

OPINION OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

The following opinion was presented by Susan Dorr Goold, MD, Chair:

1. AMENDMENT TO E-5.055, “CONFIDENTIAL CARE FOR MINORS”

Reference committee hearing: see report of [Reference Committee on Amendments to Constitution and Bylaws](#).

HOUSE ACTION: FILED

See Opinion [E-5.055](#)

INTRODUCTION

At the 2013 Annual Meeting, the American Medical Association (AMA) House of Delegates (HOD) adopted the recommendations of Council on Ethical and Judicial Affairs Report 3-A-13, “Amendment to E-5.055, ‘Confidential Care for Minors.’” 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-5.055, Confidential Care for Minors

Physicians who treat minors have an ethical duty to promote the autonomy of minor patients by involving them in the medical decision-making process to a degree commensurate with their abilities.

When minors request confidential services, physicians should encourage them to involve their parents. This includes making efforts to obtain the minor’s reasons for not involving their parents and correcting misconceptions that may be motivating their objections.

Where the law does not require otherwise, physicians should permit a competent minor to consent to medical care and should not notify parents without the patient’s consent. Depending on the seriousness of the decision, competence may be evaluated by physicians for most minors. When necessary, experts in adolescent medicine or child psychological development should be consulted. Use of the courts for competence determinations should be made only as a last resort.

When an immature minor requests contraceptive services, pregnancy-related care (including pregnancy testing, prenatal and postnatal care, and delivery services), or treatment for sexually transmitted disease, measures to prevent sexually transmitted disease, drug and alcohol abuse, or mental illness, physicians must recognize that requiring parental involvement may be counterproductive to the health of the patient. Physicians should encourage parental involvement in these situations. However, if the minor continues to object, his or her wishes ordinarily should be respected. If the physician is uncomfortable with providing services without parental involvement, and alternative confidential services are available, the minor may be referred to those services. In cases when the physician believes that without parental involvement and guidance, the minor will face a serious health threat, and there is reason to believe that the parents will be helpful and understanding, disclosing the problem to the parents is ethically justified. When the physician does breach confidentiality to the parents, he or she must discuss the reasons for the breach with the minor prior to the disclosure.

For minors who are mature enough to be unaccompanied by their parents for their examination, confidentiality of information disclosed during an exam, interview, or in counseling should be maintained. Such information may be disclosed to parents when the patient consents to disclosure. Confidentiality may be justifiably breached in situations for which confidentiality for adults may be breached, according to Opinion 5.05, “Confidentiality.” In addition, confidentiality for immature minors may be ethically breached when necessary to enable the parent to make an informed decision about treatment for the minor or when such a breach is necessary to avert serious harm to the minor. (IV)

REPORTS OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

The following reports, 1–8, were presented by Susan Dorr Goold, MD, Chair:

1. PHYSICIAN EXERCISE OF CONSCIENCE

Reference committee hearing: see report of [Reference Committee on Amendments to Constitution and Bylaws](#).

HOUSE ACTION: REFERRED

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, 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 that 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) Prospectively notify patients about any services the physician declines to offer for reasons of deeply held, well-considered personal belief.
- (c) Take care that their actions do not disproportionately burden individual patients or their fellow professionals or adversely affect patient or public trust overall.
- (d) Uphold standards of informed consent and inform the patient about all relevant options for treatment, including options to which the physician morally objects.
- (e) 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 inform the patient in some manner about how to access the desired services.
- (f) 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. AMENDMENT TO E-8.061, "GIFTS TO PHYSICIANS FROM INDUSTRY"

Reference committee hearing: see report of [Reference Committee on Amendments to Constitution and Bylaws](#).

HOUSE ACTION: RECOMMENDATIONS ADOPTED AND REMAINDER OF REPORT FILED

See Opinion [E-8.061](#)

[Opinion E-8.061, "Gifts to Physicians from Industry."](#) was originally issued in 1992 to provide guidance for physicians in their relationships with industry in clinical practice. The American Medical Association (AMA) was a pioneer in turning physicians' attention to the ethical concerns posed by gifts from industry. However, medicine-industry relationships have evolved significantly since [E-8.061](#) was last updated in 1998 and so has public and professional unease about the possibility that gift relationships between physicians and pharmaceutical, medical device and equipment, and biotechnology companies will have inappropriate effects. Over the intervening years empirical research has explored the question of gift relationships and other organizations have reflected on the ethical implications and issued policies in this area, many of which have built on the foundations of [E-8.061](#). As it

stands, [E-8.061](#) no longer represents best thinking with respect to gifts to physicians from industry. The Council on Ethical and Judicial Affairs (CEJA) has thus concluded that this opinion should be updated.

THE CURRENT ETHICAL CONSENSUS

Since CEJA's original report, concerns about physicians' relationships with industry, including the acceptance of gifts, have continued to grow as evidence has accumulated about the influence of such relationships on physician practice.^[1-5] A consensus has emerged over the past decade or so that recognizes the enormous value of maintaining strong relationships between medicine and industry, notably in research and innovation, but equally recognizes the need for circumspection where gifts to individual physicians are concerned. This is the case whether gifts are large or small, financial or in-kind, office supplies or patient educational materials.^[6-8]

Calls for physicians to decline industry gifts of any size or nature have become prominent among many scholars of medicine-industry relationships,^[2,3,9] in reports by distinguished national bodies,^[4,5] and among national professional organizations and in advocacy campaigns.^[10-12] In 2007, the American Medical Student Association began surveying the conflict of interest policies of all allopathic medical schools in the U.S. to create its "PharmFree Scorecard," scoring medical schools with respect to their policies on gifts and pharmaceutical samples, among other domains.^[13] In 2008 the Association of American Medical Colleges urged academic medical centers to "establish and implement policies that prohibit the acceptance of any gifts from industry by physicians and other faculty, staff, students, and trainees."^[4] The following year, in its report on conflicts of interest in medicine, the Institute of Medicine similarly recommended that all physicians decline "items of material value" from industry and urged professional societies to amend their policies to support its recommendations.

The Pharmaceutical Research & Manufacturers Association (PhRMA) 2008 *Code on Interactions with Healthcare Professionals* bans noneducational and practice-related gifts (other than samples), items intended for the physician's personal benefit, and cash or cash-equivalents other than compensation for bona fide services, though it permits "items designed primarily for the education of patients or healthcare professionals" valued at under \$100.^[14] The 2009 *Code of Ethics* of the Advanced Medical Technology Association (AdvaMed) similarly restricts gifts to physicians.^[15]

According to data collected for AMSA's most recent "PharmFree Scorecard," 73 of 149 U.S. medical schools responding to the survey now prohibit gifts from industry entirely, while another 36 have policies restricting acceptance of gifts in various ways.^[13]

PROTECTING PATIENTS' INTERESTS & PUBLIC TRUST

Patients must be able to trust that their physicians have based treatment recommendations on the physician's independent professional judgment and knowledge of the patient's unique circumstances. Gifts from industry can undermine physicians' objectivity and put at risk physicians' ability to fulfill their primary professional commitment to serve patients' interests.

RECOMMENDATION

In light of these considerations, the Council on Ethical and Judicial Affairs recommends that [Opinion E-8.061, "Gifts to Physicians from Industry,"](#) be amended by substitution as follows, its accompanying clarification be rescinded, and the remainder of this report filed:

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.

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3. MODERNIZING THE *CODE OF MEDICAL ETHICS*

Informational report; no reference committee hearing.

HOUSE ACTION: FILED

At the end of 2008, the Council on Ethical and Judicial Affairs (CEJA) launched a multi-year project to critically review and update the *Code of Medical Ethics*. This project represents the most thoroughgoing effort to update the *Code* since 1957. The intent now, as then, is to ensure that the *Code* remains the pre-eminent expression of the ethical standards of the medical profession and upholds its legacy as “a symbol which may help keep ideals uppermost in mind and practice.”[1]

The work is now entering its final stage. This report briefly reviews the project and proposes a plan for presenting the completed work product to the House of Delegates for review and deliberation.

BACKGROUND

The *Code of Medical Ethics* embodies the accumulated wisdom of the HOD and CEJA’s goal has been to preserve that wisdom and to carry out its work through a transparent process.[2] The project involves three key stages. The first stage focused on reviewing all current Opinions for relevance/timeliness of guidance, clarity, and consistency of guidance on related topics, undertaken in collaboration with the Federation of Medicine. Response from across the Federation to CEJA’s invitation for input informed CEJA’s review. As part of the initial review process CEJA re-organized Opinions into a new, more intuitive chapter structure, which the council has continued to refine as the work has progressed.

In the second stage, working groups within CEJA developed drafts of updated Opinions on a chapter-by-chapter basis, which the council as a whole then reviewed and refined. In the process, CEJA re-organized individual Opinions to conform to a uniform format to ensure that guidance is clear and easy to follow. CEJA has been conservative in suggesting substantive change, doing so only where needed to ensure that guidance remains relevant in the face of changes in biomedical science and conditions of medical practice. The Council on Constitution and Bylaws has contributed to this second stage of the project by reviewing draft updated Opinions to confirm whether individual drafts contain only editorial changes that preserve the intent and substance of the original Opinion.

In the third stage of the project, CEJA will share its work product with the HOD.

SHARING CEJA’S WORK PRODUCT

The process of critically reviewing and reorganizing the content of the *Code* has reinforced for CEJA the importance of seeing the *Code* as an inter-related whole. Although each Opinion targets specific kinds of contexts or situations and thus can be read separately to provide immediate, practical guidance, no single Opinion stands fully independent of the *Code* as a whole and the fundamental professional values that undergird it. Moreover, questions about individual updated Opinions will often implicate guidance elsewhere in the *Code* and cannot necessarily be answered without referring to guidance in other chapters. For these reasons, CEJA believes it is crucial that the updated *Code* be presented as a single, integrated work for purposes of review and discussion.

Further, given the volume of material to be digested, presenting the material as an integrated whole can best help maintain consistency across the finished product, which would be considerably more difficult to ensure under an iterative, chapter-by-chapter review.

To facilitate review and discussion of the updated *Code of Medical Ethics*, the Council on Ethical and Judicial Affairs will:

1. Post a brief document to CEJA’s online forum explaining key aspects of how CEJA has updated the Opinions in the chapter, accompanied by a detailed “crosswalk” between each original Opinion (or Opinions) and the corresponding updated Opinion. The CEJA forum is open to all members of the AMA: www.ama-assn.org/go/cejaforum (member login is required to access the site).

2. Review feedback received through the online forum to revise the draft updated *Code* and present a revised draft of the work as a whole at the earliest feasible meeting of the House of Delegates.

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1. Principles of medical ethics. [JAMA. 1957;164\(13\):1482](#).
2. The Council has updated the House over the course of the project in several informational reports ([CEJA 5-I-08](#), [CEJA 4-I-09](#), [CEJA 9-I-10](#)) and an Open Forum session at the AMA's 2011 Interim meeting.

4. ETHICALLY SOUND INNOVATION IN MEDICAL PRACTICE

Reference committee hearing: see report of [Reference Committee on Amendments to Constitution and Bylaws](#).

HOUSE ACTION: REFERRED

The AMA's *Code of Medical Ethics* provides extensive guidance for physicians in various contexts of clinical practice and in clinical research. In its review of the *Code*, however, the Council on Ethical and Judicial Affairs (CEJA) realized that the *Code* provides little if any guidance with respect to innovation in medicine. The present report identifies key issues relevant to innovation and provides guidance for ethically sound practice in this area.

CHARACTERIZING INNOVATION IN MEDICINE

The term "innovation" can refer to many things in medicine. For example, it can refer to improving an existing intervention or introducing an intervention into one's own clinical practice for the first time. Or it can refer to using an existing intervention in a novel way (e.g., off-label use of an approved drug), or to applying concepts associated with a particular condition to a different condition or bodily system.

Some have sought to define innovation by distinguishing it from research, focusing on seeming contrasts in their respective focus and goals, methods, risks, outcomes, or effects on clinical practice. For example, where research focuses on benefits for populations of patients, innovation often targets individual patients, such as patients with a particular rare disease or for whom a standard therapy is ineffective (such as "n-of-1" trials).[1,2] Where research adheres to protocols with established methods, criteria for selecting specific participant populations, and specific, clearly defined outcome measures, innovation often modifies techniques as it progresses, may select different participants over time, or may redefine goals.[3] Research is characterized as drawing conclusions that are generalizable to large populations of patients, while innovation typically draws conclusions that are confined to a single patient or small subset of patients,[3] though innovations may generalize to larger patient populations over time, and may or may not require formal research protocols to justify widespread clinical adoption.[3,4].

Others have noted similarities between research and innovation in order to distinguish innovation from clinical practice (i.e., in shared aims of learning and improving treatments,[4] or as being riskier or more burdensome than clinical treatment) [5,6]. Still others define innovation as being typically evolutionary, building incrementally on new knowledge,[7] which nonetheless over time may come to seem like a revolutionary change in practice.

Finally, some view innovation as falling on a continuum between clinical practice and clinical research.[8] For example, the Belmont Report, the foundation for research ethics in the U.S., characterizes innovation as activity that departs in a "significant way from standard or accepted practice" yet does not automatically qualify as research just because it is "new, untested or different." [9]

However, as Kass and colleagues note, "a growing number of activities in health care cannot be comfortably classified as either research or therapy, the one excluding the other." [5] For example, the distinction between seeking to benefit the individual patient versus seeking generalizable knowledge to benefit populations is critiqued for being overly subjective,[6] and for under-appreciating how both research and clinical practice can contribute to learning.[5]

Research and innovation have also been distinguished from clinical treatment as carrying greater risk, in part because they involve unproven interventions. However, both research and clinical practice carry risks and burdens.[2] Nor are outcomes always better for patients in clinical practice than for research participants.[10,11] In

fact as many as 50 percent of interventions in clinical practice lack adequate evidence of effectiveness,[5,12] while both research and clinical practice impose burdens beyond those of interventions themselves that are not related to outcomes—for research, the requirements of the protocol, for example; for clinical practice, repeat office visits, wait time, or paperwork.[13,6] In some areas of medicine, enrolling a patient in a research protocol is considered the standard of care—for example, pediatric cancers. Likewise, although research typically involves specific and discrete protocols that dictate the course of action, under the rubric of evidence-based medicine clinical practice is also increasingly expected to conform to guidelines.[5]

ETHICS & INNOVATION

Physicians' obligations to advance knowledge [14] and to enhance the quality and safety of health care [15–17] argue for a general obligation to participate in innovation. The fact that the boundaries among research, innovation, and clinical practice are increasingly blurred does not mean that characteristics of ethically sound innovation cannot be identified. Indeed, identifying such characteristics will help clarify expectations for physicians' professional conduct to inform physicians' judgments about their own innovative activities.

Activities across the research-innovation-clinical care continuum share a common ethical foundation in physicians' professional commitments to safeguard patient well-being and ensure that the interests of current and future patients are not compromised.

Conditions for Sound Innovation

More than 20 years ago, Moore identified critical aspects for responsible innovation in surgery.[18,cf.19,3] First, innovation must be scientifically well grounded—there must be reasonable evidence from animal studies or other sources that a proposed innovation is feasible and likely to be effective. Second, innovators must have appropriate skills and knowledge. Third, innovation should focus on the interests of patients, not the interests of innovators or their institutions. Lastly, innovation should be reviewed and discussed openly with peers. This analysis of aspects of responsible surgical innovation generalizes to medical innovation, as well.

Evidence Base. Requiring that a proposed innovation have a scientific justification protects the interests of patients, helps to ensure that the innovation is medically credible and amplifies the chance that other physicians will be able to introduce the innovation successfully in their own practice. Further, while innovation often relies on intuition and incremental advances in knowledge, making it difficult to reduce innovation to specific, discrete protocols, it is desirable to structure innovation in a way that maximizes objectivity, helps enable others to replicate it, and enhances the chance to gain meaningful knowledge.[5,13] For example, a proposed innovation could identify and clarify the types of patients who might benefit most, standardize the process or procedures used, and resolve technical problems in applying the procedure.[20]

Knowledge, Skill & Experience. Requiring that innovators have—or acquire—appropriate knowledge, skill, and experience is also in the interests of patients. There is a “learning curve” associated with any innovation, whether an innovation is new to medicine or simply new to an individual physician’s practice, and until physicians develop competence, outcomes may be uncertain, while morbidity and mortality may be significant.[23] Laparoscopic cholecystectomy provides an example of the importance of the learning curve and the necessity of having a mechanism to gather data about the outcome of innovation.[21] The procedure was touted as offering shorter hospital stays and lower discomfort for patients. The randomized trials that were carried out were not large enough to detect any relevant concerns. However, as the procedure became widespread it was not until a state health department established a clinical registry to track data that it became clear the surgery led to severe complications.[21] When there is unresolved controversy about an innovation or its value, physicians must make difficult choices before introducing it into their own practice, and the balance of harm and benefit may shift over the course of introducing the innovation.[22]

Identifying strategies to limit the harms associated with the learning curve is important for protecting patients. For example, using simulations when possible can enable physicians to develop needed expertise without exposing patients to undue risk.[23,24] Physicians can collaborate with colleagues to manage the learning process through institutional credentialing mechanisms to reduce the likelihood that a physician will inappropriately use an innovative intervention with patients before he or she has acquired the skill to do so safely.[23,3,25] (The pathway

of credentialing and privileging may also be appropriate where the innovation as such is not novel, but is new to the physician.)

Professional societies can play a significant role by helping to define the minimum skills and baseline competence physicians must demonstrate before introducing an innovation into their practices.[23] Professional societies can also contribute by creating “hands on” courses for new techniques,[24] and can organize and support mentorship programs where individuals with experience with a particular method or procedure teach new users.[22,24] In some cases, physicians might rely on industry representatives to demonstrate proper use of an innovative device. Industry representatives, in this capacity, play an important role in patient safety and quality of care, but physicians have an ethical responsibility to maintain patient privacy, confidentiality, and quality patient care,[26] and should exercise due diligence in adopting innovations marketed by manufacturers.

Focus on Patient Benefit. Requiring that efforts to innovate be directed first and foremost toward benefit for the patient(s), not benefit for the innovator, is in keeping with physicians’ core fiduciary responsibilities as professionals.[14,28] Physician-innovators may gain personal financial benefits, advance their careers, or garner prestige or create a competition edge for themselves or their institutions but that should not be the primary impetus to innovate [18,cf.6,7,29,30].

Entrepreneurship, career development, and financial gain undoubtedly can drive individual and institutional efforts to develop and market innovations, and to the extent that these increase innovation and progress in medicine, they should be supported—for example, by granting patents on devices.[29] Yet because the physician’s primary responsibility is always to the patient, physicians have an obligation at minimum to disclose conflicts of interest to patients, and more broadly to resolve conflicts in favor of the patient.[31,32]

Physicians should be sensitive to the outside forces that might drive the creation and adoption of innovative practices for reasons other than patient benefit. For example, in the 1990s, physicians and payers faced political pressures from breast cancer patients, lobbyists, and patient advocate groups to provide (and pay for) high-dose chemotherapy and autologous bone marrow transplant (ABMT) to treat advanced stage cancer, despite lack of evidence for its efficacy.[33] Over 41,000 patients were exposed to expensive and very toxic treatment before ABMT was proven in formal clinical trials to be no better than existing, proven treatments.[33]

Review & Consultation. Finally, requiring that physicians submit proposed innovations to some form of peer review or professional consultation can help ensure that a proposed innovation is objective and well grounded, minimizes risk, and promotes knowledge sharing. The Declaration of Helsinki similarly recommends that physicians seek expert advice before using an unproven intervention in patient care.[2] But what form of oversight or consultation, if any, is appropriate for activities that fall somewhere between research and clinical care?

Different models of oversight and peer consultation fulfill different patient care goals and these differences can inform a physician’s or institution’s decision about the most effective model in a given context. A research model with IRB formal review emphasizes the balancing of risks and benefits and the protection of research participants.[34] Yet, the IRB model is critiqued for causing “delays, confusion, and frustrations” at the boundaries of clinical care and research and for overprotecting patients from low risk interventions that could contribute to health care safety and quality.[5] Activities which involve significant risk or uncertainty related to risk benefit from an IRB review to determine how best to protect participants and minimize harm.

Institutions can create clear innovation strategies and policies to help guide their individual physicians as they introduce innovation into practice. For example, Stanford University’s “Innovative Care Guidelines” provide guidance for physicians on the level of review appropriate for a specific innovative practice. The burden of determining appropriate review is on the physician, who must seek a consultation to determine if further review is necessary; if so, an innovative care review committee is convened. A variety of outcomes are possible: the innovation is more akin to research and requires IRB review, the risk-benefit ratio does not support proceeding with the proposed care as research or innovation, or the request is not truly innovative and can be handled with an extension under the privileging process. If the proposed care is innovative and reasonable, Stanford recommends the treatment be restricted to a small number of patients (1–5), the physician obtain informed consent (which includes discussing the innovative nature of the treatment, risks, and alternatives), and continual monitoring. If a successful innovation is to be offered to a larger patient population, systematic study with a formal research protocol and IRB review might then be required.[25]

Beyond questions of public or professional oversight of innovation, physician-innovators have a responsibility to record their experiences and be transparent about the information they acquire from their innovations.[14,35,2] This might include both short- and long-term follow-up of outcomes, as well as a disclosure of both positive and negative findings. Innovation introduced prematurely or without significant evidence of its benefit can be costly and harmful to patients. Prasad and colleagues cite a report that billions of dollars were lost and significant patient harm caused by adoption of an ineffective clinical intervention that, had it simply been studied under a formal research protocol, could have cost only several million dollars.[36]

The nature, quality, and efficiency of oversight, as well as who is responsible for oversight, can have an impact on how frequently innovations occur and how rapidly and safely innovations can be translated into clinical practice. There is need for meaningful oversight by physician peers, professional societies, and health care institutions to provide reasonable guidance that can help facilitate physician innovation and clarify when additional oversight is or is not needed. To best protect patients and ensure progress into the future, medicine must strike a balance between prematurely adopting innovative therapies and delaying adoption.

IMPLICATIONS FOR PATIENT CARE

In addition to these broad considerations, long-standing ethical obligations in the realm of patient care, as well as expectations for the responsible conduct of research, offer insight into issues that physicians must address when they recommend innovative treatment for a particular patient. Prominent considerations include obligations to minimize risk and to obtain the individual's informed consent.

Minimizing Risk. When a physician recommends an innovative intervention to a patient, a key concern is whether, and to what extent, a departure from standard therapy poses distinctive risks for the patient [20] and the extent to which that risk can be minimized. The implication is that a decision to innovate in the clinical care of a patient must rest on a physician's well-considered judgment that it is in the best interest of the patient, given his or her clinical circumstances and the anticipated risks and benefits of the innovation, to depart from established therapy in the way the physician proposes. This is in keeping with physicians' general obligation to base treatment recommendations on patients' medical needs.[14,28,38,13]. The physician must also have a scientifically grounded reason to believe that the proposed departure from standard care will provide benefit to the patient [18,cf.19,38], in keeping with the obligation to avoid recommending (or providing) an intervention that is unlikely to achieve identified goals for care [39]. Physicians should not engage in medical practices that have no scientific basis [40].

Depending on what specific innovation is contemplated and how much is or is not already known, it may be more or less challenging to assess whether the proposed benefits of a proposed intervention will exceed its risks. For example, the side effects of an approved drug are likely to be known (or to be reasonably predictable), while its effectiveness in an off-label use has not been demonstrated. It may be more difficult to predict the relative risks of a never-before-used surgical technique, such as different complications or longer healing time.

Transparency & Informed Consent. As for any medical intervention or enrollment in clinical research, the patient's informed consent is required before the use of an innovative therapy. The obligation to respect patient self-determination cuts across the continuum of research, innovation, and patient care. It requires both researchers and practicing clinicians to ensure that patients can have a meaningful role in making decisions about whether to participate in research or what care plans best addresses their values, preferences, and medical needs [41,42,28,43].

Brody argues that appropriate informed consent is best achieved when physicians are transparent about why they recommend a specific course of action.[44] In the context of innovation, physicians should inform patients when they propose innovative treatment, what standard therapy is, how the proposed intervention departs from standard therapy and why the physician believes the innovative therapy is more appropriate than standard care in the patient's circumstances, as well as whether the proposed intervention is entirely novel or a new use of a proven intervention. As for any intervention, patients should always be told they may refuse the innovation or withdraw from innovative treatment at any time.

In addition to advising the patient about anticipated benefits of the innovative intervention, physicians must inform patients about its inherent risks, to the extent that risks are known (e.g., known side effects of an approved drug that will be used off label) or can reasonably be predicted. Physicians should also be transparent about medical uncertainties associated with the innovation,[45] and special measures taken to minimize risks (if any). Additionally,

physicians should discuss whether any third parties will be involved in providing the therapy (e.g., other health care professionals or manufacturers' representatives providing technical assistance [26]) and the conditions under which the physician would discontinue the novel therapy.

Patients can also make better informed decisions when they know how much experience a physician has with a proposed innovation. In a survey of 383 surgical patients, approximately 80 percent indicated they wanted to know a surgeon's level of experience with a procedure before making decision about whether to have surgery.[46] Patients also wanted information about outcomes.[46] Physicians who are new to an innovative practice should disclose their level of experience and the outcomes they have had, telling the patient, for example, "To date, I have completed 4 surgeries, one of which required an extra day of hospitalization compared to the standard surgery."[47] Determining when such disclosure is no longer required because a physician has attained sufficient expertise will likely vary with the nature of the intervention and associated risks.

BROADER IMPLICATIONS OF INNOVATION

Innovation carries implications for the health care system, and the wider community, as well as for individual patients. Among the most important are the possible influences of innovation on health care costs and access to care. For example, how should considerations of responsible stewardship influence decisions to innovate or disseminate particular innovations?

Innovation is double edged, insofar as it can both be a path to containing costs and a driver of cost increases. "Technological innovation is believed to be responsible for the rise of the cost of health care at 2 to 3 times the rate of inflation."^[3]

Nor is all innovation equally necessary—innovation for the sake of innovation alone is hard to justify. As Callahan notes, "[u]nrestrained and cost-insensitive innovation needs to be stifled. In its place must be put a prudent, priority-oriented, vision based on prevention, primary care medicine, and low-cost technologies."^[48] Like Callahan, Fuchs argues that an environment of constrained resources in health care, requires a "shift to value-conscious innovation instead of fostering the 'progress at any price' attitude that has dominated biomedical innovation."^[49] Rather, innovation must be reviewed for its effects on three areas: quality of care, cost and value.^[49] Iserson similarly argues that before an innovation is adopted into practice, consideration should be given to whether it is safer, quicker, more effective, and cheaper or more cosmetic than standard care.^[7]

Physicians' responsibility to be prudent stewards of health care resources in the interests of the community and the health of the public as well as individual patients, and to support access to medical care for all people require that they take such considerations into account before adopting or promoting innovative and as yet unproven therapies individually in their own practices and collectively as a profession.^[14,51,13,38]

RECOMMENDATION

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:

As members of the medical profession, physicians have responsibilities to advance medical knowledge and improve quality of care, as well as to promote the interests and safeguard the well-being of individual patients and the larger community. These goals can be accomplished, in part, when physicians participate in developing and disseminating innovative practices or 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 and as-yet unproven modalities have an ethical responsibility to:

- (a) Innovate on the basis of sound scientific evidence and principles.
- (b) Seek input from peers regarding the validity, design, and implementation of innovative therapies.

- (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 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) Uphold robust standards of shared decision making. Inform the patient:
 - i) that a recommended diagnostic or therapeutic service differs from standard therapy;
 - 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 the status of the innovative therapy is in the professional community and what experience the physician individually has with the recommended 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.
- (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.

Collectively, physicians should:

- (k) Require that physicians who participate in innovation have—or acquire—appropriate knowledge and skills.
- (l) Ensure that there is meaningful professional oversight of innovation.
- (m) Promote innovation that will result in higher quality, more affordable, and more readily accessible care for all patients.

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5. PROFESSIONALISM IN HEALTH CARE SYSTEMS

Reference committee hearing: see report of [Reference Committee on Amendments to Constitution and Bylaws](#).

**HOUSE ACTION: RECOMMENDATIONS ADOPTED AND
REMAINDER OF REPORT FILED**
See Opinion [E-8.051](#)

The past 20 years and more have seen significant change in health care in the United States. Over this period, new organizations for delivering health care (such as health maintenance organizations [HMOs], preferred provider organizations [PPOs], and more recently, accountable care organizations [ACOs]) have combined with new payment systems (notably capitation) and third-party payers' adoption of new roles to influence treatment recommendations and decisions, to change the landscape of health care for both patients and physicians. At the same time, the goal of controlling the cost of health care has been joined by enhanced emphasis on improving patient safety and quality of care and new visions for "learning health care organizations" that create a dynamic, rapidly changing environment.

Over this period, the Council on Ethical and Judicial Affairs (CEJA) analyzed ethical challenges that emerged with the changes in health care, including challenges to physician professionalism posed by "gag clauses" in contracts with managed care organizations and the use of formularies, financial incentives, and other tools to help contain costs and promote safety and quality. As a result, the *Code of Medical Ethics* now contains several opinions that address various aspects of professionalism in physicians' relationships with health care organizations and payers:

- E-8.051 Conflicts of Interest under Capitation (1997, updated 2002)
- E-8.054 Financial Incentives and the Practice of Medicine (1998, updated 2002)
- E-8.056 Physician Pay-for-Performance Programs (2006)
- E-8.13 Managed Care (1996, updated 2002)
- E-8.135 Cost Containment Involving Prescription Drugs in Health Care Plans (1996, updated 2002)

CEJA recently reviewed these opinions and found that each is informed by a common core analysis and the same enduring ethical values:

- the overriding importance of preserving trust in patient-physician relationships,
- the imperative to minimize the effects of financial conflicts of interest and competing responsibilities, and
- the need to sustain physicians' commitment to use their best professional judgment in the service of their patients and to preserve opportunities for physicians to advocate meaningfully on behalf of their patients.

However, CEJA also found that the ethical guidance these opinions offer is often closely tied to details of specific cost-containment mechanisms, structures for delivery of health care, or payment models. Such narrowly focused guidance can be difficult to apply, and thus of limited value, in a health care system that continues to evolve rapidly.

CEJA concluded that it could best ensure that guidance in this area remains timely and readily accessible by combining and updating guidance from these earlier opinions into a new opinion addressing core ethical considerations for physician professionalism in the context of efforts to contain costs and improve quality in health care systems. To develop updated guidance, CEJA has based its analysis on its review of current opinions and on a review of ethics literature published in the years since existing opinions were issued. The following report summarizes the Council's deliberations and updates ethical guidance.

PHYSICIAN ACCOUNTABILITY: FROM COST CONTAINMENT TO QUALITY & VALUE

Existing opinions in the *Code* addressing professionalism in health care systems were formulated largely in response to mechanisms introduced by managed care in the 1990s that sought to control health care costs, especially by holding physicians accountable in new ways.^[1-3] While many of these mechanisms, in the right environments, offered the possibility of controlling overall costs, supporting cost-effective care, and improving quality of care, they could also pose ethical conflicts for physicians.^[4-6]

Models for delivery and payment of health care focus increasingly on questions of value in health care, defined by a leading proponent as “the health outcomes achieved per dollar spent,”^[7,8] and toward models that share accountability among health care professionals differently than managed care.^[7,9] Emerging models, such as accountable care organizations (ACOs) and medical homes, take advantage of lessons learned, a stronger evidence base, ongoing refinement of quality measures, a more collaborative approach to care, and greater physician control in health care organizations than did their managed care predecessors.^[9]

ETHICAL CHALLENGES TO PROFESSIONALISM IN HEALTH CARE SYSTEMS

Models for financing and organizing the delivery of health care, whether fee for service, managed care, or ACOs and other emerging models can create financial conflicts of interest, set competing responsibilities for physicians, undermine trust and the integrity of patient-physician relationships, and have unintended consequences in relation to patients' access to care and physicians' professional satisfaction.^[10-15]

Conflicts of Interest & Competing Responsibilities

As CEJA noted in its report on ethical issues in managed care, “financial conflicts are inherent in the practice of medicine, regardless of the system of delivery” or method of payment.^[1] The intensity and immediacy of incentives, as well as how broadly or narrowly incentives are targeted shape how deeply particular incentives raise conflicts of interest.^[1,6,16-17] Physician-leaders in health care organizations have a responsibility to minimize the intensity and immediacy of incentives and to use incentives targeted to specific interventions only when there is evidence of overuse of the intervention and there are scientifically sound guidelines for appropriate use. ^[1,6,17]

Efforts to contain costs can also create conflicting loyalties and competing responsibilities for physicians in asking them to serve both the interests of individual patients and the interests of populations of patients or of health care organizations.^[1,11,18] At the same time, physicians are uniquely positioned to recognize the effects of uneven or unfair distribution of health care resources, and they do have a responsibility to be wise stewards of health care resources. To fulfill that responsibility, physicians must be able to rely on health care organizations to minimize the possible effects of competing responsibilities and to support appeals and meaningful advocacy on behalf of individual patients.^[1,19]

Trust

A defining obligation of physicians as members of the medical profession is to put patients' interests ahead of physicians' personal financial interests.^[1,4,16,17,19-21] Conflicts of interest and competing responsibilities created by models for financing and organizing the delivery of health care have the potential to undermine trust.^[4,22] Yet trust is a complex phenomenon and multiple factors can influence how strongly payment mechanisms or incentives affect patient trust in their individual physicians and the medical profession.^[22-26] Payment models and incentives

should minimize conflicts of interest and care delivery systems should support robust patient-physician communication, enable physicians to advocate effectively for individual patients, and make available resources physicians need to provide high value, cost-conscious health care.[1,17]

UNINTENDED CONSEQUENCES

Mechanisms intended to influence what care is available to patients and how or by whom care is provided can have unintended consequences for patients, physicians, and health care systems. For example, formulary restrictions may help contain medication costs for a majority of a health care organization's patient population, but provide lesser benefit or poorer outcomes for a subset of the population, possibly offsetting cost savings.[4] Inadequate capitation rates may result in pitting the needs of one patient against the needs of others in a physician's practice, undermining trust.[4] Among the issues of greatest concern are the possible adverse effects of payment and delivery models on health care disparities and physician professionalism.

Exacerbating Health Care Disparities

Incentives also carry the potential to exacerbate inequities in health care. For example, pay-for-performance programs can adversely affect care for vulnerable populations of patients if they incentivize physicians to avoid patients for whom performance targets would be difficult to achieve.[10,12–14,27] To minimize the risk that pay-for-performance or other incentives will "accentuate inequity in health care," incentives must be appropriately adjusted for case mix, practice structure, availability of resources, etc.[1] Adjustment methods must be carefully considered, however. Hong and colleagues note that "to the extent that health systems reward physicians for higher measured quality of care, lack of adjustment for patient panel characteristics may penalize physicians for taking care of more vulnerable patients, incentivize physicians to select patients to improve their quality scores, and result in the misallocation of resources away from physicians taking care of more vulnerable populations. Conversely, adjustment for patient panel characteristics may remove the incentive to improve care or may inappropriately reward lower-quality physicians caring for more vulnerable patients."[13]

Physician Professionalism & Satisfaction

Experience with managed care has also led to questions about other ways in which payment models, delivery structures, and incentives built into health care can have unintended consequences for physicians as well, especially for physician professionalism. Pressures to contain costs "may encourage some physicians to try to manage cases longer than they should," especially under a capitated system of payment.[1] Incentives may perversely encourage physicians to "treat to the measure, rather than the patient's presenting complaint,"[28] or to "game" the system in various ways to improve performance ratings.[27] Similarly, incentives in one practice area may shift physicians' attention away from other, unmeasured areas,[27] including "communication, compassion, and trust."[11] Research has also indicated that incentives can undermine physician satisfaction—for example, studies showing reduced satisfaction among physicians in pay-for-performance programs.[14]

FLAWED ASSUMPTIONS & UNCERTAIN UTILITY

The use of incentives rests on the assumption that a given incentive will motivate a specific desired behavior—in health care, that incentives will motivate physicians to act in specific ways so as to help lower health care costs and improve quality of care. But whether the use of incentives in health care is an effective way to influence the behavior of professionals is open to question. Moreover, there is growing evidence that incentives, particularly financial incentives, are not effective in controlling costs or improving quality.

Incentives as Motivators

Financial incentives presume that money is an important motivator for physicians. As Glasziou and colleagues note, financial incentives "assume that paying more for a service will lead to better quality."[27] However, financial rewards are only one among several extrinsic motivators, which can include lifestyle considerations, recognition, and patient appreciation.[27,29] For physicians, intrinsic motivators, including "feelings of accomplishment associated with completing difficult tasks; satisfaction in delivering positive clinical outcomes; and experiencing autonomy, respect and collegial relationships" may play a stronger role than financial rewards (or penalties) in

shaping behavior.[29] Further, incentives to reach specific performance targets fail to reward skills that are central for physicians, such as managing complexity or solving problems,[29] or creating rapport with patients.

Perversely, incentives may have the opposite of their intended effect, undermining motivation instead of enhancing performance.[29,30] Rewards can “worsen performance on complex cognitive tasks, especially when motivation is high to begin with” and “undermine the intrinsic motivation crucial to maintaining quality when nobody is looking.”[30]

Biller-Andorno and Lee argue that the most appropriate incentives for physicians are those that are based in a sense of shared purpose and protect and promote physicians’ sense of moral responsibility and enable physicians to “take ownership” of the incentive.[15] With shared purpose incentives “instead of being passively graded or rewarded, physicians engage in the development, ongoing evaluation, and critical review” of an incentive scheme. Physicians should also have opportunity to report “any negative effects on quality, efficiency, and equity of patient care” that result from an incentive scheme.

Weaknesses in Design & Implementation; Uncertain Utility

Criticism has also been voiced about the design of incentives. In its report on ethical issues in managed care, CEJA noted that flawed incentives based on too large or too small a sample of patients (or physicians), or on too long or short a time interval of measurement can have the effect of penalizing physicians whose panel includes patients with difficult to treat medical conditions [1; cf. 17]. If not carefully designed, performance measures can hold physicians accountable for aspects of quality over which they have no control, including limitations in the delivery system itself or social factors external to health care that affect patient outcomes.[11]

Measures may also be based on a problematic understanding of quality that “equates quality with the achievement of non-individualized, pre-determined health goals for broad populations.” [11] Measures also have tended to focus on processes rather than clinical outcomes or other endpoints of value to patient.[7,14]

Evidence to date also suggests that incentives are not necessarily effective in controlling health care costs or improving health care quality. Glasziou and colleagues note that “evidence on the effectiveness of financial incentives is modest and inconsistent.”[27] The absence of robust evidence for the effectiveness of pay-for-performance programs led the Society for General Internal Medicine to criticize pay-for-performance from an ethical perspective “because of significant potential for unintended consequences but scant data regarding its impact.”[28] The Society further noted that pay-for-performance programs “generally lack key safeguards as well as monitoring” and may be unable to identify adverse events to which they give rise.[28]

PRESERVING PROFESSIONALISM

Models for financing and organizing the delivery of health care undoubtedly will, and should, continue to evolve. However, efforts to refine payment mechanisms or to reorganize where and by whom care is provided in the interests of promoting high value, cost conscious care and better outcomes for patients must be sensitive to the ethical risks such efforts can pose. They must be designed and implemented with an eye toward preserving the core values of medicine and sustaining physicians’ professionalism and patients trust.

RECOMMENDATION

The Council on Ethical and Judicial Affairs recommends that Opinions E-8.051, Conflicts of Interest under Capitation; E-8.054, Financial Incentives and the Practice of Medicine; E-8.056, Physician Pay-for-Performance Programs; E-8.13, Managed Care; and E-8.135, Cost Containment Involving Prescription Drugs in Health Care Plans, be amended by substitution as follows and the remainder of this report be filed:

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 under treatment and over treatment, 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 have an ethical responsibility to 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 ethical guidelines.
 - 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 have an ethical responsibility to:

- 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.

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6. NOMINATION FOR AFFILIATE MEMBERSHIP – DAVID G. ARMSTRONG

No reference committee hearing; adopted during general session Sunday, Nov 17.

HOUSE ACTION: RECOMMENDATION ADOPTED AND REMAINDER OF REPORT FILED

In keeping with Bylaw 1.12(f), Affiliate Members, the Council on Ethical and Judicial Affairs (CEJA) recommends the following individuals for affiliate membership in the American Medical Association (AMA):

Individuals engaged in scientific endeavors allied to medicine and others who have attained distinction in their fields of endeavor but who are not eligible for other categories of membership.

David G. Armstrong, DPM, MD, PhD

Dr. Armstrong is the Director of the Southern Arizona Limb Salvage Alliance and a Professor of Surgery at the University of Arizona, College of Medicine. At the University of Arizona, Dr. Armstrong leads a team of clinicians and researchers dedicated to advancing therapeutic interventions and scientific investigations in the areas of wound healing, the prevention of diabetic foot amputation, and the epidemiology of diabetes complications, among others. He has authored and coauthored over 400 scientific articles related to the management and prevention of diabetic foot conditions, with a particular focus on foot amputation prevention, and has received numerous awards for his dedication to this field of medicine, including the Georgetown Distinguished Lifetime Achievement Award in Diabetic Limb Salvage, the American Podiatric Medical Association Award for Excellence, and American Diabetes Association Roger Pecoraro Award for Lifetime Achievement in Advancement in Diabetic Foot Care. Dr. Armstrong received his academic and professional training at Occidental College, the California College of Podiatric Medicine (DPM), the University of Wales College of Medicine (MS), the University of Manchester College of Medicine (MD), and the Victoria University of Manchester (PhD). He completed a Diabetic Foot Fellowship at the University of Texas Health Science Center, and his residency in Foot and Ankle Surgery at Monsignor Clement Kern Hospital for Special Surgery in Warren, Michigan.

Dr. Armstrong has been board certified by the American College of Podiatric Surgery since 1999, holds a teaching license with the Arizona Medical Board, and is licensed by the Arizona State Board of Podiatry Examiners.

Dr. Armstrong's application is endorsed by Rainer W.G. Gruessner, MD, FACS, chair of the Department of Surgery at the University of Arizona College of Medicine. Dr. Gruessner is a member of the American Medical Association.

7. NOMINATION FOR AFFILIATE MEMBERSHIP – HARINDER PAUL

No reference committee hearing; adopted during general session Sunday, Nov 17.

HOUSE ACTION: RECOMMENDATION ADOPTED AND REMAINDER OF REPORT FILED

In keeping with Bylaw 1.12(a), Affiliate Members, the Council on Ethical and Judicial Affairs (CEJA) recommends the following individuals for affiliate membership in the American Medical Association (AMA):

Physicians in foreign countries who have attained distinction in medicine and who are members of their national medical society or such other medical organization as will verify their professional credentials.

Dr. Harinder Paul is a general practitioner with the North Street Medical Centre in Perth, Australia. Alongside his clinical work, Dr. Paul supervises medical students from the University of Western Australia and the University of Notre Dame Australia in their general practitioner training, and serves as an examiner for the Royal Australian College of General Practitioners (RACGP). Separate from his work at North Street, Dr. Paul has been a resident medical officer in psychiatry and pediatrics at Modbury Public Hospital, and held a one-year clinical observership in obstetrics and gynecology at the Women's and Children's Hospital in Adelaide. He received his Bachelor of Medicine and Bachelor of Surgery from Awadhesh Pratap Singh (APS) University, Rewa, India in 1977, where he

received first class marks in Medicine, Physiology, and Anatomy. He went on to obtain his Master of Surgery from APS in 1981. Following the completion of his academic training, Dr. Paul served as a senior medical officer to Mission Hospital in India from 1982-1986, and thereafter, conducted clinical work and research throughout India, the United States, and Australia.

Dr. Paul has been a member of the RACGP since January 2005, and received a fellowship from the College in 2008. He is currently a member in good standing RACGP.

8. NOMINATION FOR AFFILIATE MEMBERSHIP – DANIEL E. BUFFINGTON

No reference committee hearing; adopted during general session Sunday, Nov 17.

HOUSE ACTION: RECOMMENDATION ADOPTED AND REMAINDER OF REPORT FILED

In keeping with Bylaw 1.12(f), Affiliate Members, the Council on Ethical and Judicial Affairs recommends the following individuals for affiliate membership in the American Medical Association (AMA):

Pharmacists who are active members of the American Pharmaceutical Association

Daniel E. Buffington, PharmD, MBA

Dr. Daniel Buffington is President and CEO of Clinical Pharmacology Service, Inc. in Tampa, FL, where he is also a Clinical Assistant Professor of Medicine at the University of South Florida's (USF) College of Medicine, Division of Clinical Pharmacology, and College of Pharmacy, Division of Pharmacy Practice. In addition, Dr. Buffington serves as the President of the American Institute of Pharmaceutical Sciences. He has been a faculty member at USF since 1991, and during his tenure has provided educational support and curriculum design for a wide range of topics, including psychopharmacology, forensic pharmacology, collaborative drug therapy management, prescribing strategies, and patient safety. Dr. Buffington received his undergraduate degree in biology from USF in 1983, and then went on to complete his Doctor of Pharmacy and Master of Business Administration from Mercer University in 1987 and 1995, respectively. From 1987 to 1988, he completed his residency in Clinical Pharmacokinetics at Emory University Hospital, and then undertook a Clinical Research Fellowship at Emory from 1988 to 1989. Dr. Buffington has been recognized with numerous awards for his work in pharmacy, including the University of Florida's 2013 Outstanding Pharmacy Service Award, the 2005 Dr. G. Van Greene Distinguished Lectureship from Mercer University, and the 2008 Pinnacle Award from the American Pharmacists Association Foundation.

Dr. Buffington has worked with the AMA since 2004 via his contributions to the Current Procedural Terminology (CPT) Editorial Panel. Within CPT, he has worked with the Drug Infusion Workgroup (2005-2009), the Therapeutic Drug Monitoring Workgroup (2013-present), and in 2004 was awarded the Burgess L. Gordon Award by the AMA.

Dr. Buffington holds pharmacy licenses in Georgia and Florida, and his application for AMA Affiliate Membership is supported by the Florida Medical Association.