unduly encouraging perception of the human body as a source of profit.

These concerns merit further study to determine whether, overall, the benefits of financial incentives for organ donation outweigh their potential harms. It would be appropriate to carry out pilot studies among limited populations to investigate the effects of such financial incentives for the purpose of examining and possibly revising current policies in the light of scientific evidence.

Physicians who develop or participate in pilot studies of financial incentives to increase donation of cadaveric organs should ensure that the study:

(a) Is strictly limited to circumstances of voluntary cadaveric donation with an explicit prohibition of the selling of organs.

(b) Is scientifically well designed and clearly defines measurable outcomes and time frames in a written protocol.

(c) Has been developed in consultation with the population among whom it is to be carried out.

(d) Has been reviewed and approved by an appropriate oversight body, such as an institutional review board, and is carried out in keeping with guidelines for ethical research.

(e) Offers incentives of only modest value and at the lowest level that can reasonably be expected to increase organ donation.

*AMA Principles of Medical Ethics: I,III,V,VII,VIII,IX*

### *6.1.4 Presumed Consent & Mandated Choice for Organs from Deceased Donors*

Organ transplantation offers hope for patients suffering end-stage organ failure. However, the supply of organs for transplantation is inadequate to meet the clinical need. Proposals to increase donation have included studying possible financial incentives for donation and changing the approach to consent for cadaveric donation through "presumed consent" and "mandated choice."

Both presumed consent and mandated choice models contrast with the prevailing traditional model of voluntary consent to donation, in which prospective donors indicate their preferences, but the models raise distinct ethical concerns. Under presumed consent, deceased individuals are presumed to be organ donors unless they have indicated their refusal to donate. Donations under presumed consent would be ethically appropriate only if it could be determined that individuals were aware of the presumption that they were willing to donate organs and if effective and easily accessible mechanisms for documenting and honoring refusals to donate had been established. Physicians could proceed with organ procurement based on presumed consent only after verifying that there was no documented prior refusal and that the family was not aware of any objection to donation by the deceased.

Under mandated choice, individuals are required to express their preferences regarding donation at the time they execute a state-regulated task. Donations under mandated choice would be ethically appropriate only if an individual's choice was made on the basis of a meaningful exchange of information about organ donation in keeping with the principles of informed consent. Physicians could proceed with organ procurement based on mandated choice only after verifying that the individual's consent to donate was documented.

These models merit further study to determine whether either or both can be implemented in a way that meets fundamental ethical criteria for informed consent and provides clear evidence that their benefits outweigh ethical concerns.

Physicians who propose to develop or participate in pilot studies of presumed consent or mandated choice should ensure that the study adheres to the following guidelines:

(a) Is scientifically well designed and defines clear, measurable outcomes in a written protocol.

(b) Has been developed in consultation with the population among whom it is to be carried out.

(c) Has been reviewed and approved by an appropriate oversight body and is carried out in keeping with guidelines for ethical research.

Unless there are data that suggest a positive effect on donation, neither presumed consent nor mandated choice for cadaveric organ donation should be widely implemented.

*AMA Principles of Medical Ethics: I,III,V*

### *6.1.5 Umbilical Cord Blood Banking*

Transplants of umbilical cord blood have been recommended or performed to treat a variety of conditions. Cord blood is also a potential source of stem and progenitor cells with possible therapeutic applications. Nonetheless, collection and storage of cord blood raise ethical concerns with regard to patient safety,

autonomy, and potential for conflict of interest. In addition, storage of umbilical cord blood in private as opposed to public banks can raise concerns about access to cord blood for transplantation.

Physicians who provide obstetrical care should be prepared to inform pregnant women of the various options regarding cord blood donation or storage and the potential uses of donated samples.

Physicians who participate in collecting umbilical cord blood for storage should:

(a) Ensure that collection procedures do not interfere with standard delivery practices or the safety of a newborn or the mother.

(b) Obtain informed consent for the collection of umbilical cord blood stem cells before the onset of labor whenever feasible. Physicians should disclose their ties to cord blood banks, public or private, as part of the informed consent process.

(c) Decline financial or other inducements for providing samples to cord blood banks.

(d) Encourage women who wish to donate umbilical cord blood to donate to a public bank if one is available when there is low risk of predisposition to a condition for which umbilical cord blood cells are therapeutically indicated:

(i) in view of the cost of private banking and limited likelihood of use;

(ii) to help increase availability of stem cells for transplantation.

(e) Discuss the option of private banking of umbilical cord blood when there is a family predisposition to a condition for which umbilical cord stem cells are therapeutically indicated.

(f) Continue to monitor ongoing research into the safety and effectiveness of various methods of cord blood collection and use.

*AMA Principles of Medical Ethics: I,V*

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### *6.1.6 Anencephalic Newborns as Organ Donors*

Permitting parents of an anencephalic newborn to donate their child's organs has been proposed as a way to increase the organ supply for pediatric transplantation.

However, organ donation in these circumstances also raises concerns, particularly about the accuracy of diagnosis and the potential implications for other vulnerable individuals who lack decision-making capacity and are not able to participate in decisions to donate their organs, although anencephalic newborns are thought to be unique among other brain- damaged beings because they lack past consciousness and have no potential for future consciousness.

In the context of prospective organ donation from an anencephalic newborn, physicians may ethically:

(a) Provide ventilator assistance and other medical therapies that are necessary to sustain organ perfusion and viability until such time as a determination of death can be made in accordance with accepted medical standards.

(b) Retrieve and transplant the organs of an anencephalic newborn only after such determination of death, and in accordance with ethics guidance for transplantation and for medical decisions for minors.

*AMA Principles of Medical Ethics: I,III,V*

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### *6.2.1 Guidelines for Organ Transplantation from Deceased Donors*

Transplantation offers hope to patients with organ failure. As in all patient-physician relationships, the physician's primary concern must be the well-being of the patient. However, organ transplantation is also unique in that it involves two patients, donor and recipient, both of whose interests must be protected. Concern for the patient should always take precedence over advancing scientific knowledge.

Physicians who participate in transplantation of organs from deceased donors should:

(a) Avoid actual or perceived conflicts of interest by ensuring that:

  (i) to the greatest extent possible that the health care professionals who provide care at the end of life are not directly involved in retrieving or transplanting organs from the deceased donor. Physicians should encourage health care institutions to distinguish the roles of health care professionals who solicit or coordinate organ transplantation from those who provide care at the time of death;

  (ii) no member of the transplant team has any role in the decision to withdraw treatment or the pronouncement of death.

(b) Ensure that death is determined by a physician not associated with the transplant team and in accordance with accepted clinical and ethical standards.

(c) Ensure that transplant procedures are undertaken only by physicians who have the requisite medical knowledge and expertise and are carried out in adequately equipped medical facilities.

(d) Ensure that the prospective recipient (or the recipient's authorized surrogate if the individual lacks decision-making capacity) is fully informed about the procedure and has given voluntary consent in keeping with ethics guidance.

(e) Except in situations of directed donation, ensure that organs for transplantation are allocated to recipients on the basis of ethically sound criteria, including but not limited to likelihood of benefit, urgency of need, change in quality of life, duration of benefit, and, in certain cases, amount of resources required for successful treatment.

(f) Ensure that organs for transplantation are treated as a national, rather than a local or regional, resource.

(g) Refrain from placing transplant candidates on the waiting lists of multiple local transplant centers, but rather place candidates on a single waiting list for each type of organ.

*AMA Principles of Medical Ethics: I,III,V*

### *6.2.2 Directed Donation of Organs for Transplantation*

Efforts to increase the supply of organs available for transplant can serve the interests of individual patients and the public and are in keeping with physicians' obligations to promote the welfare of their patients and to support access to care. Although public solicitations for directed donation—that is, for donation to a specific patient—may benefit individual patients, such solicitations have the potential to adversely affect the equitable distribution of organs among patients in need, the efficacy of the transplant system, and trust in the overall system.

Donation of needed organs to specified recipients has long been permitted in organ transplantation. However, solicitation of organs from potential donors who have no pre-existing relationship with the intended recipient remains controversial. Directed donation policies that produce a net gain of organs for transplantation and do not unreasonably disadvantage other transplant candidates are ethically acceptable.

Physicians who participate in soliciting directed donation of organs for transplantation on behalf of their patients should:

(a) Support ongoing collection of empirical data to monitor the effects of solicitation of directed donations on the availability of organs for transplantation.

(b) Support the development of evidence-based policies for solicitation of directed donation.

(c) Ensure that solicitations do not include potentially coercive inducements. Donors should receive no payment beyond reimbursement for travel, lodging, lost wages, and the medical care associated with donation.

(d) Ensure that prospective donors are fully evaluated for medical and psychosocial suitability by health care professionals who are not part of the transplant team, regardless of any relationship, or lack of relationship, between prospective donor and transplant candidate.

(e) Refuse to participate in any transplant that he or she believes to be ethically improper and respect the decisions of other health care professionals should they choose not to participate on ethical or moral grounds.

*AMA Principles of Medical Ethics: VII,VIII,IX*

### *6.3.1 Xenotransplantation*

Physicians have an obligation to participate in efforts to increase the supply of organs available for transplantation. In fulfilling that obligation, they must also be mindful of their obligations to protect the interests of patients and the welfare of the public. Xenotransplantation, i.e., using organs or tissues from nonhuman animal species for transplantation into human patients, is a possible novel means of addressing the shortage of transplantable organs that can pose distinctive ethical challenges with respect to patient safety and public health.

Some forms of transplantation, implantation, or infusion into a human recipient of organs or tissues from a nonhuman animal source have a significant history in clinical practice—for example the use of porcine heart valves. Other proposed procedures are more controversial and are restricted to research protocols

Physicians who choose to participate in clinical research that involves transplantation of organs or tissues from nonhuman sources should:

(a) Encourage education and public discussion of xenotransplantation in light of the unique risks such procedures pose to individual patients and the public.

(b) Ensure that research in which they participate is well designed and adheres to institutional review board requirements, applicable national guidelines, and ethical standards for research with human participants.

(c) Ensure that research in which they participate is adequately funded to assure lifelong surveillance of xenotransplant recipients and treatment of medical complications related to transplantation.

(d) Ensure that recruitment is restricted to patients with serious or life-threatening conditions for whom no adequately safe and effective alternative therapies are available unless there is documented, very high assurance of safety.

(e) Ensure that if participation by individuals who lack decision-making capacity is contemplated, appropriate measures are taken to safeguard their interests. In exceptional circumstances, minors with substantial decision-making capacity may, with the informed consent of their legal guardians, be considered as recipients in xenotransplantation. When an unemancipated minor proposes to participate in xenotransplantation, it may be appropriate to seek advice from another adult trusted by the minor or to seek consultation with an independent body, such as an ethics committee, pastoral service, or other counseling resource.

(f) Ensure that participants are informed about and consent to the unique risks and burdens posed by xenotransplantation, including:

  (i) novel infectious diseases (zoonoses);

  (ii) potential psychological concerns arising from receiving an organ or tissue from a nonhuman animal;

  (iii) the need for lifelong surveillance and ongoing clinical and laboratory monitoring, with archiving of biological samples when appropriate;

  (iv) the need to inform intimate contacts of potential risk to their health;

  (v) the need for an autopsy when appropriate.

(g) Ensure that high standards of care and humane treatment of all animals used in research are upheld.

*AMA Principles of Medical Ethics: IV,VII*

## CHAPTER 7: OPINIONS ON RESEARCH & INNOVATION

The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.

*7.1 Physician Involvement in Research*


7.1.1 Physician Involvement in Research
7.1.2 Informed Consent in Research
7.1.3 Study Design & Sampling
7.1.4 Conflicts of Interest in Research
7.1.5 Misconduct in Research


*7.2 Disseminating Research Results*


7.2.1 Principles for Disseminating Research Results
7.2.2 Release of Data from Unethical Experiments
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*7.3 Special Issues in Research*


7.3.1 Ethical Use of Placebo Controls in Research
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7.3.7 Safeguards in the Use of DNA Databanks
7.3.8 Research with Stem Cells
7.3.9 Commercial Use of Human Biological Materials
7.3.10 Expanded Access to Investigational Therapies


### *7.1.1 Physician Involvement in Research*

Biomedical and health research is intended to contribute to the advancement of knowledge and the welfare of society and future patients, rather than to the specific benefit of the individuals who participate as research subjects.

However, research involving human participants should be conducted in a manner that minimizes risks and avoids unnecessary suffering. Because research depends on the willingness of participants to accept risk, they must be able to make informed decisions about whether to participate or continue in a given protocol.

Physician researchers share their responsibility for the ethical conduct of research with the institution that carries out research. Institutions have an obligation to oversee the design, conduct, and dissemination of research to ensure that scientific, ethical, and legal standards are upheld. Institutional review boards (IRBs) as well as individual investigators should ensure that each participant has been appropriately informed and has given voluntary consent.

Physicians who are involved in any role in research with human participants have an ethical obligation to ensure that participants' interests are protected and to safeguard participants' welfare, safety, and comfort.

To fulfill these obligations, individually, physicians who are involved in research should:

(a) Participate only in those studies for which they have relevant expertise.

(b) Ensure that voluntary consent has been obtained from each participant or from the participant's legally authorized representative if the participant lacks the capacity to consent, in keeping with ethics guidance. This requires that:

    (i) prospective participants receive the information they need to make well-considered decisions, including informing them about the nature of the research and potential harms involved;

    (ii) physicians make all reasonable efforts to ensure that participants understand the research is not intended to benefit them individually;

    (iii) physicians also make clear that the individual may refuse to participate or may withdraw from the protocol at any time.

(c) Assure themselves that the research protocol is scientifically sound and meets ethical guidelines for research with human participants. Informed consent can never be invoked to justify an unethical study design.

(d) Demonstrate the same care and concern for the well-being of research participants that they would for patients to whom they provide clinical care in a therapeutic relationship. Physician researchers should advocate for access to experimental interventions that have proven effectiveness for patients.

(e) Be mindful of conflicts of interest and assure themselves that appropriate safeguards are in place to protect the integrity of the research and the welfare of human participants.

(f) Adhere to rigorous scientific and ethical standards in conducting, supervising, and disseminating results of the research.

*AMA Principles of Medical Ethics: I,II,III,V*

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### *7.1.2 Informed Consent in Research*

Informed consent is an essential safeguard in research. The obligation to obtain informed consent arises out of respect for persons and a desire to respect the autonomy of the individual deciding whether to volunteer to participate in biomedical or health research. For these reasons, no person may be used as a subject in research against his or her will.

Physicians must ensure that the participant (or legally authorized representative) has given voluntary, informed consent before enrolling a prospective participant in a research protocol. With certain exceptions, to be valid, informed consent requires that the individual have the capacity to provide consent and have sufficient understanding of the subject matter involved to form a decision. The individual's consent must also be voluntary.

A valid consent process includes:

(a) Ascertaining that the individual has decision-making capacity.

(b) Reviewing the process and any materials to ensure that it is understandable to the study population.

(c) Disclosing:

(i) the nature of the experimental drug(s), device(s), or procedure(s) to be used in the research;

(ii) any conflicts of interest relating to the research, in keeping with ethics guidance;

(iii) any known risks or foreseeable hazards, including pain or discomfort that the participant might experience;

(iv) the likelihood of therapeutic or other direct benefit for the participant;

(v) that there are alternative courses of action open to the participant, including choosing standard or no treatment instead of participating in the study;

(vi) the nature of the research plan and implications for the participant;

(vii) the differences between the physician's responsibilities as a researcher and as the patient's treating physician.

(d) Answering questions the prospective participant has.

(e) Refraining from persuading the individual to enroll.

(f) Avoiding encouraging unrealistic expectations.

(g) Documenting the individual's voluntary consent to participate.

Participation in research by minors or other individuals who lack decision-making capacity is permissible in limited circumstances when:

(h) Consent is given by the individual's legally authorized representative, under circumstances in which informed and prudent adults would reasonably be expected to volunteer themselves or their children in research.

(i) The participant gives his or her assent to participation, where possible. Physicians should respect the refusal of an individual who lacks decision-making capacity.

(j) There is potential for the individual to benefit from the study.

In certain situations, with special safeguards in keeping with ethics guidance, the obligation to obtain informed consent may be waived in research on emergency interventions.

*AMA Principles of Medical Ethics: I,III,V*

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### *7.1.3 Study Design & Sampling*

To be ethically justifiable, biomedical and health research that involves human subjects must uphold fundamental principles of respect for persons, beneficence, and justice. These principles apply not only to the conduct of research, but equally to the selection of research topics and study design.

Well-designed, ethically sound research aligns with the goals of medicine, addresses questions relevant to the population among whom the study will be carried out, balances the potential for benefit against the potential for harm, employs study designs that will yield scientifically valid and significant data, and generates useful knowledge. For example, research to develop biological or chemical weapons is antithetical to the goals of the medical profession, whereas research to develop defenses against such weapons can be ethically justifiable.

Physicians who engage in biomedical or health research with human participants thus have an ethical obligation to ensure that any study with which they are involved:

(a) Is consistent with the goals and fundamental values of the medical profession.

(b) Addresses research question(s) that will contribute meaningfully to medical knowledge and practice.

(c) Is scientifically well designed to yield valid data to answer the research question(s), including using appropriate population and sampling controls, clear and appropriate inclusion/exclusion criteria, a statistically sound plan for data collection and analysis, appropriate controls, and when applicable, criteria for discontinuing the study (stopping rules).

(d) Minimizes risks to participants, including risks associated with recruitment and data collection activities, without compromising scientific integrity.

(e) Provides mechanisms to safeguard confidentiality.

(f) Does not disproportionately recruit participants from historically disadvantaged populations or populations whose ability to provide fully voluntary consent is compromised. Participants who otherwise meet inclusion/exclusion criteria should be recruited without regard to race, ethnicity, gender, or economic status.

(g) Recruits participants who lack the capacity to give informed consent only when the study stands to benefit that class of participants and participants with capacity would not yield valid results. In this event, assent should be sought from the participant and consent should be obtained from the prospective participant's legally authorized representative, in keeping with ethics guidance.

(h) Has been reviewed and approved by appropriate oversight bodies.

*AMA Principles of Medical Ethics: I,II,III,V,VII*

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### *7.1.4 Conflicts of Interest in Research*

Increasing numbers of physicians, both within and outside academic health centers, are becoming involved in partnerships with industry to conduct biomedical and health research. As they do so, physicians must be mindful of the conflicts such engagement poses to the integrity of the research and the welfare of human participants. In addition to financial conflicts of interest created by incentives to conduct trials and recruit subjects, physicians must be sensitive to the differing roles of clinician and investigator, which may require them to balance dual commitments to participants and science. This conflict of commitment is particularly acute when a physician-investigator has treated or continues to treat a patient who is eligible to enroll as a participant in a clinical trial the physician is conducting.

Minimizing and mitigating conflicts of interest in clinical research is imperative if the medical community is to justify and maintain trust in the medical research community.

Physicians who engage in research should:

(a) Decline financial compensation that awards in excess of the physician's research efforts and does not reflect fair market value. Physicians should not accept payment solely for referring patients to research studies.

(b) Ensure that the research protocol includes provision for funding participants' medical care in the event of complications associated with the research. A physician should not double-bill a third-party payer for additional expenses related to conducting the trial if he or she has already received funds from a sponsor for those expenses.

(c) As part of the informed consent process, disclose to prospective participants the nature and source of funding and financial incentives offered to the investigators. This disclosure should be included in any written consent materials.

(d) Avoid engaging in any research where there is an understanding that limitations can be placed on the presentation or publication of results by the research sponsor.

(e) Refrain from knowingly participating in a financial relationship with a commercial entity with whom they have a research relationship until the research relationship ends and the research results have been published or otherwise disseminated to the public.

(f) Disclose material ties to companies whose products they are investigating or other ties that create real or perceived conflicts of interest to:

    (i) institutions where the research will be carried out;

    (ii) organizations that are funding the research;

    (iii) any journal or publication where the research results are being submitted.

(g) Physicians who have leadership roles in institutions that conduct biomedical and health research as well as the entities that fund research with human participants should promote the development of guidelines on conflicts of interest that clarify physician-investigators responsibilities.

*AMA Principles of Medical Ethics: II,IV,V*

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### *7.1.5 Misconduct in Research*

Biomedical and health research is intended to advance medical knowledge to benefit future patients. To achieve those goals physicians who are involved in such research maintain the highest standards of professionalism and scientific integrity.

Physicians with oversight responsibilities in biomedical or health research have a responsibility to ensure that allegations of scientific misconduct are addressed promptly and fairly. They should ensure that procedures to resolve such allegations:

(a) Do not damage science.

(b) Resolve charges expeditiously.

(c) Treat all parties fairly and justly. Review procedures should be sensitive to parties' reputations and vulnerabilities.

(d) Maintain the integrity of the process. Real or perceived conflicts of interest must be avoided.

(e) Maintain accurate and thorough documentation throughout the process.

(f) Maintain the highest degree of confidentiality.

(g) Take appropriate action to discharge responsibilities to all individuals involved, as well as to the public, research sponsors, the scientific literature, and the scientific community.

*AMA Principles of Medical Ethics: I,III,V*

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### *7.2.1 Principles for Disseminating Research Results*

Physicians have an ethical responsibility to learn from and contribute to the total store of scientific knowledge. When they engage in biomedical or health research, physicians have obligations as scientists, which include disseminating research findings. Prompt presentation to scientific peers and publication of research findings are foundational to good medical care and promote enhanced patient care, early evaluation of clinical innovations, and rapid dissemination of improved techniques.

To fulfill their ethical responsibilities with respect to sharing research findings for the ultimate benefit of patients, physicians should:

(a) Advocate for timely and transparent dissemination of research data and findings. Physicians should not intentionally withhold information for reasons of personal gain.

(b) Report the results of research accurately, including subsequent negative findings. This is particularly important where the findings do not support the research hypothesis.

(c) Maintain a commitment to peer review.

(d) Disclose sponsorship and conflicts of interest relating to the research, in keeping with ethics guidance.

(e) Be responsible in their release of research results to the media, ensuring that any information the researcher provides is prompt and accurate and that informed consent to the release of information has been obtained from research participants (or participants' legally authorized representative when the participant lacks decision-making capacity) prior to releasing any identifiable information.

In rare circumstances, the potential for misuse of research results could affect the decision about when and whether to disseminate research findings. Physician-researchers should assess foreseeable ramifications of their research in an effort to balance the promise of benefit against potential harms from corrupt application. Only under rare circumstances should findings be withheld, and then only to the extent required to reasonably protect against misuse.

*AMA Principles of Medical Ethics: I,II,III,V,VII*

### *7.2.2 Release of Data from Unethical Experiments*

Research that violates the fundamental principle of respect for persons and basic standards of human dignity, such as Nazi experiments during World War II or from the US Public Health Service Tuskegee Syphilis Study, is unethical and of questionable scientific value. Data obtained from such cruel and inhumane experiments should virtually never be published. If data from unethical experiments can be replaced by data from ethically sound research and achieve the same ends, then such must be done. In the rare instances when ethically tainted data have been validated by rigorous scientific analysis, are the only data of such nature available, and human lives would certainly be lost without the knowledge obtained from the data, it may be permissible to use or publish findings from unethical experiments.

Physicians who engage with data from unethical experiments as authors, peer reviewers, or editors of medical publications should:

(a) Disclose that the data derive from studies that do not meet contemporary standards for the ethical conduct of research.

(b) Clearly describe and acknowledge the unethical nature of the experiment(s) from which the data are derived.

(c) Provide ethically compelling reasons for which the data are being released or cited, such as the need to save human lives when no other relevant data are available.

(d) Pay respect to those who were the victims of the unethical experimentation.

*AMA Principles of Medical Ethics: II,V,VII*

### *7.2.3 Patents & Dissemination of Research Products*

A patent grants the holder the right, for a limited time, to prevent others from commercializing his or her inventions. By requiring full disclosure of the invention, and thus enabling another trained in the art to replicate it, the patent system protects the holder's discovery, yet also fosters information sharing. Patenting is also thought to encourage private investment into research.

With respect to genetic research, patenting raises unique questions. Arguments have been made that the patenting of human genetic material sets a troubling precedent for the ownership or commodification of human life. However, DNA sequences are not tantamount to human life and it is unclear where and whether qualities uniquely human are found in genetic material. Moreover, while genetic research holds great potential for developing new medical therapies it remains unclear what role patenting will play in ensuring such development.

Physicians who develop medical innovations may ethically patent their discoveries or products but should uphold the following guidelines:

(a) Not use patents (or other means, such as trade secrets or confidentiality agreements) to limit the availability of medical innovations. Patent protection should not hinder the goal of achieving better medical treatments and technologies.

(b) Not allow patents to languish. Physicians who hold patents should negotiate and structure licensing agreements in such a way as to encourage the development of better medical technology.

(c) For patents on genetic materials recognize that:

(i) patents on processes, e.g. to isolate and purify gene sequences, are ethically preferable to patents on the substances themselves;

(ii) patents on purified proteins (substance patents) are ethically preferable to patents on genes or DNA sequences.

Descriptions for (substance) patents on proteins, genes, or genetic sequences should be carefully constructed to ensure that the patent holder does not limit the use of a naturally occurring form of the substance in question.

*AMA Principles of Medical Ethics: V,VII*

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### *7.3.1 Ethical Use of Placebo Controls in Research*

A fundamental requirement of biomedical and health research is that it must provide scientifically valid data. In some research, this can best be achieved by comparing an intervention against a control to identify the effects of the intervention. Used appropriately, a placebo control can provide valuable data, particularly when there is no accepted therapy for the condition under study.

The existence of an accepted therapy does not necessarily preclude use of placebo controls, but because use of a placebo deprives participants in the control arm of access to accepted therapy for some period of time, it requires thoughtful ethical justification. In general, the use of a placebo control will more easily be justified as the severity and number of negative side effects of standard therapy increase.

To ensure that the interests of human participants are protected, physician-researchers and those who serve on oversight bodies should give careful attention to issues of methodological rigor, informed consent, characteristics of the medical condition under study, and safety and monitoring, in keeping with the following guidelines:

(a) Evaluate each study protocol to determine whether a placebo control is scientifically necessary or an alternative study design using a different type of control would be sufficient for the purposes of the research. Placebo controls are ethically justifiable when no other research design will yield the requisite data.

(b) Assess the use of placebo controls in relation to the characteristics of the condition under study in keeping with the following considerations:

(i) Studies that involve conditions likely to cause death or irreversible damage cannot ethically employ placebo controls if an alternative therapy would prevent or slow the progression of illness;

(ii) Studies that involve illnesses characterized by severe or painful symptoms require a thorough exploration of alternatives to the use of a placebo control;

(iii) In general, the more severe the consequences or symptoms of the illness under study, the more difficult it will be to justify the use of a placebo control when alternative therapy exists. Consequently, there will almost certainly be conditions for which placebo controls cannot ethically be justified.

(c) Design studies to minimize the amount of time participants are on placebo without compromising the scientific integrity of the study or the value of study data.

(d) Pay particular attention to the informed consent process when enrolling participants in research that uses a placebo control. In addition to general guidelines for informed consent in research, physician-researchers (or other health care professionals) who obtain informed consent from prospective subjects should:

(i) describe the differences among the research arms, emphasizing the essential intervention(s) that will or will not be performed in each;

(ii) be sensitive to the possible need for additional safeguards in the consent process, such as having a neutral third party obtain consent or using a consent monitor to oversee the consent process.

(e) Ensure that interim data analysis and monitoring are in place to allow researchers to terminate a study because of either positive or negative results, thus protecting participants from remaining on placebo longer than needed to ensure the scientific integrity of the study.

(f) Avoid using surgical placebo controls—i.e., a control arm in which participants undergo surgical procedures that have the appearance of therapeutic interventions but during which the essential therapeutic maneuver is not performed—when there is a standard treatment that is efficacious and acceptable to the patient and forgoing standard treatment would result in significant injury. In these situations, physician-researchers must offer standard treatment as part of the study design. Use of surgical placebo controls may be justified when:

(i) an existing, accepted surgical procedure is being tested for efficacy. Use of a placebo control is not justified to test the effectiveness of an innovative surgical technique that represents only a minor modification of an existing, accepted surgical procedure;

(ii) a new surgical procedure is developed with the prospect of treating a condition for which there is no known surgical therapy. In such cases, the use of placebo must be evaluated in light of whether the current standard of care includes a nonsurgical treatment and the risks, benefits, and side effects of that treatment;

(iii) the standard (nonsurgical) treatment is not efficacious or not acceptable to the patient;

(iv) Additional safeguards are in place in the informed consent process.

*AMA Principles of Medical Ethics: I,V*

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### *7.3.2 Research on Emergency Medical Interventions*

Emergency medicine often applies standard interventions that have not been scientifically evaluated for safety and effectiveness in the context of emergency care and may render unsatisfactory outcomes. However, in life-threatening situations, patients may not be able to give informed consent and a surrogate

decision maker may not be readily available, making it challenging to carry out ethically sound research. Soliciting input from the community before a research protocol is approved can help address some concerns, but not all.

Given the insufficiency of standard treatment alternatives, it can be appropriate, in certain situations and with special safeguards, to provide experimental treatment without a participant's informed consent.

To protect the rights and welfare of participants in research on emergency medical interventions, physician-researchers must adhere to the following criteria:

(a) The experimental intervention has a realistic probability of providing benefit equal to or greater than standard care.

(b) The risks associated with the research are reasonable in light of the critical nature of the medical condition and the risks associated with standard treatment.

(c) Study participants are randomized fairly.

(d) The trial is overseen by an independent data and safety monitoring board.

(e) The prospective participant lacks the capacity to give informed consent at the time he or she must be enrolled due to the emergency situation and requirements of the research protocol and it would not have been feasible to obtain prospective informed consent because the life-threatening emergency situation could not have been anticipated.

(f) The window of opportunity to administer the experimental intervention is so narrow as to make it unfeasible to obtain consent from the prospective participant's surrogate or other legally authorized representative.

(g) Participants, or their representatives, are informed as soon as possible that the individual has been enrolled in the research and asked to give consent to further participation.

(h) The representative of a patient who dies while participating in the research must be informed that the individual was involved in an experimental protocol.

(i) Study results will be publicly disclosed.

*AMA Principles of Medical Ethics: I,V*

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### *7.3.3 International Research*

Biomedical and health research in international settings often raises special ethical questions, particularly when research is carried out in resource-poor settings by sponsors or researchers from resource-rich countries. Physicians engaged in international research may encounter differing cultural traditions, economic conditions, health care systems, and ethical or regulatory standards and traditions than in the US.

While fundamental requirements to ensure scientifically sound research and to protect the welfare, safety, and comfort of human participants apply in any research setting, physicians who are involved in international research may need to address special concerns about selection of research topic and study design, informed consent, and the impact of the research on the participating community.

In addition to following general ethical guidelines for biomedical and health research, physicians who are involved in international research have obligations to:

*Study design*

(a) Ensure that the research responds to a medical need in the region in which it is undertaken.

(b) Ensure that the research does not exploit the populations and communities from which participants will be drawn.

(c) Be sensitive to special considerations in assessing the risks and benefits of the research in the particular setting and employ a research design that minimizes risks to the participant population by:

    (i) ascertaining that there is genuine uncertainty within the clinical community about the comparative merits of the experimental intervention and the intervention that will be offered as a control for the population to be enrolled;

    (ii) obtaining relevant input from representatives of the host community and from the research population;

    (iii) considering the harm that is likely to result for the host community or research population if the research is not carried out.

(d) In some instances, a three-pronged protocol that offers the standard of care in the US, an intervention that meets a level of care that can be attained in and sustained by the host community, and a placebo may offer the most ethically desirable means for evaluating the safety and efficacy of an intervention in a given population.

*Informed consent*

(e) Ensure that a suitable process for informed consent is in place. If consent is to be meaningful, physicians (or other health professionals) who obtain consent must communicate with sensitivity to local customs. Notwithstanding, they should always ensure that individual participants are informed and that their voluntary consent is sought.

*Impact on the host community*

(f) Foster research with the potential for lasting benefits to the host community, especially when the research is carried out among populations that are severely deficient in health care resources. This can be achieved by:

    (i) facilitating development of a health care infrastructure that will be of use during and after the research period itself;

    (ii) encouraging sponsors to provide interventions that have been demonstrated to be beneficial to all study participants after the study concludes.

*AMA Principles of Medical Ethics: I,IV,VII,VIII,IX*

### *7.3.4 Maternal-Fetal Research*

Maternal-fetal research, i.e., research intended to benefit pregnant women and/or their fetuses, must balance the health and safety of the woman who participates and the well-being of the fetus with the desire to develop new and innovative therapies. One challenge in such research is that pregnant women may face external pressure or expectations to enroll from partners, family members, or others that may compromise their ability to make a fully voluntary decision about whether to participate.

Physicians engaged in maternal-fetal research should demonstrate the same care and concern for the pregnant woman and fetus that they would in providing clinical care.

In addition to adhering to general guidelines for the ethical conduct of research and applicable law, physicians who are involved in maternal-fetal research should:

(a) Base studies on scientifically sound clinical research with animals and nongravid human participants that has been carried out prior to conducting maternal-fetal research whenever possible.

(b) Enroll a pregnant woman in maternal-fetal research only when there is no simpler, safer intervention available to promote the well-being of the woman or fetus.

(c) Obtain the informed, voluntary consent of the pregnant woman.

(d) Minimize risks to the fetus to the greatest extent possible, especially when the intervention under study is intended primarily to benefit the pregnant woman.

*AMA Principles of Medical Ethics: I,III,V*

### *7.3.5 Research Using Human Fetal Tissue*

Research with human fetal tissue research has led to the development of a number of important research and medical advances, such as the development of polio vaccine. Fetal tissue has also been used to study the mechanism of viral infections and to diagnose viral infections and inherited diseases, as well as to develop transplant therapies for a variety of conditions, for example, parkinsonism.

However, the use of fetal tissue for research purposes also raises a number of ethical considerations, including the degree to which a woman's decision to have an abortion might be influenced by the opportunity to donate fetal tissue. Concerns have also been raised about potential conflict of interest when there is possible financial benefit to those who are involved in the retrieval, storage, testing, preparation, and delivery of fetal tissues.

To protect the interests of pregnant women as well as the integrity of science, physicians who are involved in research that uses human fetal tissues should:

(a) Abstain from offering money in exchange for fetal tissue.

(b) In all instances, obtain the woman's voluntary, informed consent in keeping with ethics guidance, including when using fetal tissue from a spontaneous abortion for purposes of research or transplantation. Informed consent includes a disclosure of the nature of the research including the purpose of using fetal tissue, as well as informing the woman of a right to refuse to participate.

(c) Ensure that when fetal tissue from an induced abortion is used for research purposes:

(i) the woman's decision to terminate the pregnancy is made prior to and independent of any discussion of using the fetal tissue for research purposes;

(ii) decisions regarding the technique used to induce abortion and the timing of the abortion in relation to the gestational age of the fetus are based on concern for the safety of the pregnant woman.

(d) Ensure that when fetal tissue is to be used for transplantation in research or clinical care:

(i) the donor does not designate the recipient of the tissue;

(ii) both the donor and the recipient of the tissue give voluntary, informed consent.

(e) Ensure that health care personnel involved in the termination of a pregnancy do not benefit from their participation in the termination, or from use of the fetal tissue for transplantation.

*AMA Principles of Medical Ethics: I,III,IV,V*

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### *7.3.6 Research in Gene Therapy & Genetic Engineering*

Gene therapy involves the replacement or modification of a genetic variant to restore or enhance cellular function or the improve response to nongenetic therapies. Genetic engineering involves the use of recombinant DNA techniques to introduce new characteristics or traits. In medicine, the goal of gene therapy and genetic engineering is to alleviate human suffering and disease. As with all therapies, this goal should be pursued only within the ethical traditions of the profession, which gives primacy to the welfare of the patient.

In general, genetic manipulation should be reserved for therapeutic purposes. Efforts to enhance "desirable" characteristics or to "improve" complex human traits are contrary to the ethical tradition of medicine. Because of the potential for abuse, genetic manipulation of nondisease traits or the eugenic development of offspring may never be justifiable.

Moreover, genetic manipulation can carry risks to both the individuals into whom modified genetic material is introduced and to future generations. Somatic cell gene therapy targets nongerm cells and thus does not carry risk to future generations. Germ-line therapy, in which a genetic modification is introduced into the genome of human gametes or their precursors, is intended to result in the expression of the modified gene in the recipient's offspring and subsequent generations. Germ-line therapy thus may be associated with increased risk and the possibility of unpredictable and irreversible results that adversely affect the welfare of subsequent generations.

Thus in addition to fundamental ethical requirements for the appropriate conduct of research with human participants, research in gene therapy or genetic engineering must put in place additional safeguards to vigorously protect the safety and well-being of participants and future generations.

Physicians should not engage in research involving gene therapy or genetic engineering with human participants unless the following conditions are met:

(a) Experience with animal studies is sufficient to assure that the experimental intervention will be safe and effective and its results predictable.

(b) No other suitable, effective therapies are available.

(c) Gene therapy is restricted to somatic cell interventions, in light of the far-reaching implications of germ-line interventions.

(d) Evaluation of the effectiveness of the intervention includes determination of the natural history of the disease or condition under study and follow-up examination of the participants' descendants.

(e) The research minimizes risks to participants, including those from any viral vectors used.

(f) Special attention is paid to the informed consent process to ensure that the prospective participant (or legally authorized representative) is fully informed about the distinctive risks of the research, including use of viral vectors to deliver the modified genetic material, possible implications for the participant's descendants, and the need for follow-up assessments.

Physicians should be aware that gene therapy or genetic engineering interventions may require additional scientific and ethical review, and regulatory oversight, before they are introduced into clinical practice.

*AMA Principles of Medical Ethics: I,V,VII*

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### *7.3.7 Safeguards in the Use of DNA Databanks*

DNA databanks facilitate population-based research into the genetic components of complex diseases. These databanks derive their power from integrating genetic and clinical data, as well as data on health, lifestyle, and environment about large samples of individuals. However, the use of DNA databanks in genomic research also raises the possibility of harm to individual participants, their families, and even populations.

Breach of confidentiality of information contained in DNA databanks may result in discrimination or stigmatization and may carry implications for important personal choices, such as reproductive choices. Human participants who contribute to research involving DNA databanks have a right to be informed about the nature and scope of the research and to make decisions about how their information may be used.

In addition to having adequate training to be able to discuss genomic research and related ethical issues with patients or prospective research participants, physician-researchers who are involved in genomic research using DNA databanks should:

*Research involving individuals*

(a) Obtain informed consent from participants in genomic research, in keeping with ethics guidance. In addition, physicians should put special emphasis in the consent process on disclosing:

    (i) the specific privacy standards to which the study will adhere, including whether the information or biological sample will be encrypted and remain identifiable to the researcher or will be completely de-identified;

    (ii) whether participants whose data will be encrypted rather than de-identified can expect to be contacted in the future about findings or be invited to participate in additional research, either related to the current protocol or for other research purposes;

(iii) whether researchers or participants stand to gain financially from research findings, and any conflicts of interest researchers may have in regard to the research, in keeping with ethics guidance;

(iv) when, if ever, archived information or samples will be discarded;

(v) participants' freedom to refuse use of their biological materials without penalty.

*Research involving identifiable communities*

(b) When research is to be conducted within a defined subset of the general population, physicians should:

(i) consult with the community in advance to design a study that is sensitive to community concerns and that will minimize harm for the community, as well as for individual participants. Physicians should not carry out a study when there is substantial opposition to the research within the community of interest;

(ii) protect confidentiality by encrypting any demographic or identifying information that is not required for the study's purpose.

*AMA Principles of Medical Ethics: I,IV,V,VII*

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### *7.3.8 Research with Stem Cells*

Human stem cells are widely seen as offering a source of potential treatment for a range of diseases and are thus the subject of much research. Clinical studies have validated the use of adult stem cells in a limited number of therapies, but have yet to confirm the utility of embryonic stem cells.

Physicians who conduct research using stem cells obtained from any source (established tissue, umbilical cord blood, or embryos) must, at a minimum:

(a) Adhere to institutional review board (IRB) requirements.

(b) Ensure that the research is carried out with appropriate oversight and monitoring.

(c) Ensure that the research is carried out with appropriate informed consent. In addition to disclosure of research risks and potential benefits, at minimum, the consent disclosure should address:

(i) for a donor of cells to be used in stem cell research:

a the process by which stem cells will be obtained;

b. what specifically will be done with the stem cells;

c. whether an immortal cell line will result; and

d. the primary and anticipated secondary uses of donated embryos and/or derived stem cells, including potential commercial uses.

(ii) for a recipient of stem cells in clinical research:

a. the types of tissue from which the stem cells derive (e.g., established tissue, umbilical cord blood, or embryos); and

b. unique risks posed by investigational stem cell products (when applicable), such as tumorigenesis, immunological reactions, unpredictable behavior of cells, and unknown long-term health effects.

The professional community as well as the public remains divided about the use of embryonic stem cells for either research or therapeutic purposes. The conflict regarding research with embryonic stem cells centers on the moral status of embryos, a question that divides ethical opinion and that cannot be resolved by medical science. Regardless whether they are obtained from embryos donated by individuals or couples undergoing in vitro fertilization, or from cloned embryos created by somatic cell nuclear transfer (SCNT), use of embryonic stem cells currently requires the destruction of the human embryo from which the stem cells derive.

The pluralism of moral visions that underlies this debate must be respected. Participation in research involving embryonic stem cells requires respect for embryos, research participants, donors, and recipients. Embryonic stem cell research does not violate the ethical standards of the profession. Every physician remains free to decide whether to participate in stem cell research or to use its products. Physicians should continue to be guided by their commitment to the welfare of patients and the advancement of medical science.

Physicians who conduct research using embryonic stem cells should be able to justify greater risks for subjects, and the greater respect due embryos than stem cells from other sources, based on expectations that the research offers substantial promise of contributing significantly to scientific or therapeutic knowledge.

*AMA Principles of Medical Ethics: V*

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### *7.3.9 Commercial Use of Human Biological Materials*

Research using human tissues has resulted in numerous commercially available products for use in both research and treatment. The development of these products raises questions about who holds property rights in human biological materials, how to distribute profits derived from human tissues equitably, and what constitutes appropriately informed consent when patients donate biological materials to research that may ultimately result in one or more commercial products.

Physicians involved in research with human biological materials should:

(a) Disclose potential commercial applications to the tissue donor before a profit is realized on products developed from biological materials.

(b) Obtain informed consent to use biological materials in research from the tissue donor. Human biological materials and their products may not be used for commercial purposes without the consent of the tissue donor.

(c) Share profits from the commercial use of human biological materials with the tissue donor in accordance with lawful contractual agreements.

Physicians must make diagnostic and treatment recommendations in keeping with standards of good medical practice. They must not allow the commercial potential of the patient's tissue to influence professional judgment.

*AMA Principles of Medical Ethics: II,V*

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### *E-7.3.10 – Expanded Access to Investigational Therapies*

Physicians who care for patients with serious, life-threatening illness for whom standard therapies have failed, are unlikely to be effective, or do not exist should determine whether questions about access to investigational therapy through the U.S. Food and Drug Administration's "expanded access" program are likely to arise in their clinical practice. If so, physicians should familiarize themselves with the program to be better able to engage in shared decision making with patients.

When a patient requests expanded access to an investigational therapy, physicians should:

(a) Assess the patient's individual clinical situation to determine whether an investigational therapy would be appropriate, including:

  (i) whether there is a satisfactory alternative therapy available to diagnose, monitor, or treat the patient's disease or condition;

  (ii) the nature of potential risks of the investigational therapy and whether those risks are not unreasonable in the context of the patient's disease or condition;

  (iii) whether the potential benefit to the patient justifies the risks of the investigational therapy;

  (iv) whether the patient meets inclusion criteria for an existing clinical trial of the investigational therapy.

(b) As part of the informed consent process, advise the patient (or parent/guardian if the patient is a minor) that the investigational therapy has not yet been demonstrated to be effective in treating the patient's condition and may pose as yet unknown risks. Physicians should explain the importance of clinical trials, encourage patients who meet inclusion criteria to participate in an existing trial rather than seek access to investigational therapy through the FDA expanded access program, and direct patients who wish to participate in research to appropriate resources.

(c) Decline to support an application for expanded access to an investigational therapy when:

  (i) the physician judges the treatment with the investigational therapy not to be in the patient's best interest, and explain why; or

(ii) the physician does not have appropriate resources and ability to safely supervise the patient's care under expanded access.

In such cases, physicians should refer the patient to another physician with whom to discuss possible application for expanded access.

(d) Discuss the implications of expanded access for the patient and family and help them form realistic expectations about what it will mean to be treated with the investigational therapy outside a clinical trial. Physicians should alert patients:

(i) to the possibility of financial or other responsibilities associated with receiving an investigational therapy through expanded access;

(ii) to the lack of infrastructure to systematically monitor and evaluate the effects of the investigational therapy outside a clinical trial;

(iii) that they need information about how to contact the manufacturer for guidance if they seek emergency care from a health care professional who is not affiliated with a clinical trial of the investigational therapy;

(iv) that the physician has a responsibility to collect and share clinical information about the patient's course of treatment with the investigational therapy, as well as to report any adverse events that may occur over the course of treatment;

(v) to the conditions under which the physician would recommend stopping treatment with the investigational therapy.

*AMA Principles of Medical Ethics: V,VI*

## CHAPTER 8: OPINIONS ON PHYSICIANS & THE HEALTH OF THE COMMUNITY

The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.


8.1 Routine Universal Screening for HIV
8.2 Impaired Drivers & Their Physicians
8.3 Physicians' Responsibilities in Disaster Response & Preparedness
8.4 Ethical Use of Quarantine & Isolation
8.5 Disparities in Health Care
8.6 Promoting Patient Safety
8.7 Routine Universal Immunization of Physicians
8.8 Required Reporting of Adverse Events
8.9 Expedited Partner Therapy
8.10 Preventing, Identifying & Treating Violence and Abuse
8.11 Health Promotion and Preventive Care
8.12 Ethical Physician Conduct in the Media
8.13 Physician Responsibility for Self-Awareness


### *8.1 Routine Universal Screening for HIV*

Physicians' primary ethical obligation is to their individual patients. However, physicians also have a long-recognized responsibility to participate in activities to protect and promote the health of the public. Routine universal screening of adult patients for HIV helps promote the welfare of individual patients, avoid injury to third parties, and protect public health.

Medical and social advances have enhanced the benefits of knowing one's HIV status and at the same time have minimized the need for specific written informed consent prior to HIV testing. Nonetheless, the ethical tenets of respect for autonomy and informed consent require that physicians continue to seek patients' informed consent, including informed refusal of HIV testing.

To protect the welfare and interests of individual patients and fulfill their public health obligations in the context of HIV, physicians should:

(a) Support routine, universal screening of adult patients for HIV with opt-out provisions.

(b) Make efforts to persuade reluctant patients to be screened, including explaining potential benefits to the patient and to the patient's close contacts.

(c) Continue to uphold respect for autonomy by respecting a patient's informed decision to opt out.

(d) Test patients without prior consent only in limited cases in which the harms to individual autonomy are offset by significant benefits to known third parties, such as testing to protect occupationally exposed health care professionals or patients.

(e) Work to ensure that patients who are identified as HIV positive receive appropriate follow-up care and counseling.

(f) Attempt to persuade patients who are identified as HIV positive to cease endangering others.

(g) Be aware of and adhere to state and local guidelines regarding public health reporting and disclosure of HIV status when a patient who is identified as HIV positive poses significant risk of infecting an identifiable third party. The doctor may, if permitted, notify the endangered third party without revealing the identity of the source person.

(h) Safeguard the confidentiality of patient information to the greatest extent possible when required to report HIV status.

*AMA Principles of Medical Ethics: I,VI,VII*

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### *8.2 Impaired Drivers & Their Physicians*

A variety of medical conditions can impair an individual's ability to operate a motor vehicle safely, whether a personal car or boat or a commercial vehicle, such as a bus, train, plane, or commercial vessel. Those who operate a vehicle when impaired by a medical condition pose threats to both public safety and their own well-being. Physicians have unique opportunities to assess the impact of physical and mental conditions on patients' ability to drive safely and have a responsibility to do so in light of their professional obligation to protect public health and safety. In deciding whether or how to intervene when a patient's medical condition may impair driving, physicians must balance dual responsibilities to promote the welfare and confidentiality of the individual patient, and to protect public safety.

Not all physicians are in a position to evaluate the extent or effect of a medical condition on a patient's ability to drive, particularly physicians who treat patients only on a short-term basis. Nor do all physicians necessarily have appropriate training to identify and evaluate physical or mental conditions in relation to the ability to drive. In such situations, it may be advisable to refer a potentially at-risk patient for assessment.

To serve the interests of their patients and the public, within their areas of expertise physicians should:

(a) Assess at-risk patients individually for medical conditions that might adversely affect driving ability, using best professional judgment and keeping in mind that not all physical or mental impairments create an obligation to intervene.

(b) Tactfully but candidly discuss driving risks with the patient and, when appropriate, the family when a medical condition may adversely affect the patient's ability to drive safely. Help the patient (and family) formulate a plan to reduce risks, including options for treatment or therapy if available, changes in driving behavior, or other adjustments.

(c) Recognize that safety standards for those who operate commercial transportation are subject to governmental medical standards and may differ from standards for private licenses.

(d) Be aware of applicable state requirements for reporting to the licensing authority those patients whose impairments may compromise their ability to operate a motor vehicle safely.

(e) Prior to reporting, explain to the patient (and family, as appropriate) that the physician may have an obligation to report a medically at-risk driver:

    (i) when the physician identifies a medical condition clearly related to the ability to drive;

    (ii) when continuing to drive poses a clear risk to public safety or the patient's own well-being and the patient ignores the physician's advice to discontinue driving; or

(iii) when required by law.

(f) Inform the patient that the determination of inability to drive safely will be made by other authorities, not the physician.

(g) Disclose only the minimum necessary information when reporting a medically at-risk driver, in keeping with ethics guidance on respect for patient privacy and confidentiality.

*AMA Principles of Medical Ethics: I,III,IV,VII*

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### *8.3 Physicians' Responsibilities in Disaster Response & Preparedness*

Whether at the national, regional, or local level, responses to disasters require extensive involvement from physicians individually and collectively. Because of their commitment to care for the sick and injured, individual physicians have an obligation to provide urgent medical care during disasters. This obligation holds even in the face of greater than usual risks to physicians' own safety, health, or life.

However, the physician workforce is not an unlimited resource. Therefore, when providing care in a disaster with its inherent dangers, physicians also have an obligation to evaluate the risks of providing care to individual patients versus the need to be available to provide care in the future.

With respect to disaster, whether natural or manmade, individual physicians should:

(a) Take appropriate advance measures, including acquiring and maintaining appropriate knowledge and skills to ensure they are able to provide medical services when needed.

Collectively, physicians should:

(b) Provide medical expertise and work with others to develop public health policies that:

(i) are designed to improve the effectiveness and availability of medical services during a disaster;

(ii) are based on sound science;

(iii) are based on respect for patients.

(c) Advocate for and participate in ethically sound research to inform policy decisions.

*AMA Principles of Medical Ethics: V,VI,VII,VIII*

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### *8.4 Ethical Use of Quarantine & Isolation*

Although physicians' primary ethical obligation is to their individual patients, they also have a long-recognized public health responsibility. In the context of infectious disease, this may include the use of quarantine and isolation to reduce the transmission of disease and protect the health of the public. In such situations, physicians have a further responsibility to protect their own health to ensure that they remain able to provide care. These responsibilities potentially conflict with patients' rights of self-determination

and with physicians' duty to advocate for the best interests of individual patients and to provide care in emergencies.
With respect to the use of quarantine and isolation as public health interventions in situations of epidemic disease, individual physicians should:

(a) Participate in implementing scientifically and ethically sound quarantine and isolation measures in keeping with the duty to provide care in epidemics.

(b) Educate patients and the public about the nature of the public health threat, potential harm to others, and benefits of quarantine and isolation.

(c) Encourage patients to adhere voluntarily to quarantine and isolation.

(d) Support mandatory quarantine and isolation when a patient fails to adhere voluntarily.

(e) Inform patients about and comply with mandatory public health reporting requirements.

(f) Take appropriate protective and preventive measures to minimize transmission of infectious disease from physician to patient, including accepting immunization for vaccine-preventable disease, in keeping with ethics guidance.

(g) Seek medical evaluation and treatment if they suspect themselves to be infected, including adhering to mandated public health measures.

The medical profession, in collaboration with public health colleagues and civil authorities, has an ethical responsibility to:

(h) Ensure that quarantine measures are ethically and scientifically sound:

  (i) use the least restrictive means available to control disease in the community while protecting individual rights;

  (ii) without bias against any class or category of patients.

(i) Advocate for the highest possible level of confidentiality when personal health information is transmitted in the context of public health reporting.

(j) Advocate for access to public health services to ensure timely detection of risks and implementation of public health interventions, including quarantine and isolation.

(k) Advocate for protective and preventive measures for physicians and others caring for patients with communicable disease.

(l) Develop educational materials and programs about quarantine and isolation as public health interventions for patients and the public.

*AMA Principle of Medical Ethics: I,III,VI,VII,VIII*

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### *8.5 Disparities in Health Care*

Stereotypes, prejudice, or bias based on gender expectations and other arbitrary evaluations of any individual can manifest in a variety of subtle ways. Differences in treatment that are not directly related to

differences in individual patients' clinical needs or preferences constitute inappropriate variations in health care. Such variations may contribute to health outcomes that are considerably worse in members of some populations than those of members of majority populations.

This represents a significant challenge for physicians, who ethically are called on to provide the same quality of care to all patients without regard to medically irrelevant personal characteristics.

To fulfill this professional obligation in their individual practices physicians should:

(a) Provide care that meets patient needs and respects patient preferences.

(b) Avoid stereotyping patients.

(c) Examine their own practices to ensure that inappropriate considerations about race, gender identify, sexual orientation, sociodemographic factors, or other nonclinical factors, do not affect clinical judgment.

(d) Work to eliminate biased behavior toward patients by other health care professionals and staff who come into contact with patients.

(e) Encourage shared decision making.

(f) Cultivate effective communication and trust by seeking to better understand factors that can influence patients' health care decisions, such as cultural traditions, health beliefs and health literacy, language or other barriers to communication and fears or misperceptions about the health care system.

The medical profession has an ethical responsibility to:

(g) Help increase awareness of health care disparities.

(h) Strive to increase the diversity of the physician workforce as a step toward reducing health care disparities.

(i) Support research that examines health care disparities, including research on the unique health needs of all genders, ethnic groups, and medically disadvantaged populations, and the development of quality measures and resources to help reduce disparities.

*AMA Principles of Medical Ethics: I,IV,VII,VIII,IX*

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### *8.6 Promoting Patient Safety*

In the context of health care, an error is an unintended act or omission or a flawed system or plan that harms or has the potential to harm a patient. Patients have a right to know their past and present medical status, including conditions that may have resulted from medical error. Open communication is fundamental to the trust that underlies the patient-physician relationship, and physicians have an obligation to deal honestly with patients at all times, in addition to their obligation to promote patient welfare and safety. Concern regarding legal liability should not affect the physician's honesty with the patient.

Even when new information regarding the medical error will not alter the patient's medical treatment or therapeutic options, individual physicians who have been involved in a (possible) medical error should:

(a) Disclose the occurrence of the error, explain the nature of the (potential) harm, and provide the information needed to enable the patient to make informed decisions about future medical care.

(b) Acknowledge the error and express professional and compassionate concern toward patients who have been harmed in the context of health care.

(c) Explain efforts that are being taken to prevent similar occurrences in the future.

(d) Provide for continuity of care to patients who have been harmed during the course of care, including facilitating transfer of care when a patient has lost trust in the physician.

Physicians who have discerned that another health care professional (may have) erred in caring for a patient should:

(e) Encourage the individual to disclose.

(f) Report impaired or incompetent colleagues in keeping with ethics guidance.

As professionals uniquely positioned to have a comprehensive view of the care patients receive, physicians must strive to ensure patient safety and should play a central role in identifying, reducing, and preventing medical errors. Both as individuals and collectively as a profession, physicians should:

(g) Support a positive culture of patient safety, including compassion for peers who have been involved in a medical error.

(h) Enhance patient safety by studying the circumstances surrounding medical error. A legally protected review process is essential for reducing health care errors and preventing patient harm.

(i) Establish and participate fully in effective, confidential, protected mechanisms for reporting medical errors.

(j) Participate in developing means for objective review and analysis of medical errors.

(k) Ensure that investigation of root causes and analysis of error leads to measures to prevent future occurrences and that these measures are conveyed to relevant stakeholders.

*AMA Principles of Medical Ethics: I,II,III,IV,VIII*

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### *8.7 Routine Universal Immunization of Physicians*

As professionals committed to promoting the welfare of individual patients and the health of the public and to safeguarding their own and their colleagues' well-being, physicians have an ethical responsibility to encourage patients to accept immunization when the patient can do so safely, and to take appropriate measures in their own practice to prevent the spread of infectious disease in health care settings. Conscientious participation in routine infection control practices, such as hand washing and respiratory precautions is a basic expectation of the profession. In some situations, however, routine infection control is not sufficient to protect the interests of patients, the public, and fellow health care workers.

In the context of a highly transmissible disease that poses significant medical risk for vulnerable patients or colleagues, or threatens the availability of the health care workforce, particularly a disease that has potential to become epidemic or pandemic, and for which there is an available, safe, and effective

vaccine, physicians have a responsibility to accept immunization absent a recognized medical contraindication or when a specific vaccine would pose a significant risk to the physician's patients.

Physicians who are not or cannot be immunized have a responsibility to voluntarily take appropriate action to protect patients, fellow health care workers and others. They must adjust their practice activities in keeping with decisions of the medical staff, institutional policy, or public health policy, including refraining from direct patient contact when appropriate.

Physician practices and health care institutions have a responsibility to proactively develop policies and procedures for responding to epidemic or pandemic disease with input from practicing physicians, institutional leadership, and appropriate specialists. Such policies and procedures should include robust infection control practices, provision and required use of appropriate protective equipment, and a process for making appropriate immunization readily available to staff. During outbreaks of vaccine-preventable disease for which there is a safe, effective vaccine, institutions' responsibility may extend to requiring immunization of staff. Physician practices and health care institutions have a further responsibility to limit patient and staff exposure to individuals who are not immunized, which may include requiring unimmunized individuals to refrain from direct patient contact

*AMA Principles of Medical Ethics: I,II*

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***8.8 Required Reporting of Adverse Events***

Physicians' professional commitment to advance scientific knowledge and make relevant information available to patients, colleagues, and the public carries with it the responsibility to report suspected adverse events resulting from the use of a drug or medical device.

Mandated pre- and post-marketing studies provide basic safeguards for public health, but are inherently limited in their ability to detect rare or unexpected consequences of use of a drug or medical device. Thus spontaneous reports of adverse events, especially rare or delayed effects or effects in vulnerable populations are irreplaceable as a source of information about the safety of drugs and devices. As the professionals who prescribe and monitor the use of drugs and medical devices, physicians are best positioned to observe and communicate about adverse events.

Cases in which there is clearly a causal relationship between use of a drug/device and an adverse event, especially a serious event, will be rare. Physicians need not be certain that there is such an event, or even that there is a reasonable likelihood of a causal relationship, to suspect that an adverse event has occurred. A physician who suspects that an adverse reaction to a drug or medical device has occurred has an ethical responsibility to:

(a) Communicate that information to the professional community through established reporting mechanisms.

(b) Promptly report serious adverse events requiring hospitalization, death, or medical or surgical intervention to the appropriate regulatory agency.

*AMA Principles of Medical Ethics: I,V,VII*

***8.9 Expedited Partner Therapy***

Expedited partner therapy seeks to increase the rate of treatment for partners of patients with sexually transmitted infections through patient-delivered therapy without the partner receiving a medical evaluation or professional prevention counseling.

Although expedited partner therapy has been demonstrated to be effective at reducing the burden of certain diseases, such as gonorrhea and chlamydia, it also has ethical implications. Expedited partner therapy potentially abrogates the standard informed consent process, compromises continuity of care for patients' partners, encroaches upon the privacy of patients and their partners, increases the possibility of harm by a medical or allergic reaction, leaves other diseases or complications undiagnosed, and may violate state practice laws.

Before initiating expedited partner therapy, physicians should:

(a) Determine the legal status of expedited partner therapy in the jurisdiction in which they practice.

(b) Seek guidance from public health officials.

(c) Engage in open discussions with patients to ascertain partners' ability to access medical services.

(d) Initiate expedited partner therapy only when the physician reasonably believes that a patient's partner(s) will be unwilling or unable to seek treatment within the context of a traditional patient-physician relationship.

When initiating expedited partner therapy, physicians should:

(e) Instruct patients regarding expedited partner therapy and the medications involved.

(f) Answer any questions the patient has.

(g) Provide to patients educational materials to share with their partners that:

  (i) encourage the partner to consult a physician as a preferred alternative to expedited partner therapy;

  (ii) disclose the risk of potential adverse drug reactions;

  (iii) disclose the possibility of dangerous interactions between the medication delivered by the patient and other medications the partner may be taking;

  (iv) disclose that the partner may be affected by other sexually transmitted diseases that may be left untreated by the medication delivered by the patient.

(h) Make reasonable efforts to refer the patient's partner(s) to appropriate health care professionals.

### *8.10 Preventing, Identifying & Treating Violence & Abuse*

All patients may be at risk for interpersonal violence and abuse, which may adversely affect their health or ability to adhere to medical recommendations. In light of their obligation to promote the well-being of patients, physicians have an ethical obligation to take appropriate action to avert the harms caused by violence and abuse.

To protect patients' well-being, physicians individually should:

(a) Become familiar with:

  (i) how to detect violence or abuse, including cultural variations in response to abuse;

  (ii) community and health resources available to abused or vulnerable persons;

  (iii) public health measures that are effective in preventing violence and abuse;

  (iv) legal requirements for reporting violence or abuse.

(b) Consider abuse as a possible factor in the presentation of medical complaints.

(c) Routinely inquire about physical, sexual, and psychological abuse as part of the medical history.

(d) Not allow diagnosis or treatment to be influenced by misconceptions about abuse, including beliefs that abuse is rare, does not occur in "normal" families, is a private matter best resolved without outside interference, or is caused by victims' own actions.

(e) Treat the immediate symptoms and sequelae of violence and abuse and provide ongoing care for patients to address long-term consequences that may arise from being exposed to violence and abuse.

(f) Discuss any suspicion of abuse sensitively with the patient, whether or not reporting is legally mandated, and direct the patient to appropriate community resources.

(g) Report suspected violence and abuse in keeping with applicable requirements. Before doing so, physicians should:

  (i) inform patients about requirements to report;

  (ii) obtain the patient's informed consent when reporting is not required by law. Exceptions can be made if a physician reasonably believes that a patient's refusal to authorize reporting is coerced and therefore does not constitute a valid informed treatment decision.

(h) Protect patient privacy when reporting by disclosing only the minimum necessary information.

Collectively, physicians should:

(i) Advocate for comprehensive training in matters pertaining to violence and abuse across the continuum of professional education.

(j) Provide leadership in raising awareness about the need to assess and identify signs of abuse, including advocating for guidelines and policies to reduce the volume of unidentified cases and help ensure that all patients are appropriately assessed.
(k) Advocate for mechanisms to direct physicians to community or private resources that might be available to aid their patients.

(l) Support research in the prevention of violence and abuse and collaborate with public health and community organizations to reduce violence and abuse.

(m) Advocate for change in mandatory reporting laws if evidence indicates that such reporting is not in the best interests of patients.

*AMA Principles of Medical Ethics: I,III*

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### *8.11 Health Promotion and Preventive Care*

Medicine and public health share an ethical foundation stemming from the essential and direct role that health plays in human flourishing. While a physician's role tends to focus on diagnosing and treating illness once it occurs, physicians also have a professional commitment to prevent disease and promote health and well-being for their patients and the community.

The clinical encounter provides an opportunity for the physician to engage the patient in the process of health promotion. Effective elements of this process may include educating and motivating patients regarding healthy lifestyle, helping patients by assessing their needs, preferences, and readiness for change and recommending appropriate preventive care measures. Implementing effective health promotion practices is consistent with physicians' duties to patients and also with their responsibilities as stewards of health care resources.

While primary care physicians are typically the patient's main source for health promotion and disease prevention, specialists can play an important role, particularly when the specialist has a close or long-standing relationship with the patient or when recommended action is particularly relevant for the condition that the specialist is treating. Additionally, while all physicians must balance a commitment to individual patients with the health of the public, physicians who work solely or primarily in a public health capacity should uphold accepted standards of medical professionalism by implementing policies that appropriately balance individual liberties with the social goals of public health policies.

Health promotion should be a collaborative, patient-centered process that promotes trust and recognizes patients' self-directed roles and responsibilities in maintaining health. In keeping with their professional commitment to the health of patients and the public, physicians should:

(a) Keep current with preventive care guidelines that apply to their patients and ensure that the interventions they recommend are well supported by the best available evidence.

(b) Educate patients about relevant modifiable risk factors.

(c) Recommend and encourage patients to have appropriate vaccinations and screenings.

(d) Encourage an open dialogue regarding circumstances that may make it difficult to manage chronic conditions or maintain a healthy lifestyle, such as transportation, work and home environments, and social support systems.

(e) Collaborate with the patient to develop recommendations that are most likely to be effective.

(f) When appropriate, delegate health promotion activities to other professionals or other resources available in the community who can help counsel and educate patients.

(g) Consider the health of the community when treating their own patients and identify and notify public health authorities if and when they notice patterns in patient health that may indicate a health risk for others.

(h) Recognize that modeling health behaviors can help patients make changes in their own lives.

Collectively, physicians should:

(i) Promote training in health promotion and disease prevention during medical school, residency and in continuing medical education.

(j) Advocate for healthier schools, workplaces and communities.

(k) Create or promote healthier work and training environments for physicians.

(l) Advocate for community resources designed to promote health and provide access to preventive services.

(m) Support research to improve the evidence for disease prevention and health promotion.

*AMA Principles of Medical Ethics: V,VII*

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### *8.12 Ethical Physician Conduct in the Media*

Physicians who participate in the media can offer effective and accessible medical perspectives leading to a healthier and better informed society. However, ethical challenges present themselves when the worlds of medicine, journalism, and entertainment intersect. In the context of the media marketplace, understanding the role as a physician being distinct from a journalist, commentator, or media personality is imperative.

Physicians involved in the media environment should be aware of their ethical obligations to patients, the public, and the medical profession; and that their conduct can affect their medical colleagues, other health care professionals, as well as institutions with which they are affiliated. They should also recognize that members of the audience might not understand the unidirectional nature of the relationship and might think of themselves as patients. Physicians should:

(a) Always remember that they are physicians first and foremost, and must uphold the values, norms, and integrity of the medical profession.

(b) Encourage audience members to seek out qualified physicians to address the unique questions and concerns they have about their respective care when providing general medical advice.

(c) Be aware of how their medical training, qualifications, experience, and advice are being used by media forums and how this information is being communicated to the viewing public.

(d) Understand that as physicians, they will be taken as authorities when they engage with the media and therefore should ensure that the medical information they provide is:

(i) accurate;

(ii) inclusive of known risks and benefits;

(iii) commensurate with their medical expertise;

(iv) based on valid scientific evidence and insight gained from professional experience.

(e) Confine their medical advice to their area(s) of expertise, and should clearly distinguish the limits of their medical knowledge where appropriate.

(f) Refrain from making clinical diagnoses about individuals (e.g., public officials, celebrities, persons in the news) they have not had the opportunity to personally examine.

(g) Protect patient privacy and confidentiality by refraining from the discussion of identifiable information, unless given specific permission by the patient to do so.

(h) Fully disclose any conflicts of interest and avoid situations that may lead to potential conflicts.

*AMA Principles of Medical Ethics: II,V,VII*

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***8.13 Physician Competence, Self-Assessment and Self-Awareness***

The expectation that physicians will provide competent care is central to medicine. It undergirds professional autonomy and the privilege of self-regulation granted by society. To this end, medical schools, residency and fellowship programs, specialty boards, and other health care organizations regularly assess physicians' technical knowledge and skills.

However, as an ethical responsibility competence encompasses more than medical knowledge and skill. It requires physicians to understand that as a practical matter in the care of actual patients, competence is fluid and dependent on context. Each phase of a medical career, from medical school through retirement, carries its own implications for what a physician should know and be able to do to practice safely and to maintain effective relationships with patients and with colleagues. Physicians at all stages of their professional lives need to be able to recognize when they are and when they are not able to provide appropriate care for the patient in front of them or the patients in their practice as a whole.

To fulfill the ethical responsibility of competence, individual physicians and physicians in training should strive to:

(a) Cultivate continuous self-awareness and self-observation.

(b) Recognize that different points of transition in professional life can make different demands on competence.

(c) Take advantage of well-designed tools for self-assessment appropriate to their practice settings and patient populations.

(d) Seek feedback from peers and others.

(e) Be attentive to environmental and other factors that may compromise their ability to bring appropriate skills to the care of individual patients and act in the patient's best interest.

(f) Maintain their own health, in collaboration with a personal physician, in keeping with ethics guidance on physician health and wellness.

(g) Intervene in a timely, appropriate, and compassionate manner when a colleague's ability to practice safely is compromised by impairment, in keeping with ethics guidance on physician responsibilities to impaired colleagues.

Medicine as a profession should continue to refine mechanisms for assessing knowledge and skill and should develop meaningful opportunities for physicians and physicians in training to hone their ability to be self-reflective and attentive in the moment.

*AMA Principles of Medical Ethics: I,VII,VII*

## CHAPTER 9: OPINIONS ON PROFESSIONAL SELF-REGULATION

The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.

*9.1 Sexual Boundaries*

9.1.1 Romantic or Sexual Relationships with Patients
9.1.2 Romantic or Sexual Relationships with Key Third Parties
9.1.3 Sexual Harassment in the Practice of Medicine

*9.2 Physician Education & Training*

9.2.1 Medical Student Involvement in Patient Care
9.2.2 Resident & Fellow Physicians' Involvement in Patient Care
9.2.3 Performing Procedures on the Newly Deceased
9.2.4 Disputes between Medical Supervisors & Trainees
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9.2.6 Continuing Medical Education
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*9.3 Physician Wellness*

9.3.1 Physician Health & Wellness
9.3.2 Physician Responsibilities to Impaired Colleagues

*9.4 Peer Review & Disciplinary Action*

9.4.1 Peer Review & Due Process
9.4.2 Reporting Incompetent or Unethical Behavior by Colleagues
9.4.3 Discipline & Medicine
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*9.5 Physician Involvement in Health Care Institutions*

9.5.1 Organized Medical Staff
9.5.2 Staff Privileges
9.5.3 Accreditation
9.5.4 Civil Rights & Medical Professionals
9.5.5 Gender Discrimination in Medicine

*9.6 Physician Promotion & Marketing Practices*

9.6.1 Advertising & Publicity
9.6.2 Gifts to Physicians from Industry
9.6.3 Incentives to Patients for Referrals
9.6.4 Sale of Health-Related Products
9.6.5 Sale of Non-Health-Related Goods
9.6.6 Prescribing & Dispensing Drugs & Devices
9.6.7 Direct-to-Consumer Advertisement of Prescription Drugs
9.6.8 Direct-to-Consumer Diagnostic Imaging Tests
9.6.9 Physician Self-Referral

*9.7 Physician Interactions with Government Agencies*

9.7.1 Medical Testimony
9.7.2 Court-Initiated Medical Treatment in Criminal Cases

9.7.3 Capital Punishment
9.7.4 Physician Participation in Interrogation
9.7.5 Torture

### *9.1.1 Romantic or Sexual Relationships with Patients*

Romantic or sexual interactions between physicians and patients that occur concurrently with the patient physician relationship are unethical. Such interactions detract from the goals of the patient-physician relationship and may exploit the vulnerability of the patient, compromise the physician's ability to make objective judgments about the patient's health care, and ultimately be detrimental to the patient's well-being.

A physician must terminate the patient-physician relationship before initiating a dating, romantic, or sexual relationship with a patient.

Likewise, sexual or romantic relationships between a physician and a former patient may be unduly influenced by the previous physician-patient relationship. Sexual or romantic relationships with former patients are unethical if the physician uses or exploits trust, knowledge, emotions, or influence derived from the previous professional relationship, or if a romantic relationship would otherwise foreseeably harm the individual.

In keeping with a physician's ethical obligations to avoid inappropriate behavior, a physician who has reason to believe that nonsexual, nonclinical contact with a patient may be perceived as or may lead to romantic or sexual contact should avoid such contact.

*AMA Principles of Medical Ethics: I,II,IV*

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### *9.1.2 Romantic or Sexual Relationships with Key Third Parties*

Patients are often accompanied by third parties who play an integral role in the patient-physician relationship, including, but not limited to, spouses or partners, parents, guardians, or surrogates. Sexual or romantic interactions between physicians and third parties such as these may detract from the goals of the patient-physician relationship, exploit the vulnerability of the third party, compromise the physician's ability to make objective judgments about the patient's health care, and ultimately be detrimental to the patient's well-being.

Third parties may be deeply involved the in the clinical encounter and in medical decision making. The physician interacts and communicates with these individuals and often is in a position to offer them information, advice, and emotional support. The more deeply involved the individual is in the clinical encounter and in medical decision making, the stronger the argument against sexual or romantic contact between the physician and a key third party. Physicians should avoid sexual or romantic relations with any individual whose decisions directly affect the health and welfare of the patient.

For these reasons, physicians should refrain from sexual or romantic interactions with key third parties when the interaction would exploit trust, knowledge, influence, or emotions derived from a professional relationship with the third party or could compromise the patient's care.

Before initiating a relationship with a key third party, physicians should take into account:

(a) The nature of the patient's medical problem and the likely effect on patient care.

(b) The length of the professional relationship.

(c) The degree of the third party's emotional dependence on the physician.

(d) The importance of the clinical encounter to the third party and the patient.

(e) Whether the patient-physician relationship can be terminated in keeping with ethics guidance and what implications doing so would have for patient.

*AMA Principles of Medical Ethics: I,II*

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### *9.1.3 Sexual Harassment in the Practice of Medicine*

Sexual harassment can be defined as unwelcome sexual advances, requests for sexual favors, and other verbal or physical conduct of a sexual nature.

Sexual harassment in the practice of medicine is unethical. Sexual harassment exploits inequalities in status and power, abuses the rights and trust of those who are subjected to such conduct; interferes with an individual's work performance, and may influence or be perceived as influencing professional advancement in a manner unrelated to clinical or academic performance harm professional working relationships, and create an intimidating or hostile work environment; and is likely to jeopardize patient care. Sexual relationships between medical supervisors and trainees are not acceptable, even if consensual. The supervisory role should be eliminated if the parties wish to pursue their relationship.

Physicians should promote and adhere to strict sexual harassment policies in medical workplaces. Physicians who participate in grievance committees should be broadly representative with respect to gender identity or sexual orientation, profession, and employment status, have the power to enforce harassment policies, and be accessible to the persons they are meant to serve.

*AMA Principles of Medical Ethics: II,IV,VII*

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### *9.2.1 Medical Student Involvement in Patient Care*

Having contact with patients is essential for training medical students, and both patients and the public benefit from the integrated care that is provided by health care teams that include medical students. However, the obligation to develop the next generation of physicians must be balanced against patients' freedom to choose from whom they receive treatment.

All physicians share an obligation to ensure that patients are aware that medical students may participate in their care and have the opportunity to decline care from students. Attending physicians may be best suited to fulfill this obligation. Before involving medical students in a patient's care, physicians should:

(a) Convey to the patient the benefits of having medical students participate in their care.

(b) Inform the patients about the identity and training status of individuals involved in care. Students, their supervisors, and all health care professionals should avoid confusing terms and properly identify themselves to patients.

(c) Inform the patient that trainees will participate before a procedure is undertaken when the patient will be temporarily incapacitated.

(d) Discuss student involvement in care with the patient's surrogate when the patient lacks decision-making capacity.

(e) Confirm that the patient is willing to permit medical students to participate in care.

*AMA Principles of Medical Ethics: V,VII*

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### *9.2.2 Resident & Fellow Physicians' Involvement in Patient Care*

Residents and fellows have dual roles as trainees and caregivers. Residents and fellows share responsibility with physicians involved in their training to facilitate educational and patient care goals.

Residents and fellows are physicians first and foremost and should always regard the interests of patients as paramount. When they are involved in patient care, residents and fellows should:

(a) Interact honestly with patients, including clearly identifying themselves as members of a team that is supervised by the attending physician and clarifying the role they will play in patient care. They should notify the attending physician if a patient refuses care from a resident or fellow.

(b) Participate fully in established mechanisms in their training programs and hospital systems for reporting and analyzing errors. They should cooperate with attending physicians in communicating errors to patients.

(c) Monitor their own health and level of alertness so that these factors do not compromise their ability to care for patients safely. Residents and fellows should recognize that providing patient care beyond time permitted by their programs (for example, "moonlighting" or other activities that interfere with adequate rest during off hours) might be harmful to themselves and patients.

Physicians involved in training residents and fellows should:

(d) Take steps to help ensure that training programs are structured to be conducive to the learning process as well as to promote the patient's welfare and dignity.

(e) Address patient refusal of care from a resident or fellow. If after discussion, a patient does not want to participate in training, the physician may exclude residents or fellows from the patient's care. If appropriate, the physician may transfer the patient's care to another physician or nonteaching service or another health care facility.

(f) Provide residents and fellows with appropriate faculty supervision and availability of faculty consultants, and with graduated responsibility relative to level of training and expertise.

(g) Observe pertinent regulations and seek consultation with appropriate institutional resources, such as an ethics committee, to resolve educational or patient care conflicts that arise in the course of training. All parties involved in such conflicts must continue to regard patient welfare as the first priority. Conflict resolution should not be punitive, but should aim at assisting residents and fellows to complete their training successfully.

*AMA Principles of Medical Ethics: I,II,V,VIII*

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### *9.2.3 Performing Procedures on the Newly Deceased*

Medical training sometimes involves practicing procedures on newly deceased patients, in particular, critical medical skills for which adequate educational alternatives are not available. Such training must balance protecting the interests of newly deceased patients, their families, society, and the profession with the need to educate health care providers.

Physicians should work to develop clear institutional policies for performing procedures on newly deceased patients for training purposes. Before medical trainees practice any procedure on a newly deceased patient, the supervising physician has an ethical responsibility to ensure that:

(a) The interests of all parties are respected and the risks and benefits of permitting the procedure have been carefully considered, including:

  (i) the rights of deceased patients and their families;

  (ii) benefits to trainees and society;

  (iii) risks to trainees, staff, the institution, and the profession.

(b) The procedure is carried out:

  (i) as part of an appropriately structured training sequence;

  (ii) in a manner and an environment that is respectful of the values of all involved parties.

(c) Permitting trainees to perform the procedure is in keeping with the previously expressed preferences of the deceased individual regarding handling of the body or procedures performed after death.

(d) Permission for a trainee to perform the procedure is obtained from the decedent's family if the individual's preferences are not known. Procedures should never be performed for training purposes if the decedent's wishes are not known and permission is not available from an appropriate surrogate.

(e) The procedure is entered in the medical record.

*AMA Principles of Medical Ethics: I,V*

### *9.2.4 Disputes between Medical Supervisors & Trainees*

The relationship between medical students, resident physicians or fellows, and their supervisors is a major determinant of the quality of medical education. When conflicts arise, it is essential to ensure that disputes are resolved fairly.

Retaliatory or punitive actions against those who raise complaints are unethical and are a legitimate cause for filing a grievance with the appropriate institutional committee.

Physicians who are involved in training or supervising medical students, residents, and fellows should ensure that institutional policies and procedures are in place to:

(a) Protect complainants' confidentiality whenever possible, so long as protecting confidentiality does not hinder the subject's ability to respond to the complaint.

(b) Carefully monitor employment and evaluation files to prevent possible tampering.

(c) Permit resident physicians and fellows to access to their employment files and copy the contents, within the provisions of applicable law.

(d) Support medical students, residents, and fellows in fulfilling their responsibility to:

(i) withdraw from care ordered by a supervisor when the trainee believes the order reflects serious errors in clinical or ethical judgment, or physician impairment, that could pose a risk of imminent harm to the patient or others, provided withdrawing does not itself threaten the patient's immediate welfare;

(ii) communicate concerns to the physician issuing the orders and, if necessary, to the persons or institutional programs responsible for mediating such disputes, which may involve third parties.

*AMA Principles of Medical Ethics: II,III,VII*

### *9.2.5 Medical Students Practicing Clinical Skills on Fellow Students*

Medical students often learn basic clinical skills by practicing on classmates, patients, or trained instructors. Unlike patients in the clinical setting, students who volunteer to act as "patients" are not seeking to benefit medically from the procedures being performed on them. Their goal is to benefit from educational instruction, yet their right to make decisions about their own bodies remains.

To protect medical students' privacy, autonomy, and sense of propriety in the context of practicing clinical skills on fellow students, instructors should:

(a) Explain to students how the clinical skills will be performed, making certain that students are not placed in situations that violate their privacy or sense of propriety.

(b) Discuss the confidentiality, consequences, and appropriate management of a diagnostic finding.

(c) Ask students to specifically consent to clinical skills being performed by fellow students. The stringency of standards for ensuring explicit, noncoerced informed consent increases as the invasiveness and intimacy of the procedure increase.

(d) Allow students the choice of whether to participate prior to entering the classroom.

(e) Never require that students provide a reason for their unwillingness to participate.

(f) Never penalize students for refusing to participate. Instructors must refrain from evaluating students' overall performance based on their willingness to volunteer as "patients."

*AMA Principles of Medical Ethics: IV,V*

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### *9.2.6 Continuing Medical Education*

Physicians should strive to further their medical education throughout their careers, to ensure that they serve patients to the best of their abilities and live up to professional standards of excellence.

Participating in certified continuing medical education (CME) activities is critical to fulfilling this professional commitment to lifelong learning. As attendees of CME activities, physicians should:

(a) Select activities that are of high quality and are appropriate for the physician's educational needs.

(b) Choose activities that are carried out in keeping with ethics guidance and applicable professional standards.

(c) Claim only the credit commensurate with the extent of participation in the CME activity.

(d) Decline any subsidy offered by a commercial entity other than the physician's employer to compensate the physician for time spent or expenses of participating in a CME activity.

*AMA Principles of Medical Ethics: I,V*

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### *9.2.7 Financial Relationships with Industry in Continuing Medical Education*

In an environment of rapidly changing information and emerging technology, physicians must maintain the knowledge, skills, and values central to a healing profession. They must protect the independence and commitment to fidelity and service that define the medical profession.

Financial or in-kind support from pharmaceutical, biotechnology or medical device companies that have a direct interest in physicians' recommendations creates conditions in which external interests could influence the availability and/or content of continuing medical education (CME). Financial relationships between such sources and individual physicians who organize CME, teach in CME, or have other roles in continuing professional education can carry similar potential to influence CME in undesired ways.

CME that is independent of funding or in-kind support from sources that have financial interests in physicians' recommendations promotes confidence in the independence and integrity of professional education, as does CME in which organizers, teachers, and others involved in educating physicians do not have financial relationships with industry that could influence their participation. When possible, CME

should be provided without such support or the participation of individuals who have financial interests in the educational subject matter.

In some circumstances, support from industry or participation by individuals who have financial interests in the subject matter may be needed to enable access to appropriate, high-quality CME. In these circumstances, physician-learners should be confident that vigorous efforts will be made to maintain the independence and integrity of educational activities.

Individually and collectively physicians must ensure that the profession independently defines the goals of physician education, determines educational needs, and sets its own priorities for CME. Physicians who attend CME activities should expect that, in addition to complying with all applicable professional standards for accreditation and certification, their colleagues who organize, teach, or have other roles in CME will:

(a) Be transparent about financial relationships that could potentially influence educational activities.

(b) Provide the information physician-learners need to make critical judgments about an educational activity, including:

  (i) the source(s) and nature of commercial support for the activity; and/or

  (ii) the source(s) and nature of any individual financial relationships with industry related to the subject matter of the activity; and

  (iii) what steps have been taken to mitigate the potential influence of financial relationships.

(c) Protect the independence of educational activities by:

  (i) ensuring independent, prospective assessment of educational needs and priorities;

  (ii) adhering to a transparent process for prospectively determining when industry support is needed;

  (iii) giving preference in selecting faculty or content developers to similarly qualified experts who do not have financial interests in the educational subject matter;

  (iv) ensuring a transparent process for making decisions about participation by physicians who may have a financial interest in the educational subject matter;

  (v) permitting individuals who have a substantial financial interest in the educational subject matter to participate in CME only when their participation is central to the success of the educational activity; the activity meets a demonstrated need in the professional community; and the source, nature, and magnitude of the individual's specific financial interest is disclosed; and

  (vi) taking steps to mitigate potential influence commensurate with the nature of the financial interest(s) at issue, such as prospective peer review.

*AMA Principles of Medical Ethics: I,V*

### *9.3.1 Physician Health & Wellness*

When physician health or wellness is compromised, so may the safety and effectiveness of the medical care provided. To preserve the quality of their performance, physicians have a responsibility to maintain their health and wellness, broadly construed as preventing or treating acute or chronic diseases, including mental illness, disabilities, and occupational stress.

To fulfill this responsibility individually, physicians should:

(a) Maintain their own health and wellness by:

(i) following healthy lifestyle habits;

(ii) ensuring that they have a personal physician whose objectivity is not compromised.

(b) Take appropriate action when their health or wellness is compromised, including:

(i) engaging in honest assessment of their ability to continue practicing safely;

(ii) taking measures to mitigate the problem;

(iii) taking appropriate measures to protect patients, including measures to minimize the risk of transmitting infectious disease commensurate with the seriousness of the disease;

(iv) seeking appropriate help as needed, including help in addressing substance abuse. Physicians should not practice if their ability to do so safely is impaired by use of a controlled substance, alcohol, other chemical agent or a health condition.

Collectively, physicians have an obligation to ensure that colleagues are able to provide safe and effective care, which includes promoting health and wellness among physicians.

*AMA Principles of Medical Ethics: I,II,IV*

### *9.3.2 Physician Responsibilities to Impaired Colleagues*

Physical or mental health conditions that interfere with a physician's ability to engage safely in professional activities can put patients at risk, compromise professional relationships, and undermine trust in medicine. While protecting patients' well-being must always be the primary consideration, physicians who are impaired are deserving of thoughtful, compassionate care.

To protect patient interests and ensure that their colleagues receive appropriate care and assistance, individually physicians have an ethical obligation to:

(a) Intervene in a timely manner to ensure that impaired colleagues cease practicing and receive appropriate assistance from a physician health program.

(b) Report impaired colleagues in keeping with ethics guidance and applicable law.

(c) Assist recovered colleagues when they resume patient care.

Collectively, physicians have an obligation to ensure that their colleagues are able to provide safe and effective care. This obligation is discharged by:

(d) Promoting health and wellness among physicians.

(e) Establishing mechanisms to assure that impaired physicians promptly cease practice.

(f) Supporting peers in identifying physicians in need of help.

(g) Establishing or supporting physician health programs that provide a supportive environment to maintain and restore health and wellness.

*AMA Principles of Medical Ethics: II*

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### *9.4.1 Peer Review & Due Process*

Physicians have mutual obligations to hold one another to the ethical standards of their profession. Peer review, by the ethics committees of medical societies, hospital credentials and utilization committees, or other bodies, has long been established by organized medicine to scrutinize professional conduct. Peer review is recognized and accepted as a means of promoting professionalism and maintaining trust. The peer review process is intended to balance physicians' right to exercise medical judgment freely with the obligation to do so wisely and temperately.

Fairness is essential in all disciplinary or other hearings where the reputation, professional status, or livelihood of the physician or medical student may be adversely affected.

Individually, physicians and medical students who are involved in reviewing the conduct of fellow professionals, medical students, residents or fellows should:

(a) Always adhere to principles of a fair and objective hearing, including:

  (i) a listing of specific charges,

  (ii) adequate notice of the right of a hearing,

  (iii) the opportunity to be present and to rebut the evidence, and

  (iv) the opportunity to present a defense.

(b) Ensure that the reviewing body includes a significant number of persons at a similar level of training.

(c) Disclose relevant conflicts of interest and, when appropriate, recuse themselves from a hearing.

Collectively, through the medical societies and institutions with which they are affiliated, physicians should ensure that such bodies provide procedural safeguards for due process in their constitutions and bylaws or policies.

*AMA Principles of Medical Ethics: II,III,VII*

### *9.4.2 Reporting Incompetent or Unethical Behaviors by Colleagues*

Medicine has a long tradition of self-regulation, based on physicians' enduring commitment to safeguard the welfare of patients and the trust of the public. The obligation to report incompetent or unethical conduct that may put patients at risk is recognized in both the ethical standards of the profession and in law and physicians should be able to report such conduct without fear or loss of favor.

Reporting a colleague who is incompetent or who engages in unethical behavior is intended not only to protect patients, but also to help ensure that colleagues receive appropriate assistance from a physician health program or other service to be able to practice safely and ethically. Physicians must not submit false or malicious reports.

Physicians who become aware of or strongly suspect that conduct threatens patient welfare or otherwise appears to violate ethical or legal standards should:

(a) Report the conduct to appropriate clinical authorities in the first instance so that the possible impact on patient welfare can be assessed and remedial action taken. This should include notifying the peer review body of the hospital, or the local or state medical society when the physician of concern does not have hospital privileges.

(b) Report directly to the state licensing board when the conduct in question poses an immediate threat to the health and safety of patients or violates state licensing provisions.

(c) Report to a higher authority if the conduct continues unchanged despite initial reporting.

(d) Protect the privacy of any patients who may be involved to the greatest extent possible, consistent with due process.

(e) Report the suspected violation to appropriate authorities.

Physicians who receive reports of alleged incompetent or unethical conduct should:

(f) Evaluate the reported information critically and objectively.

(g) Hold the matter in confidence until it is resolved.

(h) Ensure that identified deficiencies are remedied or reported to other appropriate authorities for action.

(i) Notify the reporting physician when appropriate action has been taken, except in cases of anonymous reporting.

*AMA Principles of Medical Ethics: II*

### *9.4.3 Discipline & Medicine*

Incompetence, corruption, dishonest, or unethical conduct on the part of members of the medical profession is reprehensible. In addition to posing a real or potential threat to patients, such conduct undermines the public's confidence in the profession. The obligation to address misconduct falls on both individual physicians and on the profession as a whole.

The goal of disciplinary review is both to protect patients and to help ensure that colleagues receive appropriate assistance from a physician health program or other service to enable them to practice safely and ethically. Disciplinary review must not be undertaken falsely or maliciously.

Individually, physicians should report colleagues whose behavior is incompetent or unethical in keeping with ethics guidance.

Collectively, medical societies have a civic and professional obligation to:

(a) Report to the appropriate governmental body or state board of medical examiners credible evidence that may come to their attention involving the alleged criminal conduct of any physician relating to the practice of medicine.

(b) Initiate disciplinary action whenever a physician is alleged to have engaged in misconduct whenever there is credible evidence tending to establish unethical conduct, regardless of the outcome of any civil or criminal proceedings relating to the alleged misconduct.

(c) Impose a penalty, up to and including expulsion from membership, on a physician who violates ethical standards.

*AMA Principles of Medical Ethics: II,III,VII*

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### *9.4.4 Physicians with Disruptive Behavior*

The importance of respect among all health professionals as a means of ensuring good patient care is foundational to ethics. Physicians have a responsibility to address situations in which individual physicians behave disruptively, that is, speak or act in ways that may negatively affect patient care, including conduct that interferes with the individual's ability to work with other members of the health care team, or for others to work with the physician.

Disruptive behavior is different from criticism offered in good faith with the aim of improving patient care and from collective action on the part of physicians. Physicians must not submit false or malicious reports of disruptive behavior.

Physicians who have leadership roles in a health care institution must be sensitive to the unintended effects institutional structures, policies, and practices may have on patient care and professional staff.

As members of the medical staff, physicians should develop and adopt policies or bylaw provisions that:

(a) Establish a body authorized to receive, review, and act on reports of disruptive behavior, such as a medical staff wellness committee. Members must be required to disclose relevant conflicts of interest and to recuse themselves from a hearing.

(b) Establish procedural safeguards that protect due process.

(c) Clearly state principal objectives in terms that ensure high standards of patient care, and promote a professional practice and work environment.

(d) Clearly describe the behaviors or types of behavior that will prompt intervention.

(e) Provide a channel for reporting and appropriately recording instances of disruptive behavior. A single incident may not warrant action, but individual reports may help identify a pattern that requires intervention.

(f) Establish a process to review or verify reports of disruptive behavior.

(g) Establish a process to notify a physician that his or her behavior has been reported as disruptive, and provide opportunity for the physician to respond to the report.

(h) Provide for monitoring and assessing whether a physician's disruptive conduct improves after intervention.

(i) Provide for evaluative and corrective actions that are commensurate with the behavior, such as self-correction and structured rehabilitation. Suspending the individual's responsibilities or privileges should be a mechanism of final resort.

(j) Identify who will be involved in the various stages of the process, from reviewing reports to notifying physicians and monitoring conduct after intervention.

(k) Provide clear guidelines for protecting confidentiality.

(l) Ensure that individuals who report instances of disruptive behavior are appropriately protected.

*AMA Principles of Medical Ethics: I,II,VIII*

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### *9.5.1 Organized Medical Staff*

The organized medical staff performs essential hospital functions even though it may often consist primarily of independent practicing physicians who are not hospital employees. The core responsibilities of the organized medical staff are the promotion of patient safety and the quality of care.

Members of the organized medical staff may choose to act as a group for the purpose of communicating and dealing with the governing board and others with respect to matters that concerns the interest of the organized medical staff and its members. This is ethical so long as there is no adverse effect on patient safety and the quality of care.

*AMA Principles of Medical Ethics: IV,VI*

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### *9.5.2 Staff Privileges*

The purpose of medical staff privileging is to improve the quality and efficiency of patient care in the hospital.

Physicians who are involved in granting, denying, or terminating hospital privileges have an ethical responsibility to be guided by concern for the welfare and best interests of patients. They should:

(a) Base privilege decisions on:

(i) the candidate's training, experience, demonstrated competence;

(ii) the availability of facilities;

(iii) the overall medical needs of the community, the hospital, and especially patients.

(b) Avoid basing privilege decisions on:

(i) numbers of patients the candidate has admitted to the facility;

(ii) economic or insurance status of patients admitted by the candidate;

(iii) personal friendships, antagonisms, jurisdictional disputes, or fear of competition.

*AMA Principles of Medical Ethics: IV,VI,VII*

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### *9.5.3 Accreditation*

Physicians who engage in activities that involve the accreditation, approval, or certification of institutions, facilities, and programs that provide patient care or medical education or certify the attainment of specialized professional competence have the ethical responsibility to develop and apply standards that are:

(a) Relevant, fair, reasonable, and nondiscriminatory.

(b) Focused on the quality of patient care achieved.

They must avoid adopting or using standards as a means of minimizing competition solely for economic gain.

*AMA Principles of Medical Ethics: II,IV,VII*

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### *9.5.4 Civil Rights & Medical Professionals*

Opportunities in medical society activities or membership, medical education and training, employment and remuneration, academic medicine and all other aspects of professional endeavors must not be denied to any physician or medical trainee because of race, color, religion, creed, ethnic affiliation, national origin, gender or gender identity, sexual orientation, age, family status, or disability or for any other reason unrelated to character, competence, ethics, professional status, or professional activities.

*AMA Principles of Medical Ethics: IV*

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### *9.5.5 Gender Discrimination in Medicine*

Inequality of professional status in medicine among individuals based on gender can compromise patient care, undermine trust, and damage the working environment. Physician leaders in medical schools and

medical institutions should advocate for increased leadership in medicine among individuals of underrepresented genders and equitable compensation for all physicians.

Collectively, physicians should actively advocate for and develop family-friendly policies that:

(a) Promote fairness in the workplace, including providing for:

(i) retraining or other programs that facilitate re-entry by physicians who take time away from their careers to have a family;

(ii) on-site child care services for dependent children;

(iii) job security for physicians who are temporarily not in practice due to pregnancy or family obligations.

(b) Promote fairness in academic medical settings by:

(i) ensuring that tenure decisions make allowance for family obligations by giving faculty members longer to achieve standards for promotion and tenure;

(ii) establish more reasonable guidelines regarding the quantity and timing of published material needed for promotion or tenure that emphasize quality over quantity and encourage the pursuit of careers based on individual talent rather than tenure standards that undervalue teaching ability and overvalue research;

(iii) fairly distribute teaching, clinical, research, administrative responsibilities, and access to tenure tracks;

(iv) structuring the mentoring process through a fair and visible system.

(c) Take steps to mitigate gender bias in research and publication.

*AMA Principles of Medical Ethics: II,VII*

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### *9.6.1 Advertising & Publicity*

There are no restrictions on advertising by physicians except those that can be specifically justified to protect the public from deceptive practices. A physician may publicize him or herself as a physician through any commercial publicity or other form of public communication (including any newspaper, magazine, telephone directory, radio, television, direct mail, or other advertising) provided that the communication shall not be misleading because of the omission of necessary material information, shall not contain any false or misleading statement, or shall not otherwise operate to deceive.

Because the public can sometimes be deceived by the use of medical terms or illustrations that are difficult to understand, physicians should design the form of communication to communicate the information contained therein to the public in a readily comprehensible manner. Aggressive, high pressure advertising and publicity should be avoided if they create unjustified medical expectations or are accompanied by deceptive claims. The key issue, however, is whether advertising or publicity, regardless of format or content, is true and not materially misleading.

The communication may include (1) the educational background of the physician, (2) the basis on which fees are determined (including charges for specific services), (3) available credit or other methods of payment, and (4) any other nondeceptive information.

Nothing in this opinion is intended to discourage or to limit advertising and representations which are not false or deceptive within the meaning of Section 5 of the Federal Trade Commission Act. At the same time, however, physicians are advised that certain types of communications have a significant potential for deception and should therefore receive special attention. For example, testimonials of patients as to the physician's skill or the quality of the physician's professional services tend to be deceptive when they do not reflect the results that patients with conditions comparable to the testimoniant's condition generally receive.

Objective claims regarding experience, competence, and the quality of physicians and the services they provide may be made only if they are factually supportable. Similarly, generalized statements of satisfaction with a physician's services may be made if they are representative of the experiences of that physician's patients.

Because physicians have an ethical obligation to share medical advances, it is unlikely that a physician will have a truly exclusive or unique skill or remedy. Claims that imply such a skill or remedy therefore can be deceptive. Statements that a physician has an exclusive or unique skill or remedy in a particular geographic area, if true, however, are permissible. Similarly, a statement that a physician has cured or successfully treated a large number of cases involving a particular serious ailment is deceptive if it implies a certainty of result and creates unjustified and misleading expectations in prospective patients.

Consistent with federal regulatory standards which apply to commercial advertising, a physician who is considering the placement of an advertisement or publicity release, whether in print, radio, or television, should determine in advance that the communication or message is explicitly and implicitly truthful and not misleading. These standards require the advertiser to have a reasonable basis for claims before they are used in advertising. The reasonable basis must be established by those facts known to the advertiser, and those which a reasonable, prudent advertiser should have discovered. Inclusion of the physician's name in advertising may help to assure that these guidelines are being met.

*AMA Principles of Medical Ethics: II*

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### *9.6.2 Gifts to Physicians from Industry*

Relationships among physicians and professional medical organizations and pharmaceutical, biotechnology, and medical device companies help drive innovation in patient care and contribute to the economic well-being of the community to the ultimate benefit of patients and the public. However, an increasingly urgent challenge for both medicine and industry is to devise ways to preserve strong, productive collaborations at the same time that they take clear effective action to prevent relationships that damage public trust and tarnish the reputation of both parties.

Gifts to physicians from industry create conditions that carry the risk of subtly biasing—or being perceived to bias—professional judgment in the care of patients.

To preserve the trust that is fundamental to the patient-physician relationship and public confidence in the profession, physicians should:

(a) Decline cash gifts in any amount from an entity that has a direct interest in physicians' treatment recommendations.

(b) Decline any gifts for which reciprocity is expected or implied.

(c) Accept an in-kind gift for the physician's practice only when the gift:

(i) will directly benefit patients, including patient education; and

(ii) is of minimal value.

(d) Academic institutions and residency and fellowship programs may accept special funding on behalf of trainees to support medical students', residents', and fellows' participation in professional meetings, including educational meetings, provided:

(i) the program identifies recipients based on independent institutional criteria; and

(ii) funds are distributed to recipients without specific attribution to sponsors.

*AMA Principles of Medical Ethics: II*

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### *9.6.3 Incentives to Patients for Referrals*

Endorsement by current patients can be a strong incentive to direct new patients to a medical practice and physicians often rely on word of mouth as a source of referrals. However, to be ethically appropriate, word-of-mouth referrals must be voluntary on the part of current patients and should reflect honestly on the practice.

Physicians must not offer financial incentives or other valuable incentives to current patients in exchange for recruitment of other patients. Such incentives can distort the information patients provide and skew the expectations of prospective patients, thus compromising the trust that is the foundation of patient-physician relationships.

*AMA Principles of Medical Ethics: I,II,VIII*

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### *9.6.4 Sale of Health-Related Products*

The sale of health-related products by physicians can offer convenience for patients, but can also pose ethical challenges. "Health-related products" are any products other than prescription items that, according to the manufacturer or distributor, benefit health. "Selling" refers to dispensing items from the physician's office or website in exchange for money or endorsing a product that the patient may order or purchase elsewhere that results in remuneration for the physician.

Physician sale of health-related products raises ethical concerns about financial conflict of interest, risks placing undue pressure on the patient, threatens to erode patient trust, undermine the primary obligation of physicians to serve the interests of their patients before their own, and demean the profession of medicine.

Physicians who choose to sell health-related products from their offices or through their office website or other online venues have ethical obligations to:

(a) Offer only products whose claims of benefit are based on peer-reviewed literature or other sources of scientific review of efficacy that are unbiased, sound, systematic, and reliable. Physicians should not offer products whose claims to benefit lack scientific validity.

(b) Address conflict of interest and possible exploitation of patients by:

(i) fully disclosing the nature of their financial interest in the sale of the product(s), either in person or through written notification, and informing patients of the availability of the product or other equivalent products elsewhere;

(ii) limiting sales to products that serve immediate and pressing needs of their patients (e.g., to avoid requiring a patient on crutches to travel to a local pharmacy to purchase the product). Distributing products free of charge or at cost makes products readily available and helps to eliminate the elements of personal gain and financial conflict of interest that may interfere, or appear to interfere with the physician's independent medical judgment.

(c) Provide information about the risks, benefits, and limits of scientific knowledge regarding the products in language that is understandable to patients.

(d) Avoid exclusive distributorship arrangements that make the products available only through physician offices. Physicians should encourage manufacturers to make products widely accessible to patients.

*AMA Principles of Medical Ethics: II*

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### *9.6.5 Sale of Non-Health-Related Goods*

Unlike the sale of health-related products, sale of non-health-related products by physicians through their offices or websites, even at cost, does not offer health benefits to patients. The sale of non-health-related goods by physicians presents a conflict of interest and threatens to erode the primary obligation of physicians to serve the interests of their patients before their own. Furthermore, this activity risks placing undue pressure on the patient and demeaning the practice of medicine.

However, such sales can be acceptable under the following limited conditions:

(a) The goods in question are low cost.

(b) The physician takes no share in profit from their sale.

(c) The sale is:

(i) for the benefit of community organizations;

(ii) conducted in a dignified manner;

(iii) conducted in such a way as to assure that patients are not pressured into making purchases;

(iv) not a regular part of the physician's business.

*AMA Principles of Medical Ethics: I,II*

### *9.6.6 Prescribing & Dispensing Drugs & Devices*

In keeping with physicians' ethical responsibility to hold the patient's interests as paramount, in their role as prescribers and dispensers of drugs and devices, physicians should:

(a) Prescribe drugs, devices, and other treatments based solely on medical considerations, patient need, and reasonable expectations of effectiveness for the particular patient.

(b) Dispense drugs in their office practices only if such dispensing primarily benefits the patient.

(c) Avoid direct or indirect influence of financial interests on prescribing decisions by:

(i) declining any kind of payment or compensation from a drug company or device manufacturer for prescribing its products, including offers of indemnification;

(ii) respecting the patient's freedom to choose where to fill prescriptions. In general, physicians should not refer patients to a pharmacy the physician owns or operates.

*AMA Principles of Medical Ethics: II,III,IV,V*

### *9.6.7 Direct-to-Consumer Advertisements of Prescription Drugs*

Direct-to-consumer advertising may raise awareness about diseases and treatment and may help inform patients about the availability of new diagnostic tests, drugs, treatments, and devices. However, direct-to-consumer advertising also carries the risk of creating unrealistic expectations for patients and conflicts of interest for physicians, adversely affecting patients' health and safety, and compromising patient physician relationships.

In the context of direct-to-consumer advertising of prescription drugs, physicians individually should:

(a) Remain objective about advertised tests, drugs, treatments, and devices, avoiding bias for or against advertised products.

(b) Engage in dialogue with patients who request tests, drugs, treatments, or devices they have seen advertised to:

(i) assess and enhance the patient's understanding of the test, drug or device;

(ii) educate patients about why an advertised test, drug, or device may not be suitable for them, including providing cost-effectiveness information about different options.

(c) Resist commercially induced pressure to prescribe tests, drugs, or devices that may not be indicated.

(d) Obtain informed consent before prescribing an advertised test, drug, or device, in keeping with professional standards.

(e) Deny requests for an inappropriate test, drug, or device.

(f) Consider reporting to the sponsoring manufacturer or appropriate authorities direct-to-consumer advertising that:

(i) promotes false expectations;

(ii) does not enhance consumer education;

(iii) conveys unclear, inaccurate, or misleading health education messages;

(iv) fails to refer patients to their physicians for additional information;

(v) does not identify the target population at risk;

(vi) encourages consumer self-diagnosis and treatment.

Collectively, physicians should:

(g) Encourage and engage in studies that examine the impact of direct-to-consumer advertising on patient health and medical care.

(h) Whenever possible, assist authorities to enforce existing law by reporting advertisements that do not:

(i) provide a fair and balanced discussion of the use of the drug product for the disease, disorder, or condition;

(ii) clearly explain warnings, precautions, and potential adverse reactions associated with the drug product;

(iii) present summary information in language that can be understood by the consumer

(iv) comply with applicable regulations;

(v) provide collateral materials to educate both physicians and consumers.

*AMA Principles of Medical Ethics: II,III*

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### *9.6.8 Direct-to-Consumer Diagnostic Imaging Tests*

Diagnostic imaging tests are sometimes marketed directly to consumers before they have been scientifically validated. This can help consumers prevent disease and promote health, but may also expose patients to risk without benefit, create conflicts of interests for physicians, and be abused for profits.

Individually, physicians who offer diagnostic imaging services that have not been scientifically validated and for which a patient has not been referred by another physician have an ethical obligation to:

(a) Perform a requested diagnostic imaging test only when, in the physician's judgment, the possible benefits of the service outweigh its risks.

(b) Recognizing that in agreeing to perform diagnostic imaging on request, the physician:

(i) establishes a patient-physician relationship, with all the ethical and professional obligations such relationship entails;

(ii) assumes responsibility for relevant clinical evaluation, including pre- and post-test counseling about the test, its results, and indicated follow-up. Physicians may choose to refer the patient for post-test counseling to an appropriate physician who accepts the patient.

(c) Obtain the patient's informed consent. In addition to the usual elements of informed consent, the physician should disclose:

(i) that the diagnostic imaging test has not been validated scientifically;

(ii) the inaccuracies inherent in the proposed test;

(iii) the possibility of inconclusive results;

(iv) the likelihood of false positive and false negative results;

(v) circumstances that may require further assessments and additional cost.

(d) Ensure that the patient's interests are primary and place patient welfare above physician interests when the physician has a financial interest in the imaging facility.

(e) Ensure that any advertisements for the services are truthful and not misleading or deceptive, in keeping with ethics guidance and applicable law.

Collectively, physicians should:

(f) Advocate for the conduct of appropriate trials aimed at determining the predictive power of diagnostic imaging tests and their sensitivity and specificity for target populations.

(g) Develop suitable guidelines for specific diagnostic imaging tests when adequate scientific data become available.

*AMA Principles of Medical Ethics: I,II,V,VIII*

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### *9.6.9 Physician Self-Referral*

Business arrangements among physicians in the health care marketplace have the potential to benefit patients by enhancing quality of care and access to health care services. However, these arrangements can also be ethically challenging when they create opportunities for self-referral in which patients' medical interests can be in tension with physicians' financial interests. Such arrangements can undermine a robust commitment to professionalism in medicine as well as trust in the profession.

In general, physicians should not refer patients to a health care facility that is outside their office practice and at which they do not directly provide care or services when they have a financial interest in that facility. Physicians who enter into legally permissible contractual relationships—including acquisition of ownership or investment interests in health facilities, products, or equipment; or contracts for service in group practices—are expected to uphold their responsibilities to patients first.

When physicians enter into arrangements that provide opportunities for self-referral they must:

(a) Ensure that referrals are based on objective, medically relevant criteria.

(b) Ensure that the arrangement:

(i) is structured to enhance access to appropriate, high quality health care services or products; and

(ii) within the constraints of applicable law:

a. does not require physician-owners/investors to make referrals to the entity or otherwise generate revenues as a condition of participation;

b. does not prohibit physician-owners/investors from participating in or referring patients to competing facilities or services; and

c. adheres to fair business practices vis-à-vis the medical professional community—for example, by ensuring that the arrangement does not prohibit investment by nonreferring physicians.

(c) Take steps to mitigate conflicts of interest, including:

(i) ensuring that financial benefit is not dependent on the physician-owner/investor's volume of referrals for services or sales of products;

(ii) establishing mechanisms for utilization review to monitor referral practices; and

(iii) identifying or if possible making alternate arrangements for care of the patient when conflicts cannot be appropriately managed/mitigated.

(d) Disclose their financial interest in the facility, product, or equipment to patients; inform them of available alternatives for referral; and assure them that their ongoing care is not conditioned on accepting the recommended referral.

*AMA Principles of Medical Ethics: II,III,VIII*

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### *9.7.1 Medical Testimony*

Medical evidence is critical in a variety of legal and administrative proceedings. As citizens and as professionals with specialized knowledge and experience, physicians have an obligation to assist in the administration of justice.

Whenever physicians serve as witnesses they must:

(a) Accurately represent their qualifications.

(b) Testify honestly.

(c) Not allow their testimony to be influenced by financial compensation. Physicians must not accept compensation that is contingent on the outcome of litigation.

Physicians who testify as fact witnesses in legal claims involving a patient they have treated must hold the patient's medical interests paramount by:

(d) Protecting the confidentiality of the patient's health information, unless the physician is authorized or legally compelled to disclose the information.

(e) Delivering honest testimony. This requires that they engage in continuous self-examination to ensure that their testimony represents the facts of the case.

(f) Declining to testify if the matters could adversely affect their patients' medical interests unless the patient consents or unless ordered to do so by legally constituted authority.

(g) Considering transferring the care of the patient to another physician if the legal proceedings result in placing the patient and the physician in adversarial positions.

Physicians who testify as expert witnesses must:

(h) Testify only in areas in which they have appropriate training and recent, substantive experience and knowledge.

(i) Evaluate cases objectively and provide an independent opinion.

(j) Ensure that their testimony:

  (i) reflects current scientific thought and standards of care that have gained acceptance among peers in the relevant field;

  (ii) appropriately characterizes the theory on which testimony is based if the theory is not widely accepted in the profession;

  (iii) considers standards that prevailed at the time the event under review occurred when testifying about a standard of care.

Organized medicine, including state and specialty societies and medical licensing boards, has a responsibility to maintain high standards for medical witnesses by assessing claims of false or misleading testimony and issuing disciplinary sanctions as appropriate.

*AMA Principles of Medical Ethics: II,IV,V,VII*

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### *9.7.2 Court-Initiated Medical Treatment in Criminal Cases*

Court-initiated medical treatments raise important questions as to the rights of prisoners, the powers of judges, and the ethical obligations of physicians. Although convicted criminals have fewer rights and protections than other citizens, being convicted of a crime does not deprive an offender of all protections under the law. Court-ordered medical treatments raise the question whether professional ethics permits physicians to cooperate in administering and overseeing such treatment. Physicians have civic duties, but medical ethics do not require a physician to carry out civic duties that contradict fundamental principles of medical ethics, such as the duty to avoid doing harm.

In limited circumstances physicians can ethically participate in court-initiated medical treatments. Individual physicians who provide care under court order should:

(a) Participate only if the procedure being mandated is therapeutically efficacious and is therefore undoubtedly not a form of punishment or solely a mechanism of social control.

(b) Treat patients based on sound medical diagnoses, not court-defined behaviors. While a court has the authority to identify criminal behavior, a court does not have the ability to make a medical diagnosis or to determine the type of treatment that will be administered. When the treatment involves in-patient therapy, surgical intervention, or pharmacological treatment, the physician's diagnosis must be confirmed by an independent physician or a panel of physicians not responsible to the state. A second opinion is not necessary in cases of court-ordered counseling or referrals for psychiatric evaluations.

(c) Decline to provide treatment that is not scientifically validated and consistent with nationally accepted guidelines for clinical practice.

(d) Be able to conclude, in good conscience and to the best of his or her professional judgment, that to the extent possible the patient voluntarily gave his or her informed consent, recognizing that an element of coercion that is inevitably present. When treatment involves in-patient therapy, surgical intervention, or pharmacological treatment, an independent physician or a panel of physicians not responsible to the state should confirm that voluntary consent was given.

*AMA Principles of Medical Ethics: I,III*

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### *9.7.3 Capital Punishment*

Debate over capital punishment has occurred for centuries and remains a volatile social, political, and legal issue. An individual's opinion on capital punishment is the personal moral decision of the individual. However, as a member of a profession dedicated to preserving life when there is hope of doing so, a physician must not participate in a legally authorized execution.

Physician participation in execution is defined as actions that fall into one or more of the following categories:

(a) Would directly cause the death of the condemned.

(b) Would assist, supervise, or contribute to the ability of another individual to directly cause the death of the condemned.

(c) Could automatically cause an execution to be carried out on a condemned prisoner.

These include, but are not limited to:

(d) Determining a prisoner's competence to be executed. A physician's medical opinion should be merely one aspect of the information taken into account by a legal decision maker, such as a judge or hearing officer.

(e) Treating a condemned prisoner who has been declared incompetent to be executed for the purpose of restoring competence, unless a commutation order is issued before treatment begins. The task of re-evaluating the prisoner should be performed by an independent medical examiner.

(f) Prescribing or administering tranquilizers and other psychotropic agents and medications that are part of the execution procedure.

(g) Monitoring vital signs on site or remotely (including monitoring electrocardiograms).

(h) Attending or observing an execution as a physician.

(i) Rendering of technical advice regarding execution.

and, when the method of execution is lethal injection:

(j) Selecting injection sites.

(k) Starting intravenous lines as a port for a lethal injection device.

(l) Prescribing, preparing, administering, or supervising injection drugs or their doses or types.

(m) Inspecting, testing, or maintaining lethal injection devices.

(n) Consulting with or supervising lethal injection personnel.

The following actions do not constitute physician participation in execution:

(o) Testifying as to the prisoner's medical history and diagnoses or mental state as they relate to competence to stand trial, testifying as to relevant medical evidence during trial, testifying as to medical aspects of aggravating or mitigating circumstances during the penalty phase of a capital case, or testifying as to medical diagnoses as they relate to the legal assessment of competence for execution.

(p) Certifying death, provided that the condemned has been declared dead by another person.

(q) Witnessing an execution in a totally nonprofessional capacity.

(r) Witnessing an execution at the specific voluntary request of the condemned person, provided that the physician observes the execution in a nonprofessional capacity.

(s) Relieving the acute suffering of a condemned person while awaiting execution, including providing tranquilizers at the specific voluntary request of the condemned person to help relieve pain or anxiety in anticipation of the execution.

(t) Providing medical intervention to mitigate suffering when an incompetent prisoner is undergoing extreme suffering as a result of psychosis or any other illness.

No physician should be compelled to participate in the process of establishing a prisoner's competence or be involved with treatment of an incompetent, condemned prisoner if such activity is contrary to the physician's personal beliefs. Under those circumstances, physicians should be permitted to transfer care of the prisoner to another physician.

Organ donation by condemned prisoners is permissible only if:

(u) The decision to donate was made before the prisoner's conviction.

(v) The donated tissue is harvested after the prisoner has been pronounced dead and the body removed from the death chamber.

(w) Physicians do not provide advice on modifying the method of execution for any individual to facilitate donation.

*AMA Principles of Medical Ethics: I*

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### *9.7.4 Physician Participation in Interrogation*

Interrogation is defined as questioning related to law enforcement or to military and national security intelligence gathering, designed to prevent harm or danger to individuals, the public, or national security. Interrogations of criminal suspects, prisoners of war, or any other individuals who are being held involuntarily ("detainees") are distinct from questioning used by physicians to assess an individual's physical or mental condition. To be appropriate, interrogations must avoid the use of coercion-–—that is, threatening or causing harm through physical injury or mental suffering.

Physicians who engage in any activity that relies on their medical knowledge and skills must continue to uphold principles of medical ethics. Questions about the propriety of physician participation in interrogations and in the development of interrogation strategies may be addressed by balancing obligations to individuals with obligations to protect third parties and the public. The further removed the physician is from direct involvement with a detainee, the more justifiable is a role serving the public interest.

Applying this general approach, physician involvement with interrogations during law enforcement or intelligence gathering should be guided by the following:

(a) Physicians may perform physical and mental assessments of detainees to determine the need for and to provide medical care. When so doing, physicians must disclose to the detainee the extent to which others have access to information included in medical records. Treatment must never be conditional on a patient's participation in an interrogation.

(b) Physicians must neither conduct nor directly participate in an interrogation, because a role as physician-interrogator undermines the physician's role as healer and thereby erodes trust in the individual physician-interrogator and in the medical profession.

(c) Physicians must not monitor interrogations with the intention of intervening in the process, because this constitutes direct participation in interrogation.

(d) Physicians may participate in developing effective interrogation strategies for general training purposes. These strategies must not threaten or cause physical injury or mental suffering and must be humane and respect the rights of individuals.

When physicians have reason to believe that interrogations are coercive, they must report their observations to the appropriate authorities. If authorities are aware of coercive interrogations but have not intervened, physicians are ethically obligated to report the offenses to independent authorities that have the power to investigate or adjudicate such allegations.

*AMA Principles of Medical Ethics: I,III,VII,VIII*

### *9.7.5 Torture*

Torture refers to the deliberate, systematic, or wanton administration of cruel, inhumane, and degrading treatments or punishments during imprisonment or detainment.

Physicians must oppose and must not participate in torture for any reason. Participation in torture includes, but is not limited to, providing or withholding any services, substances, or knowledge to facilitate the practice of torture. Physicians must not be present when torture is used or threatened.

Physicians may treat prisoners or detainees if doing so is in their best interest, but physicians should not treat individuals to verify their health so that torture can begin or continue.

Physicians who treat torture victims should not be persecuted.

Physicians should help provide support for victims of torture and, whenever possible, strive to change situations in which torture is practiced or the potential for torture is great.

*AMA Principles of Medical Ethics: I,III*

## CHAPTER 10: OPINIONS ON INTER-PROFESSIONAL RELATIONSHIPS

The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.


10.1 Ethics Guidance for Physicians in Nonclinical Roles
10.1.1 Ethical Obligations of Medical Directors
10.2 Physician Employment by a Nonphysician Supervisee
10.3 Peers as Patients
10.4 Nurses
10.5 Allied Health Professionals
10.6 Industry Representatives in Clinical Settings
10.7 Ethics Committees in Health Care Institutions
10.7.1 Ethics Consultations
10.8 Collaborative Care


### *10.1 Ethics Guidance for Physicians in Nonclinical Roles*

Physicians earn and maintain the trust of their patients and the public by upholding norms of fidelity to patients, on which the physician's professional identity rests.

Even when they fulfill roles that do not involve directly providing care for patients in clinical settings, physicians are seen by patients and the public, as well as their colleagues and coworkers as professionals who have committed themselves to the values and norms of medicine. Whatever roles they may play in the system of health care delivery, when physicians use the knowledge and values they gained through medical training and practice in roles that affect the care and well-being of individual patients or groups of patients, they are functioning within the sphere of their profession.

When physicians take on obligations that compete with their fiduciary obligations to patients, those fiduciary obligations may ethically be tempered by the following considerations:

(a) The impact of the nonclinical role on the health of individuals and communities.

(b) The degree to which they are perceived to be acting as representatives of the medical profession.

(c) The extent to which they rely on their medical training or expertise to fulfill the nonclinical role.

*AMA Principles of Medical Ethics: I,VII*

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### *10.1.1 Ethical Obligations of Medical Directors*

Physicians' core professional obligations include acting in and advocating for patients' best interests. When they take on roles that require them to use their medical knowledge on behalf of third parties, physicians must uphold these core obligations.

When physicians accept the role of medical director and must make benefit coverage determinations on behalf of health plans or other third parties or determinations about individuals' fitness to engage in an activity or need for medical care, they should:

(a) Use their professional expertise to help craft plan guidelines to ensure that all enrollees receive fair, equal consideration.

(b) Review plan policies and guidelines to ensure that decision-making mechanisms:

(i) are objective, flexible, and consistent;

(ii) rest on appropriate criteria for allocating medical resources in accordance with ethics guidance.

(c) Apply plan policies and guidelines evenhandedly to all patients.

(d) Encourage third-party payers to provide needed medical services to all plan enrollees and to promote access to services by the community at large.

(e) Put patient interests over personal interests (financial or other) created by the nonclinical role.

*AMA Principles of Medical Ethics: I,III,VII*

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### *10.2 Physician Employment by a Nonphysician Supervisee*

Physicians' relationships with midlevel practitioners must be based on mutual respect and trust as well as their shared commitment to patient well-being. Health care professionals recognize that clinical tasks should be shared and delegated in keeping with each practitioner's training, expertise, and scope of practice. Given their comprehensive training and broad scope of practice, physicians have a professional responsibility for the quality of overall care that patients receive, even when aspects of that care are delivered by nonphysician clinicians.

Accepting employment to supervise a nonphysician employer's clinical practice can create ethical dilemmas for physicians. If maintaining an employment relationship with a midlevel practitioner contributes significantly to the physician's livelihood, the personal and financial influence that employer status confers creates an inherent conflict for a physician who is simultaneously an employee and a clinical supervisor of his or her employer.

Physicians who are simultaneously employees and clinical supervisors of nonphysician practitioners must:

(a) Give precedence to their ethical obligation to act in the patient's best interest.

(b) Exercise independent professional judgment, even if that puts the physician at odds with the employer-supervisee.

*AMA Principles of Medical Ethics: II,VI,VIII*

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### *10.3 Peers as Patients*

The opportunity to care for a fellow physician is a privilege or physician-in-training and may represent a gratifying experience and serve as a show of respect or competence. However, physicians must recognize that providing medical care for a fellow professional can pose special challenges for objectivity, open exchange of information, privacy and confidentiality, and informed consent.

In emergencies or isolated rural settings when options for care by other physicians are limited or where there is no other qualified physician available, physicians should not hesitate to treat colleagues.

Physicians must make the same fundamental ethical commitments when treating peers as when treating any other patient. Physicians who provide medical care to a colleague should:

(a) Exercise objective professional judgment and make unbiased treatment recommendations despite the personal or professional relationship they may have with the patient.

(b) Be sensitive to the potential psychological discomfort of the physician-patient, especially when eliciting sensitive information or conducting an intimate examination.

(c) Respect the physical and informational privacy of physician-patients. Discuss how to respond to inquiries about the physician-patient's medical care from colleagues. Recognize that special measures may be needed to ensure privacy.

(d) Provide information to enable the physician-patient to make voluntary, well-informed decisions about care. The treating physician should not assume that the physician-patient is knowledgeable about his or her medical condition.

Physicians-in-training and medical students (when they provide care as part of their supervised training) face unique challenges when asked to provide or participate in care for peers, given the circumstances of their roles in residency programs and medical schools. Except in emergency situations or when other care is not available, physicians-in-training should not be required to provide medical care for fellow trainees, faculty members, or attending physicians if they are reluctant to do so.

*AMA Principles of Medical Ethics: VI*

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***10.4 Nurses***

Like physicians, nurses hold a primary ethical obligation to promote patients' well-being. Nurses' training, expertise, and scope of practice complement physicians' professional commitments and expertise.

While physicians have overall responsibility for the quality of care that patients receive, good nursing practice requires that nurses voice their concerns when, in the nurse's professional judgment, a physician order is in error or is contrary to good medical practice.

In light of their shared professional commitments, physicians' relationships with nurses should be based on mutual respect and trust. As leaders of the health care team, physicians should:

(a) Listen respectfully and take seriously the concerns a nurse raises about the physician's order and explain the order to the nurse and modify if appropriate.

(b) Recognize nurses' professional responsibility not to follow orders that are contrary to good medical practice.

(c) Acknowledge that in an emergency situation when the physician is not immediately available, nurses may have a professional obligation to take prompt action contrary to the physician's order to protect the patient's health.

(d) Seek assistance from the ethics committee or other institutional resource to resolve disagreement in nonemergent situations when disagreement about patient care persists.

*AMA Principles of Medical Ethics: IV,V*

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### *10.5 Allied Health Professionals*

Physicians often practice in concert with optometrists, nurse anesthetists, nurse midwives, and other allied health professionals. Although physicians have overall responsibility for the quality of care that patients receive, allied health professionals have training and expertise that complements physicians'. With physicians, allied health professionals share a common commitment to patient well-being.

In light of this shared commitment, physicians' relationships with allied health professionals should be based on mutual respect and trust. It is ethically appropriate for physicians to:

(a) Help support high quality education that is complementary to medical training, including by teaching in recognized schools for allied health professionals.

(b) Work in consultation with or employ appropriately trained and credentialed allied health professionals.

(c) Delegate provision of medical services to an appropriately trained and credentialed allied health professional within the individual's scope of practice.

*AMA Principles of Medical Ethics: I,V,VII*

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### *10.6 Industry Representatives in Clinical Settings*

Representatives of medical device manufacturers can play an important role in patient safety and quality of care by providing information about the proper use of their companies' devices or equipment and by offering technical assistance to physicians. However, allowing industry representative to be present in clinical settings while care is being given also raises concerns. Their presence can raise pose challenges for patient autonomy, privacy, and confidentiality as well as safety and professionalism in care-giving.

Physicians have a responsibility to protect patient interests and thus have a corresponding obligation to exercise good professional judgment in inviting industry representatives into the clinical setting. Physicians should recognize that in this setting appropriately trained industry representatives function as consultants. Participation by industry representatives should not be allowed to substitute for training physicians to use devices and equipment safely themselves.

Physicians who invite industry representatives into the clinical setting should ensure that:

(a) The representative's participation will improve the safety and effectiveness of patient care.

(b) The representative's qualifications to provide the desired assistance have been appropriately screened.

(c) The patient is aware that an industry representative will facilitate care, has been informed about the scope and nature of the representative's role in care, and has agreed to the representative's participation.

(d) The representative understands and is committed to upholding medical standards of respect for patient privacy and confidentiality.

(e) The representative has agreed to abide by the policies of the health care institution governing his or her presence and clinical activities.

(f) The representative does not exceed the bounds of his or her training, is adequately supervised, and does not engage in the practice of medicine.

*AMA Principles of Medical Ethics: I,IV,V*

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### *10.7 Ethics Committees in Health Care Institutions*

In making decisions about health care, patients, families, and physicians and other health care professionals often face difficult, potentially life-changing situations. Such situations can raise ethically challenging questions about what would be the most appropriate or preferred course of action. Ethics committees, or similar institutional mechanisms, offer assistance in addressing ethical issues that arise in patient care and facilitate sound decision making that respects participants' values, concerns, and interests.

In addition to facilitating decision making in individual cases (as a committee or through the activities of individual members functioning as ethics consultants), many ethics committees assist ethics-related educational programming and policy development within their institutions.

To be effective in providing the intended support and guidance in any of these capacities, ethics committees should:

(a) Serve as advisors and educators rather than decision makers. Patients, physicians and other health care professionals, health care administrators, and other stakeholders should not be required to accept committee recommendations. Physicians and other institutional stakeholders should explain their reasoning when they choose not to follow the committee's recommendations in an individual case.

(b) Respect the rights and privacy of all participants and the privacy of committee deliberations and take appropriate steps to protect the confidentiality of information disclosed during the discussions.

(c) Ensure that all stakeholders have timely access to the committee's services for facilitating decision making in nonemergent situations and as feasible for urgent consultations.

(d) Be structured, staffed, and supported appropriately to meet the needs of the institution and its patient population. Committee membership should represent diverse perspectives, expertise, and experience, including one or more community representatives.

(e) Adopt and adhere to policies and procedures governing the committee and, where appropriate, the activities of individual members as ethics consultants, in keeping with medical staff by-laws. This includes standards for resolving competing responsibilities and for documenting committee recommendations in the patient's medical record when facilitating decision making in individual cases.

(f) Draw on the resources of appropriate professional organizations, including guidance from national specialty societies, to inform committee recommendations.

Ethics committees that serve faith-based or other mission-driven heath care institutions have a dual responsibility to:

(g) Uphold the principles to which the institution is committed.

(h) Make clear to patients, physicians, and other stakeholders that the institution's defining principles will inform the committee's recommendations.

*AMA Principles of Medical Ethics: II,IV,VII*

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### *10.7.1 Ethics Consultations*

The goal of ethics consultation is to support informed, deliberative decision making on the part of patients, families, physicians, and the health care team. By helping to clarify ethical issues and values, facilitating discussion, and providing expertise and educational resources, ethics consultants promote respect for the values, needs, and interests of all participants, especially when there is disagreement or uncertainty about treatment decisions.

Whether they serve independently or through an institutional ethics committee or similar mechanism, physicians who provide ethics consultation services should:

(a) Seek to balance the concerns of all stakeholders, focusing on protecting the patient's needs and values.

(b) Serve as advisors and educators rather than decision makers. Patients, physicians, and other members of the care team, health care administrators, and other stakeholders should not be required to accept the consultant's recommendations. Physicians and other institutional stakeholders should explain their reasoning when they choose not to follow the consultant's recommendations in an individual case.

(c) Inform the patients when an ethics consultation has been requested (if the request was not made by the patient or family) and seek patients' agreement to participate. Ethics consultants should respect the decision of a patient or family not to participate, whether that decision is indicated formally through explicit refusal or informally by not taking part in discussions.

(d) Respect the rights and privacy of all participants and ensure that appropriate steps are taken to protect the confidentiality of information disclosed in the consultation.

(e) Have appropriate expertise or training—for example, familiarity with the relevant professional literature, training in clinical/philosophical ethics, or competence in conflict resolution— and relevant experience to fulfill their role effectively.

(f) Adopt and adhere to policies and procedures governing ethics consultation activities in keeping with medical staff bylaws, including accountability and standards for documenting the consultation in the patient's medical record.

(g) Ensure that all stakeholders have timely access to consultation services in nonemergent situations and as feasible for urgent consultations.

*AMA Principles of Medical Ethics: IV,V*

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*10.8 Collaborative Care*

In health care, teams that collaborate effectively can enhance the quality of care for individual patients. By being prudent stewards and delivering care efficiently, teams also have the potential to expand access to care for populations of patients. Such teams are defined by their dedication to providing patient-centered care, protecting the integrity of the patient-physician relationship, sharing mutual respect and trust, communicating effectively, sharing accountability and responsibility, and upholding common ethical values as team members.

An effective team requires the vision and direction of an effective leader. In medicine, this means having a clinical leader who will ensure that the team as a whole functions effectively and facilitates decision-making. Physicians are uniquely situated to serve as clinical leaders. By virtue of their thorough and diverse training, experience, and knowledge, physicians have a distinctive appreciation of the breadth of health issues and treatments that enables them to synthesize the diverse professional perspectives and recommendations of the team into an appropriate, coherent plan of care for the patient.

As leaders within health care teams, physicians individually should:

(a) Model ethical leadership by:

  (i) understanding the range of their own and other team members' skills and expertise and roles in the patient's care;

  (ii) clearly articulating individual responsibilities and accountability;

  (iii) encouraging insights from other members and being open to adopting them; and

  (iv) mastering broad teamwork skills.

(b) Promote core team values of honesty, discipline, creativity, humility, and curiosity and commitment to continuous improvement.

(c) Help clarify expectations to support systematic, transparent decision making.

(d) Encourage open discussion of ethical and clinical concerns and foster a team culture in which each member’s opinion is heard and considered and team members share accountability for decisions and outcomes.

(e) Communicate appropriately with the patient and family and respect their unique relationship as members of the team.

As leaders within health care institutions, physicians individually and collectively should:

(f) Advocate for the resources and support health care teams need to collaborate effectively in providing high-quality care for the patients they serve, including education about the principles of effective teamwork and training to build teamwork skills.

(g) Encourage their institutions to identify and constructively address barriers to effective collaboration.

(h) Promote the development and use of institutional policies and procedures, such as an institutional ethics committee or similar resource, to address constructively conflicts within teams that adversely affect patient care.

*AMA Principles of Medical Ethics II,V,VIII*

## CHAPTER 11: OPINIONS ON FINANCING & DELIVERY OF HEALTH CARE

The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.

*11.1 Access to Health Care*


11.1.1 Defining Basic Health Care
11.1.2 Physician Stewardship of Health Care Resources
11.1.3 Allocating Limited Health Care Resources
11.1.4 Financial Barriers to Health Care Access


*11.2 Health Care Organizations & Physician Practice*


11.2.1 Professionalism in Health Care Systems
11.2.2 Conflicts of Interest in Patient Care
11.2.3 Contracts to Deliver Health Care Services
11.2.3.1 Restrictive Covenants
11.2.4 Transparency in Health Care
11.2.5 Retainer Practices
11.2.6 Mergers of Secular and Religiously Affiliated Health Care Institutions


*11.3 Fees & Charges*


11.3.1 Fees for Medical Services
11.3.2 Fees for Nonclinical & Administrative Services
11.3.3 Interest & Finance Charges
11.3.4 Fee Splitting


### *11.1.1 Defining Basic Health Care*

Health care is a fundamental human good because it affects our opportunity to pursue life goals, reduces our pain and suffering, helps prevent premature loss of life, and provides information needed to plan for our lives. Society has an obligation to make access to an adequate level of care available to all its members, regardless of ability to pay.

Physicians regularly confront the effects of lack of access to adequate care and have a corresponding responsibility to contribute their expertise to societal decisions about what health care services should be included in a minimum package of care for all.

Individually and collectively as a profession, physicians should advocate for fair, informed decision making about basic health care that:

(a) Is transparent.

(b) Strives to include input from all stakeholders, including the public, throughout the process.

(c) Protects the most vulnerable patients and populations, with special attention to historically disadvantaged groups.

(d) Considers best available scientific data about the efficacy and safety of health care services.

(e) Seeks to improve health outcomes to the greatest extent possible, in keeping with principles of wise stewardship.

(f) Monitors for variations in care that cannot be explained on medical grounds to ensure that the defined threshold of basic care does not have discriminatory impact.

(g) Provides for ongoing review and adjustment in consideration of innovation in medical science and practice to ensure continued, broad public support for the defined threshold of basic care.

*AMA Principles of Medical Ethics: VII*

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### *11.1.2 Physician Stewardship of Health Care Resources*

Physicians' primary ethical obligation is to promote the well-being of individual patients. Physicians also have a long-recognized obligation to patients in general to promote public health and access to care. This obligation requires physicians to be prudent stewards of the shared societal resources with which they are entrusted. Managing health care resources responsibly for the benefit of all patients is compatible with physicians' primary obligation to serve the interests of individual patients.

To fulfill their obligation to be prudent stewards of health care resources, physicians should:

(a) Base recommendations and decisions on patients' medical needs.

(b) Use scientifically grounded evidence to inform professional decisions when available.

(c) Help patients articulate their health care goals and help patients and their families form realistic expectations about whether a particular intervention is likely to achieve those goals.

(d) Endorse recommendations that offer reasonable likelihood of achieving the patient's health care goals.

(e) Choose the course of action that requires fewer resources when alternative courses of action offer similar likelihood and degree of anticipated benefit compared to anticipated harm for the individual patient but require different levels of resources.

(f) Be transparent about alternatives, including disclosing when resource constraints play a role in decision making.

(g) Participate in efforts to resolve persistent disagreement about whether a costly intervention is worthwhile, which may include consulting other physicians, an ethics committee, or other appropriate resource.

Physicians are in a unique position to affect health care spending. But individual physicians alone cannot and should not be expected to address the systemic challenges of wisely managing health care resources. Medicine as a profession must create conditions for practice that make it feasible for individual physicians to be prudent stewards by:

(h) Encouraging health care administrators and organizations to make cost data transparent (including cost accounting methodologies) so that physicians can exercise well-informed stewardship.

(i) Ensuring that physicians have the training they need to be informed about health care costs and how their decisions affect overall health care spending.

(j) Advocating for policy changes, such as medical liability reform, that promote professional judgment and address systemic barriers that impede responsible stewardship.

*AMA Principles of Medical Ethics: I,V,VII,VIII,IX*

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### *11.1.3 Allocating Limited Health Care Resources*

Physicians' primary ethical obligation is to promote the well-being of their patients. Policies for allocating scarce health care resources can impede their ability to fulfill that obligation, whether those policies address situations of chronically limited resources, such as ICU (intensive care unit) beds, medications, or solid organs for transplantation, or "triage" situations in times of scarcity, such as access to ventilators during an influenza pandemic.

As professionals dedicated to protecting the interests of their patients, physicians thus have a responsibility to contribute their expertise to developing allocation policies that are fair and safeguard the welfare of patients.

Individually and collectively through the profession, physicians should advocate for policies and procedures that allocate scarce health care resources fairly among patients, in keeping with the following criteria:

(a) Base allocation policies on criteria relating to medical need, including urgency of need, likelihood and anticipated duration of benefit, and change in quality of life. In limited circumstances, it may be appropriate to take into consideration the amount of resources required for successful treatment. It is not appropriate to base allocation policies on social worth, perceived obstacles to treatment, patient contribution to illness, past use of resources, or other non-medical characteristics.

(b) Give first priority to those patients for whom treatment will avoid premature death or extremely poor outcomes, then to patients who will experience the greatest change in quality of life, when there are very substantial differences among patients who need access to the scarce resource(s).

(c) Use an objective, flexible, transparent mechanism to determine which patients will receive the resource(s) when there are not substantial differences among patients who need access to the scarce resource(s).

(d) Explain the applicable allocation policies or procedures to patients who are denied access to the scarce resource(s) and to the public.

*AMA Principles of Medical Ethics: I,VII*

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### *11.1.4 Financial Barriers to Health Care Access*

Health care is a fundamental human good because it affects our opportunity to pursue life goals, reduces our pain and suffering, helps prevent premature loss of life, and provides information needed to plan for our lives. As professionals, physicians individually and collectively have an ethical responsibility to ensure that all persons have access to needed care regardless of their economic means.

In view of this obligation,

(a) Individual physicians should:

(i) take steps to promote access to care for individual patients, such as providing pro bono care in their office or through freestanding facilities or government programs that provide health care for the poor, or, when permissible, waiving insurance copayments in individual cases of hardship. Physicians in the poorest communities should be able to turn for assistance to colleagues in more prosperous communities.

(ii) help patients obtain needed care through public or charitable programs when patients cannot do so themselves.

(b) Physicians, individually and collectively through their professional organizations and institutions, should participate in the political process as advocates for patients (or support those who do) so as to diminish financial obstacles to access health care.

(c) The medical profession must work to ensure that societal decisions about the distribution of health resources safeguard the interests of all patients and promote access to health services.

(d) All stakeholders in health care, including physicians, health facilities, health insurers, professional medical societies, and public policymakers must work together to ensure sufficient access to appropriate health care for all people.

*AMA Principles of Medical Ethics: I,II,VI,VII,IX*

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### *11.2.1 Professionalism in Health Care Systems*

Containing costs, promoting high-quality care for all patients, and sustaining physician professionalism are important goals. Models for financing and organizing the delivery of health care services often aim to promote patient safety and to improve quality and efficiency. However, they can also pose ethical challenges for physicians that could undermine the trust essential to patient-physician relationships.

Payment models and financial incentives can create conflicts of interest among patients, health care organizations, and physicians. They can encourage undertreatment and overtreatment, as well as dictate goals that are not individualized for the particular patient.

Structures that influence where and by whom care is delivered—such as accountable care organizations, group practices, health maintenance organizations, and other entities that may emerge in the future—can affect patients' choices, the patient-physician relationship, and physicians' relationships with fellow health care professionals.

Formularies, clinical practice guidelines, and other tools intended to influence decision making, may impinge on physicians' exercise of professional judgment and ability to advocate effectively for their patients, depending on how they are designed and implemented.

Physicians in leadership positions within health care organizations should ensure that practices for financing and organizing the delivery of care:

(a) Are transparent.

(b) Reflect input from key stakeholders, including physicians and patients.

(c) Recognize that over reliance on financial incentives may undermine physician professionalism.

(d) Ensure ethically acceptable incentives that:

(i) are designed in keeping with sound principles and solid scientific evidence. Financial incentives should be based on appropriate comparison groups and cost data and adjusted to reflect complexity, case mix, and other factors that affect physician practice profiles. Practice guidelines, formularies, and other tools should be based on best available evidence and developed in keeping with ethics guidance;

(ii) are implemented fairly and do not disadvantage identifiable populations of patients or physicians or exacerbate health care disparities;

(iii) are implemented in conjunction with the infrastructure and resources needed to support high-value care and physician professionalism;

(iv) mitigate possible conflicts between physicians' financial interests and patient interests by minimizing the financial impact of patient care decisions and the overall financial risk for individual physicians.

(e) Encourage, rather than discourage, physicians (and others) to:

(i) provide care for patients with difficult to manage medical conditions;

(ii) practice at their full capacity, but not beyond.

(f) Recognize physicians' primary obligation to their patients by enabling physicians to respond to the unique needs of individual patients and providing avenues for meaningful appeal and advocacy on behalf of patients.

(g) Are routinely monitored to:

(i) identify and address adverse consequences;

(ii) identify and encourage dissemination of positive outcomes.

All physicians should:

(h) Hold physician-leaders accountable to meeting conditions for professionalism in health care systems.

(i) Advocate for changes in health care payment and delivery models to promote access to high-quality care for all patients.

*AMA Principles of Medical Ethics: I,II III,V*

### *11.2.2 Conflicts of Interest in Patient Care*

The primary objective of the medical profession is to render service to humanity; reward or financial gain is a subordinate consideration. Under no circumstances may physicians place their own financial interests above the welfare of their patients.

Treatment or hospitalization that is willfully excessive or inadequate constitutes unethical practice. Physicians should not provide wasteful and unnecessary treatment that may cause needless expense solely for the physician's financial benefit or for the benefit of a hospital or other health care organization with which the physician is affiliated.

Where the economic interests of the hospital, health care organization, or other entity are in conflict with patient welfare, patient welfare takes priority.

*AMA Principles of Medical Ethics: II*

### *11.2.3 Contracts to Deliver Health Care Services*

Physicians have a fundamental ethical obligation to put the welfare of patients ahead of other considerations, including personal financial interests. This obligation requires them to consider carefully the terms and conditions of contracts to deliver health care services before entering into such contracts to ensure that those contracts do not create untenable conflicts of interests.

Ongoing evolution in the health care system continues to bring changes to medicine, including changes in reimbursement mechanisms, models for health care delivery, restrictions on referral and use of services, clinical practice guidelines, and limitations on benefits packages. While these changes are intended to enhance quality, efficiency, and safety in health care, they can also put at risk physicians' ability to uphold professional ethical standards of informed consent and fidelity to patients and can impede physicians' freedom to exercise independent professional judgment and tailor care to meet the needs of individual patients.

As physicians enter into various differently structured contracts to deliver health care services—with group practices, hospitals, health plans, or other entities—they should be mindful that while many arrangements have the potential to promote desired improvements in care, some arrangements also have the potential to impede patients' interests.

When contracting to provide health care services, physicians should:

(a) Carefully review the terms of proposed contracts or have a representative do so on their behalf to assure themselves that the arrangement:

    (i) minimizes conflict of interest with respect to proposed reimbursement mechanisms, financial or performance incentives, restrictions on care, or other mechanisms intended to influence physicians' treatment recommendations or direct what care patients receive, in keeping with ethics guidance;

    (ii) does not compromise the physician's own financial well-being or ability to provide high-quality care through unrealistic expectations regarding utilization of services or terms that expose the physician to excessive financial risk;

(iii) allows the physician to appropriately exercise professional judgment;

(iv) includes a mechanism to address grievances and supports advocacy on behalf of individual patients;

(v) permits disclosure to patients.

(b) Negotiate modification or removal of any terms that unduly compromise physicians' ability to uphold ethical standards.

*AMA Principles of Medical Ethics: I,II,III,V,VI,VIII,IX*

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### *11.2.3.1 Restrictive Covenants*

Competition among physicians is ethically justifiable when it is based on such factors as quality of services, skill, experience, conveniences offered to patients, fees, or credit terms.

Covenants-not-to-compete restrict competition, can disrupt continuity of care, and may limit access to care.

Physicians should not enter into covenants that:

(a) Unreasonably restrict the right of a physician to practice medicine for a specified period of time or in a specified geographic area on termination of a contractual relationship; and

(b) Do not make reasonable accommodation for patients' choice of physician.

Physicians in training should not be asked to sign covenants not to compete as a condition of entry into any residency or fellowship program.

*AMA Principles of Medical Ethics: III,IV,VI,VII*

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### *11.2.4 Transparency in Health Care*

Respect for patients' autonomy is a cornerstone of medical ethics. Patients must rely on their physicians to provide information that patients would reasonably want to know to make informed, well-considered decisions about their health care. Thus, physicians have an obligation to inform patients about all appropriate treatment options, the risks and benefits of alternatives, and other information that may be pertinent, including the existence of payment models, financial incentives; and formularies, guidelines or other tools that influence treatment recommendations and care. Restrictions on disclosure can impede communication between patient and physician and undermine trust, patient choice, and quality of care.

Although health plans and other entities may have primary responsibility to inform patient-members about plan provisions that will affect the availability of care, physicians share in this responsibility.

Individually, physicians should:

(a) Disclose any financial and other factors that could affect the patient's care.

(b) Disclose relevant treatment alternatives, including those that may not be covered under the patient's health plan.

(c) Encourage patients to be aware of the provisions of their health plan.

Collectively, physicians should advocate that health plans with which they contract disclose to patient-members:

(d) Plan provisions that limit care, such as formularies or constraints on referrals.

(e) Plan provisions for obtaining desired care that would otherwise not be provided, such as provision for off-formulary prescribing.

(f) Plan relationships with pharmacy benefit management organizations and other commercial entities that have an interest in physicians' treatment recommendations.

*AMA Principles of Medical Ethics: I,II,III,V,VI*

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### *11.2.5 Retainer Practices*

Physicians are free to enter into contracts to provide special non-medical services and amenities with individual patients who are willing and able to pay additional costs out of pocket for such services. While such retainer contracts are one among many diverse models for delivering and paying for health care, they can also raise ethical concerns about access, quality, and continuity of care.

Regardless of the model within which they practice, physicians must uphold their primary professional obligation of fidelity and their responsibility to treat all patients with courtesy and respect for patients' rights and dignity, and ensure that all patients in the physician's practice receive the same quality of medical care, regardless of contractual arrangements for special, non-medical services and amenities.

Physicians who enter into retainer contracts with patients must:

(a) Present the terms of the retainer arrangement clearly to patients, including implications for the patient's current health care insurance, if known, and take care not to imply that more or better medical services will be provided under a retainer contract.

(b) Ensure that patient decisions to accept retainer contracts are voluntary and that patients are free to opt-out of entering into a retainer agreement.

(c) Facilitate transfer of care for any patient who chooses not to participate in a retainer practice. If it is not feasible to transfer a patient's care to another local physician, the physician should continue to provide care under the terms of the patient's existing health care insurance until other appropriate arrangements for ongoing care can be made.

(d) Ensure that treatment recommendations for all patients are based on scientific evidence, relevant professional guidelines, sound professional judgment, and prudent stewardship.

(e) Uphold standards of honesty and transparency in billing and clearly distinguish charges for special services or amenities provided under a retainer contract from medical services reimbursable by the patient's health care insurance or third-party payer.

(f) Uphold professional obligations to promote access to health care and to provide care to those in need regardless of ability to pay, in keeping with ethics guidance.

*AMA Principles of Medical Ethics: I,II,VI,VIII,IX*

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***E-11.2.6 – Mergers of Secular and Religiously Affiliated Health Care Institutions***

The merger of secular health care institutions and those affiliated with a faith tradition can benefit patients and communities by sustaining the ability to provide a continuum of care locally in the face of financial and other pressures. Yet consolidation among health care institutions with diverging value commitments and missions may also result in limiting what services are available. Consolidation can be a source of tension for the physicians and other health care professionals who are employed by or affiliated with the consolidated health care entity.

Protecting the community that the institution serves as well as the integrity of the institution, the physicians and other professionals who practice in association with it, is an essential, but challenging responsibility.

Physician-leaders within institutions that have or are contemplating a merger of secular and faith-based institutions should:

(a) Seek input from stakeholders to inform decisions to help ensure that after a consolidation the same breadth of services and care previously offered will continue to be available to the community.

(b) Be transparent about the values and mission that will guide the consolidated entity and proactively communicate to stakeholders, including prospective patients, physicians, staff, and civic leaders, how this will affect patient care and access to services.

(c) Negotiate contractual issues of governance, management, financing, and personnel that will respect the diversity of values within the community and at minimum that the same breadth of services and care remain available to the community.

(d) Recognize that physicians' primary obligation is to their patients. Physician-leaders in consolidated health systems should provide avenues for meaningful appeal and advocacy to enable associated physicians to respond to the unique needs of individual patients.

(e) Establish mechanisms to monitor the effect of new institutional arrangements on patient care and well-being and the opportunity of participating clinicians to uphold professional norms, both to identify and address adverse consequences and to identify and disseminate positive outcomes.

Individual physicians associated with secular and faith-based institutions that have or propose to consolidate should:

(f) Work to hold leaders accountable to meeting conditions for professionalism within the institution.

(g) Advocate for solutions when there is ongoing disagreement about services or arrangements for care.

*AMA Principles of Medical Ethics: VII,VIII,IX*

### *11.3.1 Fees for Medical Services*

Physicians are expected to conduct themselves as honest, responsible professionals. They should be knowledgeable about and conform to relevant laws and should adhere to professional ethical standards and sound business practice. Physicians should not recommend, provide, or charge for unnecessary medical services. Nor should they make intentional misrepresentations to increase the level of payment they receive or to secure noncovered health benefits for their patients.

With regard to fees for medical services, physicians should:

(a) Charge reasonable fees based on the:

  (i) kind of service(s);

  (ii) difficulty or uniqueness of the service(s) performed;

  (iii) time required to perform the service(s);

  (iv) skill required to perform the service(s);

  (v) experience of the physician;

  (vi) quality of the physician's performance.

(b) Charge only for the service(s) that are personally rendered or for services performed under the physician's direct personal observation, direction, or supervision. If possible, when services are provided by more than one physician, each physician should submit his or her own bill to the patient and be compensated separately. When physicians have professional colleagues assist in the performance of a service, the physician may pay a reasonable amount for such assistance and recoup that amount through fees charged to the patient, provided the patient is notified in advance of the financial arrangement.

(c) Itemize separately charges for diagnostic, laboratory, or clinical services provided by other health care professionals and indicate who provided the service when fees for others' services cannot be billed directly to the patient, in addition to charges for the physician's own professional services.

(d) Not charge excessive fees, contingent fees, or fees solely to facilitate hospital admission. Physicians must not charge a markup or commission, or profit on services rendered by other health care professionals.

(e) Extend professional courtesy at their discretion, recognizing that it is not an ethical requirement and is prohibited in many jurisdictions.

*AMA Principles of Medical Ethics: II,VI*

### *11.3.2 Fees for Nonclinical & Administrative Services*

Physicians individually and collectively should promote access to care for individual patients, in part through being prudent stewards of resources. Thus physicians have a responsibility to balance patients' needs and expectations with responsible business practices.

With respect to fees for nonclinical or administrative services provided in conjunction with patient care, physicians should:

(a) Clearly notify patients in advance of fees charged by the practice (if any) for nonclinical or administrative services.

(b) Base fees (if any) on reasonable costs to the practice for:

    (i) providing special documentation on patient request for such purposes as insurance reimbursement to the patient, certification of immunization or fitness, or similar nonclinical services;

    (ii) missed appointments or appointments not cancelled in advance in keeping with the published policy of the practice;

    (iii) acquisition or processing charges in relation to diagnostic, laboratory, or clinical services, copies of medical records, or similar nonclinical services.

*AMA Principles of Medical Ethics: II,VI*

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### *11.3.3 Interest & Finance Charges*

Financial obstacles to medical care can directly affect patients' well-being and may diminish physicians' ability to use their knowledge and skills on patients' behalf. Physicians should not be expected to risk the viability of their practices or compromise quality of care by routinely providing care without compensation. Patients should make reasonable efforts to meet their financial responsibilities or to discuss financial hardships with their physicians.

To preserve patients' dignity and help sustain the patient-physician relationship, physicians should be candid about financial matters and:

(a) Clearly notify patients in advance about policy and practice with respect to delinquent accounts, including under what circumstances:

    (i) payment will be requested at the time of service;

    (ii) interest or finance charges may be levied;

    (iii) a past due account will be sent to a collection agency.

(b) Ensure that no bills are sent to collection without the physician's knowledge.

(c) Use discretion and compassion in hardship cases, in keeping with ethics guidance regarding financial barriers to health care access.

*AMA Principles of Medical Ethics: II,VI,IX*

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### *11.3.4 Fee Splitting*

Patients must be able to trust that their physicians will be honest with them and will make treatment recommendations, including referrals, based on medical need, the skill of other health care professionals or facilities to whom the patient is referred, and the quality of products or services provided.

Payment by or to a physician or health care institution solely for referral of a patient is fee splitting and is unethical.

Physicians may not accept:

(a) Any payment of any kind, from any source for referring a patient other than distributions of a health care organization's revenues as permitted by law.

(b) Any payment of any kind, from any source for prescribing a specific drug, product, or service.

(c) Payment for services relating to the care of a patient from any health care facility/organization to which the physician has referred the patient.

(d) Payment referring a patient to a research study.

Physicians in a capitated primary care practice may not refer patients based on whether the referring physician has negotiated a discount for specialty services.

*AMA Principles of Medical Ethics: II*