

## OPINIONS OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

The following opinions, 1–3, were presented by Patrick W. McCormick, MD, Chair:

### 1. RESTRICTIVE COVENANTS

*CEJA Opinion; no reference committee hearing.*

**HOUSE ACTION: FILED**

*See Opinion [E-9.02](#).*

#### INTRODUCTION

At the 2014 Annual Meeting, the American Medical Association House of Delegates adopted the recommendation of Council on Ethical and Judicial Affairs Reports 5-A-14, “Restrictive Covenants.” The Council issues this Opinion, which will appear in the next version of AMA PolicyFinder and the next print edition of the *Code of Medical Ethics*.

#### E-9.02 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. (I, II, III, V, VI)

### 2. ETHICALLY SOUND INNOVATION IN MEDICAL PRACTICE

*CEJA Opinion; no reference committee hearing.*

**HOUSE ACTION: FILED**

*See Opinion [E-2.072](#).*

#### INTRODUCTION

At the 2004 Annual Meeting, the American Medical Association House of Delegates adopted the recommendations of Council on Ethical and Judicial Affairs Report 2-A-14, “Ethically Sound Innovation in Medical Practice.” The Council issues this Opinion, which will appear in the next version of AMA PolicyFinder and the next print edition of the *Code of Medical Ethics*.

#### E-2.072 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; and
- (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; and
  - 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; and
- (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; and
- (m) Encourage physician-innovators to collect and share information about the resources needed to implement their innovative therapies effectively. (V, VIII)

### 3. HEALTH PROMOTION AND PREVENTIVE CARE

*CEJA Opinion; no reference committee hearing.*

**HOUSE ACTION: FILED**

*See Opinion [E-8.075](#).*

#### INTRODUCTION

At the 2014 Annual Meeting, the American Medical Association House of Delegates adopted the recommendations of Council on Ethical and Judicial Affairs Report 4-A-14, "Health Promotion and Preventive Care." The Council issues this Opinion, which will appear in the next version of AMA PolicyFinder and the next print edition of the *Code of Medical Ethics*.

#### E-8.075 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.
- (V, VII)

## REPORTS OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

The following reports, 1–4, were presented by Patrick W. McCormick, MD, Chair:

### 1. PHYSICIAN EXERCISE OF CONSCIENCE

*Reference committee hearing: see report of Reference Committee on Amendments to Constitution and Bylaws.*

#### **HOUSE ACTION: RECOMMENDATIONS ADOPTED AND REMAINDER OF REPORT FILED**

*See Policy [H-140.841](#).*

The practice of medicine is inherently a moral activity, founded in a “covenant of trust” between patient and physician.[1,2,3] The respect and autonomy that medicine enjoys rest on the profession’s commitment to fidelity and service in the patient-physician relationship, and on individual physicians’ recognition that in becoming members of the profession they commit themselves to upholding its core ethical values and obligations.

Yet physicians are not defined solely by their profession. As individuals, physicians 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, as well as the expectations of their profession. In some situations, the expectation that as healers, physicians will put patients’ needs and preferences first may be in tension with the physician’s own need to sustain the sense of moral integrity and continuity that grounds his or her personal and professional life. In such situations, physicians must decide whether and how personal conscience should guide their professional conduct.

Preserving opportunity for physicians to act in accordance with the dictates of conscience is important for preserving the integrity of the medical profession as well as the integrity of the individual physician. Ethically sound patient-physician relationships and the practice of medicine as a moral activity rest on trust in physicians’ personal and professional integrity. Thus physicians should have considerable latitude to practice in accord with well-considered, deeply held beliefs that are central to their self-identities. Nonetheless, both as individual moral agents and as members of a profession dedicated to promoting the welfare of patients, physicians have a responsibility to be thoughtful and deliberative in making such decisions.

#### CONSCIENCE, INTEGRITY & DEEPLY HELD BELIEFS

When individuals speak of “acting in good conscience” or of acting in a way that preserves their “integrity,” they are saying that they seek to align their decisions and actions with the deeply held beliefs that shape their self-identity as moral agents. To have integrity requires that “one’s words and deeds generally be true to a substantive, coherent, and relatively stable set of values and principles to which one is genuinely and freely committed.”[4] Those values and principles—which encompass not only religious beliefs, but also moral, social, and political values[5]—are central to an individual’s understanding of who he or she is[6,7,8] as an individual and, for some, as a professional.

Having integrity provides a sense of personal identity, along with satisfaction and self-respect in knowing that one lives in accord with one’s beliefs.[4] Acting against one’s conscience can create a sense of self-betrayal, loss of self-respect, and a feeling that one undermines one’s integrity.[5,6,7,8] Having integrity “provides the basis for reliance, trust, friendship, and love.”[4] When an individual’s integrity is called into question, the trust others extend to him or her is undermined.

A claim to exercise conscience is underpinned by a claim that an act supports or violates one’s deeply held beliefs. It does not rest on intuition or emotion, but requires that the individual carefully consider what is at stake for the patient, the profession, and the physician and be able to articulate how the “substantive, coherent, and reasonably stable” values and principles that constitute those beliefs justify acting one way or another. A claim to exercise conscience also requires willingness to accept the consequences of that action.[7,9]

## PHYSICIANS' PROFESSIONAL RESPONSIBILITIES

As a profession, medicine is dedicated to “a certain degree of altruism, or suppression of self-interest when the welfare of those [it serves] requires it.”[10] In becoming members of the profession of medicine, physicians commit themselves to upholding its ethical standards and expectations. Physicians’ freedom to practice medicine within the bounds of their conscience must be considered in light of their professional responsibilities to their patients.

With certain exceptions, physicians are free to choose whether and with whom to establish a patient-physician relationship.[11,12] A physician must provide emergency care unless another qualified health professional is available, but a physician may decline to provide care for any individual patient so long as the decision is not based on characteristics that would constitute “invidious discrimination,” such as race, religion, national origin, gender, sexual orientation, or disease status.[13,14,15,16,17]

Prior to forming a patient-physician relationship, physicians have considerable latitude to establish expectations in accord with their well-considered, deeply held beliefs. Certain specialties or geographic locations may incur increased responsibilities on the part of physicians to establish these expectations. However, once a physician has agreed to enter into a patient-physician relationship, his or her first responsibility is to the patient.[11,18] Physicians’ fiduciary obligations to patients include putting patient interests and well-being ahead of the physician’s personal considerations [11] and respecting the patient as an autonomous decision maker.[18,19,20] To be able to participate meaningfully in decisions about their health care, patients must be confident that their physician will present medical facts accurately and make recommendations in accordance with good medical practice,[21] and that the physician will not withhold information without the patient’s agreement.[22]

Having once taken on the care of a patient, physicians have a further duty not to abandon the patient, encompassing obligations not to neglect the patient and to “support continuity of care.”[14,23] While a physician may ethically withdraw from a case, he or she must notify the patient of the intent to withdraw sufficiently in advance to allow transfer of care to another physician.[23]

## CONSCIENCE & PROFESSIONAL PRACTICE

In some circumstances, a physician may find that the dictates of his or her conscience do not align with the professional ethical expectation that a physician will provide care in keeping not only with a patient’s medical needs, but also with the patient’s values, preferences, and goals for care. Resolving—or at least reducing—the moral tension this creates requires that the physician exercise discernment and thoughtful judgment.

Perhaps most commonly, this tension arises when a physician is asked to provide an intervention that the individual believes is inconsistent with or would outright violate his or her deeply held beliefs and, thus, compromise his or her integrity. Such situations would include, for example, those in which the physician objects to providing “a legally and professionally permitted service, such as abortion, sterilization, prescribing or dispensing emergency contraception, and organ retrieval pursuant to donation after cardiac death.”[8] These situations should be distinguished from cases in which a physician refuses to provide care in keeping with his or her clinical judgment and consistent with recognized professional standards. Physicians are not expected to provide care that, in their professional judgment, is unlikely to achieve the patient’s clinical goals. Indeed, they should not do so.[24]

Moral tension can also arise when conscience dictates that the physician provides an intervention or service that is medically permitted “when doing so is prohibited by law, institutional rules, employer policies, and so forth.”[25] Examples include when a physician feels morally obligated to prescribe emergency contraception or to care for patients regardless of their immigration status, in violation of hospital policy, law, or professional ethics.[25] Importantly, health care professionals may hold very different core beliefs and thus reach very different decisions based on those core beliefs, yet equally act according to the dictates of conscience. For example, a physician who chooses to provide abortions on the basis of a deeply held belief in protecting women’s autonomy makes the same kind of moral claim to conscience as does a physician who refuses to provide abortion on the basis of respect for the sanctity of life of the fetus.[26] It must be remembered that a physician may never impose medical care against the wishes of a patient who has decision-making capacity.[27,28]

In resolving situations of moral tension, a physician must balance preserving his or her integrity with the interests of the patient, future patients, and the medical profession. Yet, “being a conscientious medical professional may well

mean at times acting in ways contrary to one's personal ideals in order to adhere to a general professional obligation to serve patients' interests first." [29] These obligations may arise more frequently when a physician works in an area in which access to care and referral options are limited. Or it may mean structuring one's practice to avoid, to the greatest extent possible, situations in which one would be asked or expected to provide care that creates significant challenges to one's moral integrity.

Patients, the public, and fellow professionals must be reasonably able to expect that physicians will uphold the fiduciary responsibilities of the profession and will, in general, provide legally available, medically permitted interventions or services in keeping with patients' medical needs and values, preferences, and goals for care. Physicians should use great restraint in deciding to act contrary to that general expectation.

## RESOLVING OR REDUCING MORAL TENSION

As moral agents in their own right, physicians must have some scope to act so as to honor the beliefs that ground their sense of self and preserve integrity. As noted above, certain actions are beyond physicians' discretion: declining to provide care in emergency situations when no other qualified professional is available, discriminating against patients, imposing care against a competent patient's informed refusal. In other situations, when the foreseeable burdens for the patient are minimal, physicians have greater discretion to act in conscience. Between these endpoints, for physicians facing situations of moral tension, determining how best to preserve their integrity in discharging their professional ethical obligations to patients calls for thoughtful deliberation that takes into account a variety of factors. These include considerations of medical need, whether there is an established patient-physician relationship, and the burdens a decision to act in conscience will pose for the patient, the physician, and others. A physician's decision to act in conscience has ramifications at all levels of patient care: providing interventions or services, informing the patient about treatment options, and referring the patient elsewhere for care.

### *Patient-Physician Relationships*

Entering into a patient-physician relationship establishes the physician's fiduciary obligations to this particular individual. [30] Until such a relationship is established, physicians may decline to accept prospective patients (with the caveats noted above) and have considerable latitude in their exercise of conscience. Once a relationship is established, physicians must fulfill their responsibilities to promote patient welfare, respect patient autonomy, and adhere to standards of professionalism or formally terminate the relationship. [23]

In some instances, of course, patient and physician will share deeply held beliefs, and situations are unlikely to arise in which a physician would feel compelled to act in conscience contrary to the patient's values and preferences. But physicians cannot predict that they will share deeply held beliefs with all of their patients, or all of the time. A physician who knows that there are specific interventions or services he or she cannot "in good conscience" provide has a responsibility to make that clear to prospective patients before entering into a patient-physician relationship with them. [31,32] for example, by posting a notice in the waiting room. During this time, before the onset of the patient-physician relationship, the physician's discretion to exercise conscience is at its greatest. If the physician does not make this clear prior to establishing a relationship, his or her obligation to refrain from acting in conscience, or temper his or her action, is stronger than it would otherwise be. Yet disclosure alone is not always sufficient; how clearly the physician states his or her position, how well the patient understands the disclosure (and its implications for future care), and the nature of the patient's needs (e.g., emergency care), are also important factors to consider. Further, prospective efforts to inform patients are limited to the extent that physicians cannot always predict the types of care patients might request, or how advances in medical science or technology may alter the course of their practices over time.

Having discretion to follow conscience with respect to specific interventions or services does not relieve the physician of the obligation to not abandon a patient. This includes a responsibility to facilitate transfer of the patient to another physician willing to provide an intervention or service the treating physician finds morally objectionable. [20] It also includes responsibility to provide ongoing care for a patient, even if the need for that care stems from an objected-to intervention, until the patient can be transferred to another physician. [14,23,33]

*Medical Need, Timeliness & Alternatives*

Medical need constrains physicians' freedom to act according to conscience. All patients are vulnerable to some degree—they must rely on physicians' professional knowledge and skill and must trust that physicians will be dedicated to promoting their welfare.[30] The greater a patient's medical need, the more he or she must trust the physician and the greater the physician's fiduciary obligation to fulfill that trust. Thus physicians have least latitude to decline to provide care that is morally objectionable to them when that care is medically needed, unless the needed care is available to the patient elsewhere in a timely fashion.[23,33] The greater the medical need, the stronger the obligation to treat.[16] Conversely, physicians have greatest latitude to decline to provide care when that care is elective, particularly when the desired care is available elsewhere and delay in obtaining it will not unduly compromise the patient's well-being. Physicians should not act so as to create a significant barrier to the patient receiving care that is medically needed.

In some cases, delay in receiving treatment may alter the patient's outcome—for example, timely access to emergency contraception. In exercising conscience, physicians must consider whether their actions by delaying care would effectively deny the patient access to desired care and what harms the patient would experience as a result including financial, medical, psychological, or other harms.

Physician exercise of conscience often has a scalar effect where a physician might justify certain acts because the alternative would be less acceptable. For example, a physician who would decline to provide abortion may feel comfortable providing contraception to prevent an unwanted pregnancy the patient might choose to abort, or may morally oppose gender reassignment operations but justify it in the case of an otherwise self-destructive patient.

*Harms & Burdens to Patients*

The likelihood of harm to the patient and the degree of harm also constrain physicians' freedom to act on grounds of conscience. The fiduciary nature of patient-physician relationships carries with it the obligation for physicians to minimize harms, and to a lesser extent burdens, to patients. Harms to patients can come in a variety of forms and may include physical harms, dignitary harms (as when the physician fails to respect the patient and disregards the patient's values and preferences), and psychosocial harms.[34-38] As with medical need, the greater the likelihood that acting in conscience will harm the patient, the less discretion the physician has, particularly when the harm in question is serious and imminent (e.g., significant pain, disability). Some harm to the patient may be so significant and foreseeable that a physician's exercise of conscience is not justifiable—for example, death or permanent injury in contrast to minor bleeding or discomfort.

Beyond harms as such, physicians should consider other burdens that acting according to the dictates of their conscience may impose on patients. Burdens can range from the inconvenience of having to go elsewhere for care that is readily available when a physician declines to provide an intervention, to more significant challenges when the patient's access to care is limited by constraints on services in the local health care system or such patient-specific factors as health literacy or access to transportation. Time, distance to care, cost, or other logistic burdens might be so severe as to outright bar the patient from obtaining necessary care. Again, the more significant the burden, the more physicians should temper their exercise of conscience in the interests of patient welfare. Likewise a minor inconvenience to a patient should not force a physician to act outside the dictates of conscience. Yet, physicians must be aware that what may initially seem to the physician to be a minor harm or burden could act as a significant barrier to care for the patient, depending on the patient's individual situation.

*Harms and Burdens to Physicians & Others*

For an individual physician, not being able to conduct his or her life in keeping with deeply held beliefs can lead to moral distress,[39] the sense that one has fundamentally compromised one's integrity,[4] and loss of self-respect.[4] The moral and psychological harm for the individual physician can be compounded if it adversely affects his or her ability to provide high quality care.[40,41] Unaddressed moral distress can lead to dissatisfaction among health care workers, [6,40] which raises concerns that disaffected providers will be unable to provide high quality care, possibly resulting in harm to their individual patients and to patients as a class.

Moreover, prohibiting physicians from exercising conscience may deter some individuals from becoming physicians or from becoming certain types of specialists, or it may lead physicians to become callous, disrespectful toward



patients with diverging beliefs, or cavalier in upholding both their personal and their professional commitments, thus potentially compromising patient care and putting strain on the patient and public trust in personal and professional integrity of physicians.[40]

Patient care can also be affected at the institutional level. When a physician declines to provide an intervention or service on grounds of conscience, the burden falls to others to ensure that the exercise of conscience does not disrupt practice or compromise patient care, including care of the patient whom the dissenting physician has declined to treat, or the functioning of the institution.[6,41,42] Permitting individual physicians to exercise conscience without constraint can also damage professional relationships with colleagues who either do not share a physician's deeply held beliefs, or who find other ways to resolve moral tensions between their beliefs and the expectations of their profession. Finally, while patients and the public must trust the moral integrity of physicians, permitting physicians to exercise conscience freely may, paradoxically, put at risk the trust that physicians will uphold the commitments asked of them by their profession.

#### THE PROBLEM OF MORAL COMPLICITY

When a physician participates in an action that is in tension with his or her deeply held beliefs he or she may feel complicit, in some measure, in moral wrongdoing. Complicity involves “[sharing] in the guilt of an ethically improper act” by virtue of one's level of involvement with that act.[43] It is concerned with how participating in another party's immoral action (or inaction) violates one's own moral integrity.[32]

The degree to which an individual's action (or inaction) implicates him or her in a moral wrong depends on the individual's “moral distance” from the wrongdoer and/or the act, including the degree to which one shares the wrongful intent.[32,43] If one facilitates a moral wrong, but intended a morally licit purpose in doing so, then one is not morally complicit in the wrong. Moral distance also involves the extent to which one's action can be predicted to facilitate a moral wrong.[7,44] Loaning one's car to a friend who subsequently becomes drunk and kills someone while driving is morally more distant from the death than loaning one's car to a friend when one knows the friend plans to drink or has already been drinking.[32]

Other factors that influence moral complicity include the severity of the immoral act,[32] whether one was under duress in participating in the immoral act,[45] the likelihood that one's conduct will induce others to act immorally,[44] and the extent to which one's participation is needed to facilitate the wrongdoing.[32,45]

For physicians, the question of moral complicity arises when they facilitate in some manner the accomplishment of an end they believe to be morally wrong. For example, a physician who declines to provide an intervention or service, such as abortion, on grounds of conscience must still grapple with whether to inform a patient about the objected-to option and whether to refer the patient to another physician who will provide the intervention or service. (A physician who is unwilling to forgo life-sustaining treatment may similarly worry that he or she is complicit in wrongdoing with respect to informing the patient about the option to forgo care or transferring the patient to another physician willing to withhold or withdraw such care.) Physicians must grapple with the degree to which their actions will compromise their feelings of moral integrity—some physicians may be able to justify some provisions of care but not others based on their level of complicity, even if the care implicates similar moral questions (for example, sanctity of life). It may be the case, as one example, that a physician can reconcile choosing not to participate in abortions with still providing emergency or other contraception. Yet in all circumstances, whatever the dictates of conscience, physicians must recognize and fulfill their other, continuing professional ethical obligations to the patient.

#### *Duty to Inform*

The duty to provide patients with the information they need to make well-considered decisions about their care is the embodiment of respect for patients' autonomy and is one of a physician's most fundamental professional obligations. As previously noted, physicians have a duty to present medical facts accurately,[17] including the risks, benefits, and costs of treatment alternatives,[13] and not to withhold information from patients.[33]

Providing information about treatment options the physician sincerely believes are morally objectionable or about how the patient might obtain objected-to treatment elsewhere is morally distant from what the physician's deeply held beliefs tell him or her is wrong. Providing information is sufficiently distant that the risk to physician integrity

is outweighed by the professional obligation to inform, given the strong ethical import of informed consent.[5,29,32,46] Physicians can avoid any taint of complicity by notifying prospective patients prior to initiating a patient-physician relationship about interventions or services that conscience prohibits the physician from offering.[33]

### *Duty to Refer*

The matter of referring a patient to a physician who will provide an objected-to intervention or service is more challenging. Physicians have a duty not to abandon their patients and to provide for continuity of care.[14,23] While these ground an obligation to refer when one cannot or will not provide needed care oneself, referring a patient for care that violates the physician's deeply held beliefs is clearly less morally distant from the objectionable act than is providing information.

As in making a determination whether to exercise conscience with respect to providing care, determining whether or how to refer requires that the physician consider medical need, risks and burdens to the patient of referring or not referring, and the likely impact of the physician's decision on colleagues and others. The greater the likelihood or severity of harm, the stronger the physician's duty to facilitate in some way the patient's access to needed care, even in the face of becoming in some measure complicit in what the physician believes is wrong. Conversely, when there is little risk of harm, the weaker the duty to facilitate access to the objected-to intervention or service. Physicians may have a heightened duty to refer in the context of an established patient-physician relationship.[47,48]

Physicians have a number of options for discharging the duty to refer, ranging from something as simple—and morally distant from wrongdoing—as providing a toll-free number or local hospital number for the patient to inquire about services, to formally referring the patient to a specific physician or institution.[32]

Physicians may also avoid (or at least minimize) moral complicity by terminating the patient-physician relationship and encouraging the patient to find another physician better able to meet the patient's needs.[46] However, terminating the relationship is ethically permissible only when timeliness of care is not a factor and the physician adheres to ethical guidelines for terminating the relationship, including providing needed care until the patient is transferred to another physician and ensuring that the patient's records are made available to his or her new physician.[23]

## PROTECTING PATIENTS, PRESERVING INTEGRITY

The freedom to maintain moral views and act on them is central to a pluralist, democratic society.[6,7] Physicians, no less than patients, should be able to expect that they will be respected as moral agents. There is reason to think that preserving opportunity for physicians to act according to the dictates of conscience may “yield better overall medical quality by fostering a diverse workforce that possess integrity, sensitivity to patients' needs, and respect for diversity.”[40] In determining whether and how to exercise conscience physicians have a responsibility—rooted in their own status as moral agents and their commitments as medical professionals—to deliberate thoughtfully about the implications for the well-being of patients and others and to seek ways to resolve or reduce moral tension that will neither unduly compromise the physician's moral integrity nor disproportionately burden the patient.

## RECOMMENDATION

The Council on Ethical and Judicial Affairs recommends that the following be adopted and the remainder of this report be filed:

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 ethical guidelines.

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## 2. PRESCRIBING AND DISPENSING SAMPLE MEDICATIONS

*Reference committee hearing: see report of Reference Committee on Amendments to Constitution and Bylaws.*

### **HOUSE ACTION: REFERRED**

Physicians dispense free samples of medications, prescription and over-the-counter, out of a genuine desire to provide high quality care that meets their patients' needs [1,2]. Used appropriately, medication samples can benefit patients. At the same time, however, medication sampling poses challenges for physicians. Responsible practice requires that physicians consider both possible benefits and potential downsides of sample medications, particularly prescription medications.

#### **BENEFITS FOR PATIENTS: TIMELY, CONVENIENT, LOW COST**

Physicians' rationale for dispensing sample medications has not been extensively studied, but available data suggest that samples are used to enable therapy to begin immediately, to try out one or more medications for the individual patient, and to help overcome cost-related obstacles to care for the individual patient.

#### *Immediate Treatment*

Physicians may dispense samples in order to begin therapy immediately with the goal of relieving distressing symptoms or preventing possible complications [2–5]. Access to sample medications can be particularly valuable when the patient will not be able to fill a prescription immediately, e.g., when the individual does not have access to 24-hour pharmacy services [6].

#### *Assessing Medications for Efficacy, Tolerability, Patient Preference*

Physicians also use samples for other purposes, for example, to determine appropriate dosage and assess efficacy and tolerability for the individual patient [2–6]. Drug samples allow physicians and patients to test a range of medications before filling expensive prescriptions [7], including assessing the efficacy of different dosages before ordering a prescription for a patient [3]. Physicians can also use samples to test patient response to a class of medications, such as Selective Serotonin Re-uptake Inhibitors (SSRIs), in anticipation of writing a prescription for a medication in that class if the trial medication proves effective for the patient.

Samples may also enable patients to identify which of two or more medications they themselves prefer [6,8]. Samples are particularly common in dermatology, as patients can try a range of topical medications and identify that one that is most tolerable [8]. Being able to identify medications they prefer may help enhance patients' adherence to treatment [6]. Further, patients with access to samples are often exposed to more treatment choices, including brand name and generic medications [8].

#### *Overcoming Cost-Related Obstacles to Care*

Providing samples during the clinical encounter can be a convenience for patients in general, and most patients appreciate receiving samples [1,9,10]. Perhaps more important, samples can represent one way to provide access to needed medications for patients who could not otherwise afford them [2,11–14]. In some community health centers, uninsured patients are likely to receive samples, more so than Medicaid patients [15]. Dispensing samples was the second most likely strategy participating physicians in one study reported to assist patients for whom out-of-pocket costs were burdensome [11]. Many patients are reluctant to ask for samples or broach issues of financial hardship with their physicians [4,10,16]; however, when they do, physicians often provide samples [16].

However, if the samples on hand in a physician's practice do not match well with the needs of the practice's patient population, the "access" samples provide may have little meaning. One study among Australian general practitioners found that fewer than 50 percent of medications in their sample cupboards were among the medications physicians had indicated they wanted to have in their supply of samples [17].

Whether samples reach primarily the neediest patients is open to question, however [1,10,12,18]. At one time it was common practice for physicians to appropriate samples for personal or family use [1]; however, there appear to be

no current data on how widespread such practice may still be. More important, access to samples is at least in part conditioned on whether a patient has access to care at all [13,18–20]. Nevertheless, even among patients who do have access to care, samples are not necessarily targeted toward those who have the greatest need. An analysis of data from the Medical Expenditure Panel Survey concluded that for the period 1999–2005, “sample use was not associated with income and samples were less frequently provided to racial/ethnic minorities and to the elderly” [10]. Another study found that among Medicare beneficiaries, access to samples was greater for those who had higher annual incomes or some form of drug benefits than among beneficiaries who had lower incomes or no drug coverage [13]. Other research has similarly found that patients with less education, lower levels of income, and no primary care physician are less likely to receive samples than are other patients [14].

## CHALLENGES FOR PHYSICIANS: SAFETY, QUALITY & PROFESSIONALISM

Although dispensing sample medications can offer benefits for patients, there can be disadvantages to sampling as well. These include concerns about safety, quality, and continuity of care; about the administrative burdens of managing samples appropriately; and about possible undesired effects on physician prescribing practices.

### *Safety, Quality & Continuity of Care*

Sampling can carry a variety of risks for patient safety. Patients who receive sample medications directly from their physicians often forgo the benefit of screening for adverse drug interactions or the counseling and education that pharmacists provide [2,10,21]. Package inserts are not a reliable way to meet patients’ information needs. Not all sample medication packages contain consumer medical information, and those that do often contain materials above the reading skills of average patients [22]. Nor do package inserts organize information in ways that are clear for lay readers [22].

Recommendations for safe sample dispensing from the Institute for Safe Medication Practice urge physicians to label samples with the patient’s name, the reason for the medication, the amount of medication the patient should take, how frequently the patient should take the medication, special precautions, and significant side effects [23]. A study that evaluated adherence to these standards among 17 primary care practices found that none complied with all of the standards; of the 12 that had policies in place about dispensing samples, only seven had policies for labeling [5].

Safety concerns also arise with respect to how physician practices manage their supply of samples. Unless practices monitor their supply of samples and keep detailed inventory records, patients may be at risk of receiving outdated medications or of not being identified if a drug is recalled or a black box warning is issued [10,21].

Further, not all drugs are necessarily appropriate for dispensing as samples. For example, drugs with high risk profiles, such as retinoic acid or acitretin [6], or medications that must be administered under close medical supervision, pose risks that make them poor candidates for sample dispensing.

There is also reason to be concerned that using samples may put continuity of treatment at risk, especially for patients with chronic conditions [24]. Samples are primarily a promotional tool, and as such are most readily available when a company is actively marketing a medication, usually becoming less available as a company focuses on newer agents. Competition in the given drug class may also influence a company’s sampling program—the greater the competition, the more likely samples are to be provided. On the other hand, when there is little competition, a company may be less inclined to provide samples [24]. Thus the inventory of samples available to a physician can be limited at any given point in time and can vary over time [15,24].

Such variability of inventory may also mean that samples can create disparities in health care even when they are being used to help provide access to care. The limited choice of medications available through sampling has the potential to create poorer health outcomes for patients who rely on them, for example, when the sample is not the preferred method of treatment in the patient’s individual circumstances [24]. Relying on samples may actually affect adherence adversely as well, particularly among patients with chronic conditions who must return to the physician’s office for their medications. If the original sample is no longer in stock, the physician must dispense a different drug, or write a prescription for the original that the patient may or may not be able to fill [15,24].

### *Administrative Burdens*

Responsibly dispensing samples can pose a significant administrative burden for physicians as well. In addition to storing supplies securely to prevent unauthorized use or misuse [6] and monitoring supplies for expiration dates, the practice must keep detailed inventory records of which patients received specific samples to be able to notify those patients in the event of a drug recall or new FDA warning, as noted above. Failing to maintain adequate records of samples also undermines physicians' ability to uphold professional responsibilities to report adverse events [25].

### *Effects on Physician Prescribing & Informed Consent*

Much of the published work about the effect of sampling indicates that having access to samples does influence physicians' treatment recommendations in ways that can be problematic [2,3,6, 11,13,26–30]. Several studies have suggested that physicians who have access to samples prefer prescribing brand name drugs over alternatives even when the sample is not their drug of choice [2,26], or is not consistent with clinical guidelines [9,27]. Conversely, removing samples from the practice setting has been associated with increased rates of prescribing for generic medications [28–29,31]. Data suggest that some physicians consider it appropriate to accept samples even when they believe having samples available will influence their own prescribing decisions [30].

Providing drug samples may carry implications for informed consent and shared decision making as well [24]. Unless the physician explores with the patient all available treatment options, and discusses the patient's ability to pay for needed medication and what priority the patient gives to paying for medications among other needs, selecting a medication from the sample cabinet because it is available undermines the goal of informed consent [24, cf. 14,16]. Moreover, unless the physician is knowledgeable about the actual prices of treatment alternatives, it is impossible for the physician or patient to be certain whether a preferred medication would or would not be "affordable" for the patient [24].

### SAMPLING & HEALTH CARE COSTS

The relationship between providing samples and health care costs is complex, but there is relatively little data available about the effect of sampling on costs, and the available evidence is mixed [29]. "Free" samples represent a significant proportion of the overall promotional budget of pharmaceutical companies [3], a cost it is reasonable to expect companies wish to recoup. The availability of samples has also been associated with increased prescribing of more expensive, heavily advertised drugs and decreased use of less expensive medications [2,26]. At least one study found that when drug samples were available, uninsured patients received fewer prescriptions for generic medications; the percentage of prescriptions for generics more than doubled when samples were no longer available [29].

However, other data indicate that samples do not affect average prescription costs. Some studies suggest that patients' out-of-pocket costs increase when samples are not available, in contrast to others that suggest out-of-pocket expenditures may increase when samples are available [29]. One study concluded that whether prescription samples and medication assistance programs truly help patients in need or are driving the use of higher cost drugs "warrants further study" [14].

The possible cost to physician professionalism is at least as significant as possible monetary cost to patients and the health care system. The concept that having samples readily available influences physicians' prescribing behavior undermines the ethical expectation that physicians will base treatment recommendations on their best professional judgment [32]. The availability of samples can encourage physicians to disregard evidence-based guidelines and organizational formularies [2]. Moreover, having access to free samples in training settings "prevents physicians and staff from appreciating the costs of medications, removing an important motivator in changing prescribing behavior" [33] and compromising physicians' ability to uphold their responsibilities as wise stewards of health care resources [32].

### ACCESS TO MEDICATION: ALTERNATIVES TO SAMPLES

Sample medications distributed directly to patients by physicians are only one means for making medications available to patients who have limited ability to pay. Medication assistance programs sponsored by pharmaceutical

companies, publicly subsidized medication programs (such as the Public Health Service [340B] Drug Pricing Program), or other mechanisms also offer access to free or low-cost medications.

Most medication assistance programs sponsored by industry provide drugs at low or no cost. However, it is not clear how well these programs facilitate access for needy patients. Most base eligibility at least partly on income, but many also accept beneficiaries who have some coverage for prescription drugs [1,14,19–20]. One study found that fewer than 2 percent of eligible Medicare beneficiaries received medications from an industry-sponsored patient assistance program [14], although participation was highest among patients with low income and those who lacked prescription coverage.

Applying for assistance is often a complex process [20]. Primary care physicians reported not directing patients to company-sponsored assistance programs because patients were unable to apply directly, which put the burden of enrolling on office staff [34]. These physicians also cited the low income thresholds for the programs as a deterrent. In general, programs provide drugs to patients' physicians rather than directly to patients [20].

Moreover, few programs focus on drugs that have no generic equivalents or close therapeutic substitutes. Most do not set upper limits on income for eligibility [35]. There is also concern that programs may violate the federal anti-kickback statute to the extent that they "illegally induce consumption of services" [35].

Programs subsidized by government agencies, charitable institutions, or other entities also offer lower cost or free access to medications for various populations of patients. Yet even with deeply discounted costs, some of these patients may not be able to afford needed medications [24].

## CONCLUSION

Dispensing samples responsibly to maximize benefits for patients and minimize risks requires that physicians approach the use of samples systematically. For physicians in health care organizations that have centralized sample collection, management and dispensing, that task is relatively straightforward. For physicians in other practice settings, especially solo or small group practices, setting up a centralized system or gaining access to an existing system elsewhere may not be realistic.

In these latter settings, to dispense samples in keeping with their ethical obligations of fidelity and stewardship, physicians will need to implement policies and practices that balance convenience, possible clinical benefits for patients, and the opportunity to enhance access to care for individual patients with the need to ensure that samples are safely managed and dispensed and that professional judgment is not unduly influenced by the availability of samples.

## RECOMMENDATIONS

In light of the foregoing considerations, the Council on Ethical and Judicial Affairs recommends that the following be adopted and the remainder of this report be filed:

Used appropriately, medication samples can benefit patients, offering convenience, the opportunity to assess individual responses and preferences for medications, and, for some patients, access to needed medications they would not otherwise be able to afford. At the same time, however, medication sampling poses challenges for physicians, including possible unintended effects on physician judgment and prescribing practices, patient safety, and quality and continuity of care.

Physicians should always base treatment recommendations on patients' medical needs and best professional judgment, independent of whether sample medications are available. Physicians should dispense samples of a generic medication when possible and appropriate for the individual patient. Medication samples are most appropriate for limited, short-term purposes, but in some situations may ethically be used for longer term care.

Individually, physicians who prescribe or dispense medication samples have an ethical responsibility to:

- (a) Manage in-office sample inventories in keeping with best clinical practices and applicable legal requirements, and accept only those sample medications relevant to the practice and its patient population.



- (b) Dispense samples that are labeled for the patient, with appropriate education and instructions, and document the provision of samples in the patient's medical record.
- (c) Prescribe or dispense sample medications only in the context of a patient-physician relationship, in keeping with ethical guidelines.
- (d) Offer samples on a limited, short-term basis, irrespective of a patient's ability to pay, in order to:
  - (i) provide immediate treatment to relieve or prevent serious complications or relieve significant symptoms;
  - (ii) assess one or more medications to determine appropriate dosage for the patient, identify allergic reactions or serious side effects, or, when appropriate, enable the patient to identify which medication the individual prefers;
  - (iii) test patient responses to a class of medication, with the understanding that a prescription will be written for a medication in that class if the trial medication proves effective for the patient; or
  - (iv) as a bridge to therapy until a prescription for the preferred medication can be filled.
- (e) Provide medication samples on a long-term basis to treat a chronic medical condition only after inquiring about the patient's ability to obtain the preferred medication and determining that the patient would not otherwise have access to the needed medication.

Collectively, physicians should advocate for:

- (f) Patient access to affordable, comprehensive formularies;
- (g) Physician education about alternatives to samples for providing needed medications when patients cannot afford recommended treatments; and
- (h) Community resources to help patients obtain needed medications.

(New HOD/CEJA Policy)

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### 3. MODERNIZED CODE OF MEDICAL ETHICS

*Reference committee hearing: see report of Reference Committee on Amendments to Constitution and Bylaws.*

#### HOUSE ACTION: REFERRED

As the Council on Ethical and Judicial Affairs has previously reported [1], in 2008 it began a project to comprehensively review the AMA’s foundational document, the *Code of Medical Ethics*, and update the Opinions that interpret *AMA Principles of Medical Ethics*. The Council’s goal was to ensure that the *Code*’s ethical guidance keeps pace with the demands of a changing world of medical practice. This project represents the first such thoroughgoing review in more than 60 years.

With assistance from the Federation of Medicine and AMA Councils and Sections, the Council on Ethical and Judicial Affairs reviewed each individual Opinion for clarity; timeliness and ongoing relevance in today’s health

care environment; and consistency. The Council reorganized Opinions into a more intuitive chapter structure to ensure that guidance is easy to find, and adopted a uniform format for Opinions to ensure that guidance is easy to read and easy to apply. In modernizing Opinions, the Council looked for opportunities to consolidate guidance into a single, comprehensive statement; to harmonize guidance on related issues; and to identify and update or retire guidance that has become significantly outdated over time.

The report below presents the result of that project.

#### RECOMMENDATION

The Council on Ethical and Judicial Affairs recommends that the individual Opinions contained in the 2014-2015 edition of the AMA *Code of Medical Ethics* be amended by substitution as follows and that the remainder of this report be filed.

The text of the proposed *Code* is not included in the Proceedings because the report was referred and the modified *Code* will be presented at a future meeting of the House of Delegates. Contact the Council on Ethical and Judicial Affairs ([ceja@ama-assn.org](mailto:ceja@ama-assn.org)) for more information.

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1. Council on Ethical and Judicial Affairs. *Modernizing the Code of Medical Ethics*. Available at [ama-assn.org/ama/pub/about-ama/our-people/ama-councils/council-ethical-judicial-affairs.page](http://ama-assn.org/ama/pub/about-ama/our-people/ama-councils/council-ethical-judicial-affairs.page). Accessed September 15, 2014.

#### 4. PROFESSIONALISM IN TELEMEDICINE

*Informational report; no reference committee hearing.*

#### HOUSE ACTION: FILED

Policy D-480.974 instructs the Council on Ethical and Judicial Affairs (CEJA) to review Opinions relating to telemedicine/telehealth and update the *Code of Medical Ethics* as appropriate.

After a thorough review of the literature and of current policies regarding telemedicine, telehealth, and communications between a patient and a physician both in the context of and prior to a formal relationship, CEJA concluded that the request to review current related Opinions raised broader ethical questions surrounding appropriate physician behavior in these contexts. The Council recognized the need to examine the implications of a continuum of online interactions between patients and physicians for implementing core ethical obligations with respect to competence, informed consent, privacy and confidentiality, continuity of care, and responsible prescribing.

The Council continues to seek input from key stakeholders to inform its deliberations and anticipates submitting its analysis and recommendations in a report to the House at the 2015 Annual Meeting.