

## OPINION OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

The following opinion was presented by Patrick W. McCormick, MD, Chair:

### 1. PHYSICIAN EXERCISE OF CONSCIENCE

*CEJA opinion; no reference committee hearing.*

#### HOUSE ACTION: FILED

At the 2014 Interim Meeting, the American Medical Association House of Delegates adopted the recommendation of Council on Ethical and Judicial Affairs Report 1-I-14, "Physician Exercise of Conscience." 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-10.06 Physician Exercise of Conscience

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

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

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

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

In following conscience, physicians should:

- (a) Thoughtfully consider whether and how significantly an action (or declining to act) will undermine the physician's personal integrity, create emotional or moral distress for the physician, or compromise the physician's ability to provide care for the individual and other patients.
- (b) Before entering into a patient-physician relationship, make clear any specific interventions or services the physician cannot in good conscience provide because they are contrary to the physician's deeply held personal beliefs, focusing on interventions or services a patient might otherwise reasonably expect the practice to offer.

- (c) Take care that their actions do not discriminate against or unduly burden individual patients or populations of patients and do not adversely affect patient or public trust.
- (d) Be mindful of the burden their actions may place on fellow professionals.
- (e) Uphold standards of informed consent and inform the patient about all relevant options for treatment, including options to which the physician morally objects.
- (f) In general, physicians should refer a patient to another physician or institution to provide treatment the physician declines to offer. When a deeply held, well-considered personal belief leads a physician also to decline to refer, the physician should offer impartial guidance to patients about how to inform themselves regarding access to desired services.
- (g) Continue to provide other ongoing care for the patient or formally terminate the patient-physician relationship in keeping with ethical guidelines. (I, II, IV, VI, VIII, IX)

## REPORTS OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

The following reports, 1–5, were presented by Patrick W. McCormick, MD, Chair:

### 1. ETHICAL PRACTICE IN TELEMEDICINE

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

#### HOUSE ACTION: REFERRED

Innovation in information technology is radically changing the ways in which humans live their lives. It is redefining how people perceive time and distance, and is reshaping how they interact with and relate to others. This includes reshaping the ways people engage with medicine. As the public becomes increasingly fluent in utilizing novel technologies in all aspects of daily life, evolving applications in health care are altering the contours of when, where, and how patients and physicians engage with one another.

Prior to recent innovations in information technology, individuals who had a medical concern either turned to hardcopy publications, made an appointment to see their physician, or spoke with family or friends. Now, a growing number are going online to seek answers, and they can do so at virtually any time from virtually anywhere [1]. New technologies are also allowing patients to receive care remotely through telemedicine applications, which can offer opportunities for patients who are homebound, who live in rural or underserved areas, or who face other impediments that limit their access to care to overcome those obstacles. Likewise, new technologies are making it possible for patients who have rare medical disorders to obtain care from distant specialists [2-4]. Even for patients who have access to care in person, many find telemedicine a welcome convenience [5]. Given the strong consumer demand in all sectors for access and convenience, patient interest in telemedicine is likely to grow.

Moreover, patients who wish to can maintain their own health records—and share them with physicians and others without the need for geographic proximity—through online personal health records. Online patient communities [6] build on the legacy of in person “peer-to-peer” networks, such as Alcoholic Anonymous, that have long offered information and support.

Yet while these innovations, and those yet to emerge, have significant potential to benefit patients, they also raise challenges. In particular, concerns have been raised that exchanging health information and providing care electronically could create new risks to quality, safety and continuity of care and weaken the patient-physician relationship [4,7-10].

#### TELEHEALTH/TELEMEDICINE: NEW WAYS TO DELIVER HEALTH CARE

“Telehealth” and “telemedicine” represent a continuum of technologies and activities that offer new ways to deliver care. Although the two are distinguished in current usage, the reasons for doing so are largely administrative. The Health Resources and Services Administration defines “telehealth” broadly as involving electronic and telecommunications technologies to “support long-distance clinical health care, patient and professional health-related education, and public health and administration” [11]. For purposes of reimbursement, the Centers for Medicare and Medicaid Services defines “telemedicine” narrowly as activities involving “two-way, real time interactive communication between the patient and the physician or practitioner at [a] distant site” [12].

In telehealth/telemedicine as in other modes of care, patient-physician interactions span a continuum of interactions that give rise to differing levels of accountability for physicians. At one end of the telehealth/telemedicine continuum are health-related online sites where any interaction between an individual seeking health information and a physician who provides it is indirect and the physician has broad obligations to all site users, but is not specifically accountable to any individual information seeker. For example, on some sites, physician experts are responsible for ensuring the accuracy and quality of content, but are not expected to be responsible for how individuals act on the information they find on the site. The analogy is to seeking information from a book or journal article, whose author has some level of responsibility for content, but is not held to account for readers’ individual interpretations.

Farther along the continuum are interactions that are more direct, which give rise to greater accountability, and carry more potential for unethical behavior. An example would be when a patient using an online health site or service poses a specific personal health question to which a physician affiliated with the site/service offers an individualized response (which might include a recommendation to see a physician in person, of course), either in real time or within an established time frame. In such scenarios, by tailoring the response specifically to the individual, the physician takes on a greater measure of accountability than one who posts general health content for public consumption. This situation might be more like (though more formal than) a “cocktail party consult” in which a physician is approached for guidance. Disclaimers to the effect that the consultation does not establish a legally recognized patient-physician relationship, which some sites provide, do not obviate physician’s ethical responsibility.

Still further along the continuum, in a teleradiology or teledermatology consultation, for example, a specialist is able to access images (ideally accompanied by information about the patient’s history), review them, and offer insight in real time or asynchronously using store-and-forward technology [2]. The underlying expectation is that the specialist’s response will directly inform decisions about the patient’s care, for which the specialist will then share a measure of accountability with the treating physician in keeping with expectations for in person consultations.

At the far end of the continuum are interactions in which a physician participates directly in a patient’s clinical care in real time via telecommunications and is held accountable for the care he or she provides as a treating physician. Telepsychiatry is one example, in which care is electronically mediated, but is not necessarily institutionally based [13]. Tele-oncology provides a second example, in which a specialist provides care for a patient being seen in a remote clinic or other institutional setting, in coordination with on-site professionals involved in the patient’s care team [3]. Physicians are also developing new formats for follow-up of patients with chronic health conditions that take advantage of asynchronous communication to enhance care, provide greater convenience for patients, and enable physicians to make effective use of limited clinical time [14].

#### FAMILIAR CHALLENGES, NEW CONTEXT

Proponents of telehealth and telemedicine highlight how they open new channels of access to care and offer new opportunities for truly patient-centered care [1,5,10,15]. Others are more cautious, expressing concern about new (or exacerbated) risks to privacy and confidentiality, the limitations of electronically mediated interactions for physical examination, and the potential for disruption of the patient-physician relationship [4,8,16,17].

##### *Risks to Privacy & Confidentiality*

Compared to traditional in person encounters between patient and physician, the structure of telehealth/telemedicine encounters can create new risks for breaching privacy and confidentiality: at the patient end of the encounter, during transmission, and at the provider end. Protocols to protect against unauthorized access and ensure the integrity of data must be in place at all three points of the electronic interaction [8].

Electronic health encounters involve a wider range of third parties than traditional health care, notably telecommunications service providers and their possible business affiliates, in addition to health care personnel at one or both ends of the interaction. Some encounters will be protected under privacy laws and regulation, but others may not and may carry additional risks—for example, websites that offer health information may not actually be as anonymous as visitors think; or they may leak information to third parties through code on the site or implanted on patients’ computers [9]. Similar concerns may apply to home monitoring devices and mobile health applications, to which current privacy protections do not apply [8].

##### *Limitations of Electronic Encounters*

Other challenges are often attributed to perceived limitations of telehealth/telemedicine, particularly the difficulty of conducting a physical examination and potential barriers to rapport posed by telecommunications technologies. The structure of some telehealth activities may also make it difficult to verify the identity of patients, physicians, and other participants [9,13].

In some electronic encounters, the inability to examine the patient physically carries serious implications for patient safety and quality of care. In the 1990s, states began to prohibit physicians from prescribing medications without a

physical exam in an effort to protect patients from rogue Internet pharmacies; in 2008 the federal government followed suit [16].

However, requiring a physical examination in addition to the basic requirement for an in person encounter as a condition for making a clinical diagnosis and prescribing, is out of step with the evolution of telehealth/telemedicine capabilities, which offer increasingly sophisticated ways to capture relevant information. Rather than a blanket prohibition against diagnosing and prescribing, a more nuanced and sustainable approach would permit physicians utilizing telehealth/telemedicine technology to exercise discretion in conducting a diagnostic evaluation and prescribing therapy, within certain safeguards.

In real-time interactions between patient and physician who are in different locations that are carried out through video conferencing technology, other clinicians are often present at the patient's location and are in a position to carry out a physical exam as needed. Moreover, as technologies for obtaining patient information remotely continue to evolve and improve, the need for hands-on physical examination has diminished [14]. How physicians obtain information matters less than that they have access to the information they need to make well-grounded recommendations for the individual patient.

Model policy from the Federation of State Medical Boards (FSMB) requires that before a prescription is written the identity of patient and physician are clearly established [18]. It also requires the prescribing physician to evaluate the indication, appropriateness and safety of any prescription in keeping with current standards of practice, and to document the clinical evaluation and prescription in detail [18]. The FSMB further recommends that telemedicine technologies limit medication formularies in keeping with the dictates of relevant state medical boards.

From early in the development of telemedicine, some observers have been concerned that electronically mediated communication may be inherently less desirable than in-person conversation in the physician's office or exam room [17]. Even the best current interactive video conferencing technology can make the exchange of important nonverbal components of communication more difficult [19,20]. The intervening technology can make it difficult for both parties to see one another clearly enough to interpret the gestures, facial expressions, and body language that often play an important role in conveying a speaker's meaning.

At the same time, however, some patients may be more comfortable interacting electronically than in person. For example, studies indicate that patients may feel less intimidated and communicate more candidly electronically [21]. Research also suggests that patients may not feel that telemedicine adversely affects their relationships with physicians [10,22]. As with any technology, much depends on how the technology is deployed—in the case of telehealth/telemedicine, camera angles, placement of microphones, and other details [19]—and on users' expectations, skill, and level of comfort. Training in communications skills is already considered important in medicine [23]; training physicians to use technology to communicate effectively with patients should be part of this effort.

#### *Matching the Mode of Care to the Patient*

These considerations indicate that telehealth/telemedicine will not be the right model of care for every patient. To begin with, a patient must have the resources to take advantage of telehealth/telemedicine, including access to and ability to use requisite technology, appropriate support (which may include having health care professionals or others present during interactions, or access to emergency care, for example), and a level of comfort in getting care in this way—a constellation of requirements recognized by many professional society guidelines for telemedicine [13,24,25].

Telehealth/telemedicine must also be appropriate for the patient's specific situation. Despite its promise, telehealth/telemedicine is not an appropriate model of care for all medical conditions [4]. For example, telemedicine is inappropriate for encounters when a hands-on physical examination is crucial or critical data can be gleaned only through direct physical contact, and it is not possible to gather the needed data through a team-based approach, and lack of that data creates concerns about patient safety. More broadly, telemedicine is not the preferred approach when the technology does not allow physicians to meet established clinical standards.

Whether telehealth/telemedicine is appropriate for a given patient may also depend on what access the individual otherwise has to health care and appropriate technology. For some patients, in some situations, it simply may not be

feasible to deliver care in person. When the options for a patient are to receive care that may be less than ideal via telemedicine or not to receive care at all, telemedicine services can be appropriate even though the physician, or patient, would prefer that care be provided in person. For example, for a crewmember aboard a submarine or an astronaut in space, telemedicine—whatever its limitations—may be the only way to provide medical services. For a person in an isolated rural setting a six-hour drive from a specialist, telemedicine may be preferable even when an in-person encounter would be marginally superior.

## TRUST & ETHICAL PRACTICE IN TELEHEALTH/TELEMEDICINE

Forces of change have been at work in medicine for many years. The traditional scenario of a patient and a physician facing each other in the same room at the same time is no longer the only model for delivering care [20]. Express clinics in drugstores and big-box stores and free-standing urgent care centers across the country enable patients to seek advice and care from physicians on a one-time basis that doesn't carry expectations for an ongoing relationship. Group practices, "medical homes," and accountable care organizations offer patients the opportunity to receive care coordinated through a designated group of physicians and through health care facilities with which they are associated. Telehealth/ telemedicine is another stage in the ongoing evolution of models for care, modes of delivery, and patient-physician interactions.

But while new technologies and new models of care will continue to emerge, physicians' fundamental ethical responsibilities do not change. The practice of medicine is inherently a moral activity, founded in a "covenant of trust" between patient and physician [26]. In any model for care, patients need to be able to trust that physicians will place patient welfare above other interests (fidelity), provide competent care, provide the information patients need to make well-considered decisions about care (transparency), respect patient privacy and confidentiality, and take steps to ensure continuity of care [27,28]. The task is to understand how these fundamental responsibilities may play out differently in the context of telehealth/telemedicine than they do in-person patient-physician interactions.

### *Fidelity*

The obligation to put patient interests first requires that physicians who participate in telehealth activities or telemedicine programs take steps to minimize conflicts of interest and bias. It is important that physicians disclose financial or other interests that may influence them in their roles with commercial health sites/services [29]. However, disclosure by itself is not enough. Physicians' fiduciary responsibilities to patients mean physicians affiliated with telehealth/telemedicine should also take active steps to manage or eliminate conflicts of interest.

### *Competence*

The obligation to provide competent care has different implications at different points along the continuum of electronic interactions between physicians and patients or prospective patients. Thus physicians who provide general health information for online sites have a responsibility to ensure that the content they provide is accurate and objective, just as they would for any professional publication. Physicians who provide personalized responses to individual health queries have additional responsibilities in keeping with their greater accountability to the individual who is seeking guidance. In this context, the obligation of competence requires that the physician who responds to an individual query about a specific health concern have appropriate clinical qualifications and experience and have some means of obtaining the crucial information needed to offer a well-considered professional recommendation. Physicians should bear in mind that state law may further define specific expectations for competence in these situations.

For physicians who provide clinical services in telehealth/telemedicine, fulfilling the obligation to provide competent care further entails being proficient in the use of the relevant technologies; they must also be comfortable interacting with patients through these technologies. Given the limitations on physical examination, physicians must utilize other means of acquiring information that will be essential to making well-grounded recommendations in the patient's situation, as well as information that would be desirable to have to enhance confidence in their diagnosis. Developing clear understandings with health care professionals at the patient end of the interaction as to informational needs will also be important. Determining whether telehealth/telemedicine is in fact an appropriate model of care in the patient's individual circumstances may require collecting additional and different information than in an in-person interaction.

Competency also includes physicians' responsibility to be aware of the limitations of the telehealth/telemedicine technologies they use and recognize when they are reaching those limitations in caring for an individual patient. Physicians must know when to switch to a different modality, including when to shift from telehealth/telemedicine to in-person care to meet the patient's needs.

#### *Transparency & Informed Consent*

Physicians also have a responsibility to be transparent with patients/prospective patients. At one end of the continuum, this may mean no more than disclosing one's credentials as the author of health information. At the other end, it will entail obtaining the patient's informed consent for clinical services that are delivered electronically. In the context of telehealth/telemedicine, patients need to have information not only about medical issues and treatment options, but also about some of the distinctive features of telemedicine.

For example, patients need to have a basic understanding of the credentials of the physicians and other health care professionals who provide telehealth/telemedicine services. Patients also need to be aware of how telemedical technologies will be used in their care and the limitations of those technologies. Importantly, patients themselves or their family members may be asked to play a different role in telemedicine from what they are used to in traditional care, for example, by learning how to use monitoring devices at home, a factor that may influence decision making. Physicians' responsibility to ascertain whether the patient/family has the skills needed participate in the care plan may be stronger in the context of telehealth/telemedicine than in other encounters [30], especially when telehealth sites or mobile health applications connect physicians and patients with whom they have no prior relationship and with whom there is no expectation of follow-up.

#### *Privacy & Confidentiality*

The obligation to protect privacy and confidentiality is at least as important in the context of telehealth/telemedicine as in hospital and office settings. Health information websites are expected to publish their privacy policies so that users will know what information is collected from them (if any) and how that information is to be used [31]. Physicians who provide content for health websites have a responsibility to be satisfied that sites with which they are affiliated have relevant privacy policies. Physicians should refrain from participating in sites that do not make them available to site users.

Physicians who answer individual health queries or provide personalized health guidance electronically must be confident that the sites/services with which they affiliate have appropriate mechanisms in place to protect the confidentiality of individual information exchanged through the site. They should also inform site users that there are potential risks to privacy when personal health information is communicated electronically.

Physicians who provide clinical services via telehealth/telemedicine must adhere to sound privacy practices themselves, and must assure themselves that health care professionals at remote sites with whom they collaborate do likewise. Physicians should alert telehealth/telemedicine patients that issues of data security and access can arise when data is shared remotely and stored in multiple locations or record systems; patients should also be informed of steps the telehealth/telemedicine program has taken to protect confidential information.

#### *Continuity of Care*

Fulfilling the obligation not to abandon the patient and to provide for continuity of care [27] may also take on a new dimension in the context of telehealth/telemedicine. Physicians who only author general health content do not enter into a patient-physician relationship with information seekers; they therefore have no specific responsibilities regarding continuity of care. Physicians who respond to individual health queries should be understood to be responsible for encouraging the patient to seek in-person care when the physician deems that to be needed. Some telehealth/telemedicine services may also identify physicians whom service users can contact to arrange in-person care.

Physicians who provide clinical services through telehealth/telemedicine should discuss with patients the importance of preserving information for future episodes of care, and whether patients prefer to take responsibility for this or want the physician to do so, e.g., by communicating directly with the patient's primary care physician. Information should include recommendations for follow up care when appropriate. Telemedicine programs that rely on

collaboration among the physician, patient, and telemedicine team, and that routinely convey the plan to patients' primary physicians if they are not a member of the team are in a better position to develop plans of care that ensure appropriate follow up. Physicians who provide clinical telehealth/telemedicine services in settings where the encounter will not be documented in an existing medical record should consider writing a note after each clinical encounter for their own files.

## THE EVOLVING WORLD OF PATIENT CARE

Many may feel that telehealth and telemedicine, with their technological sophistication, continuous change, and rapid expansion, are standing medicine on its head. However, it may be more appropriate to see the evolution of telecommunications in patient care as part of the history of technology in medicine, and an opportunity to enhance access to care, quality of care, and satisfaction for both patients and physicians. Thoughtfully implemented, telehealth/telemedicine has the potential to enable physicians to use that most valuable of commodities, time spent in person with patients, to greater effect [14].

For individuals who are comfortable with electronic technology, telehealth/telemedicine has the potential to increase access to health care by making expert attention available to patients who would otherwise have limited or no access to such care. Yet telehealth/telemedicine cannot enhance access to high quality care if patients who might benefit from these innovations do not have access to or ability to use telecommunications technologies effectively. These include elderly individuals or others who have diminished perceptual, cognitive, or psychomotor abilities [30,32], or members of communities that tend not to have ready access to or to adopt Internet technologies [6,33-35]. Medicine as a profession can play an important role in advocating for initiatives that will help make the needed technologies more readily available to all patient populations who want to utilize telehealth/telemedicine services.

Achieving the promise and avoiding the pitfalls of electronically mediated care is not the responsibility of individual physicians alone. It requires coordinated effort across the profession, active engagement of specialty and professional organizations not only in medicine but also information technologies, and appropriate education and support for practicing clinicians [15,30].

## RECOMMENDATION

In light of these considerations, the Council on Ethical and Judicial Affairs recommends that Opinion E-5.027, "Use of Health-Related Online Sites," be amended by substitution as follows and the remainder of this report filed:

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

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

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

Similarly, all physicians who participate in telehealth/telemedicine must protect privacy and confidentiality consistent with their individual roles in telehealth/telemedicine services.

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

- (a) Inform users about the limitations of the relationship and services provided.
- (b) Assure themselves that the service appropriately protects users' confidentiality.
- (c) Advise site users about how to arrange for needed care when follow-up care is indicated.
- (d) Encourage users who have primary care physicians to inform their primary physicians about the online health consultation, even if in-person care is not immediately needed.

Physicians who provide clinical services through telehealth/telemedicine must uphold the standards of professionalism expected in in-person interactions. In the context of telehealth/telemedicine they further should:

- (e) Be proficient in the use of the relevant technologies and comfortable interacting with patients electronically.
- (f) Recognize the limitations of the relevant technologies and take appropriate steps to overcome those limitations. Physicians should ensure that they have the information they need to make well-grounded clinical recommendations when they cannot personally conduct a physical examination, such as by having another health care professional at the patient's site conduct the exam or obtaining vital information through remote technologies.
- (g) Be prudent in carrying out a diagnostic evaluation or prescribing medication by
  - (i) establishing the patient's identity;
  - (ii) confirming that telehealth/telemedicine services are appropriate for that patient's individual situation and medical needs;
  - (iii) evaluating the indication, appropriateness and safety of any prescription in keeping with best practice guidelines and any formulary limitations that apply to the electronic interaction; and
  - (iv) documenting the clinical evaluation and prescription.
- (h) Tailor the informed consent process to provide information patients need about the distinctive features of telehealth/telemedicine, in addition to information about medical issues and treatment options. Patients should have a basic understanding of how telemedicine technologies will be used in their care, the limitations of those technologies, the credentials of health care professionals involved, and what will be expected of patients for using these technologies.
- (i) Protect patient privacy and confidentiality at all stages of the telehealth/telemedicine encounter. Physicians should assure themselves that the telehealth/telemedicine services in which they participate have appropriate protocols in place to prevent unauthorized access and protect the security and integrity of data at the patient end of the electronic encounter, during transmission, and among all health care professionals and other personnel who participate in the telehealth/telemedicine service.
- (j) As in any patient-physician interaction, take steps to promote continuity of care, giving consideration to how information can be preserved and accessible for future episodes of care in keeping with patients' preferences and how follow up care can be provided when needed. Physicians should assure themselves how information will be conveyed to the patient's primary care physician when the patient has a primary care physician and to other physicians currently caring for the patient.

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

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

- (l) Advocate for policies and initiatives to promote access to telehealth/telemedicine services for all patients who could benefit from receiving care electronically.
- (m) Routinely monitor the telehealth/telemedicine landscape to:
  - (i) identify and address adverse consequences as technologies and activities evolve; and
  - (ii) identify and encourage dissemination of positive outcomes.

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## 2. PRESCRIBING AND DISPENSING PRESCRIPTION MEDICATION SAMPLES

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

### HOUSE ACTION: REFERRED

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

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

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

#### *Immediate Treatment*

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

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

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

Samples may also enable patients to identify which of two or more medications they themselves prefer [6,8]. Samples are particularly common in dermatology, as patients can try a range of topical medications and identify that

one that is most tolerable [8]. Being able to identify medications they prefer may help enhance patients' adherence to treatment [6]. Further, patients with access to samples are often exposed to more treatment choices, including brand name and generic medications [8].

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

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

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

Whether samples reach primarily the neediest patients is open to question, however [1,10,12,18]. At one time it was common practice for physicians to appropriate samples for personal or family use [1]; however, there appear to be no current data on how widespread such practice may still be. More important, access to samples is at least in part conditioned on whether a patient has access to care at all [13,18–20]. Nevertheless, even among patients who do have access to care, samples are not necessarily targeted toward those who have the greatest need. An analysis of data from the Medical Expenditure Panel Survey concluded that for the period 1999–2005, "sample use was not associated with income and samples were less frequently provided to racial/ethnic minorities and to the elderly" [10]. Another study found that among Medicare beneficiaries, access to samples was greater for those who had higher annual incomes or some form of drug benefits than among beneficiaries who had lower incomes or no drug coverage [13]. Other research has similarly found that patients with less education, lower levels of income, and no primary care physician are less likely to receive samples than are other patients [14].

## CHALLENGES FOR PHYSICIANS: SAFETY, QUALITY, PROFESSIONALISM

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

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

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

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

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

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

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

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

#### *Administrative Burdens*

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

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

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

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

#### **SAMPLING, HEALTH CARE COSTS**

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

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

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

#### ACCESS TO MEDICATION: ALTERNATIVES TO SAMPLES

Sample medications distributed directly to patients by physicians are only one means for making medications available to patients who have limited ability to pay. Medication assistance programs sponsored by pharmaceutical companies, publicly subsidized medication programs (such as the Public Health Service [34] Drug Pricing Program), or other mechanisms also offer access to free or low-cost medications.

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

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

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

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

#### CONCLUSION

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

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

## 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:

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

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

Individually, physicians who prescribe or dispense samples of prescription medications should:

- (a) Prescribe or dispense samples of prescription medications only in the context of a patient-physician relationship, in keeping with ethical guidelines.
- (b) Manage in-office inventories and dispense sample prescription medications in keeping with principles of patient safety and best practices, including appropriate documentation and instruction for patients. Physicians should be aware of and adhere to applicable legal requirements.
- (c) Offer samples on a limited, short-term basis, irrespective of a patient's ability to pay, in order to:
  - (i) provide immediate treatment to relieve or prevent serious complications or relieve significant symptoms;
  - (ii) assess one or more medications to determine appropriate dosage for the patient, identify allergic reactions or serious side effects, or, when appropriate, enable the patient to identify which medication the individual prefers;
  - (iii) test patient responses to a class of medication, with the understanding that a prescription will be written for a medication in that class if the trial medication proves effective for the patient; or
  - (iv) establish a bridge to therapy until a prescription for the preferred medication can be filled.
- (d) Accept only prescription medication samples that are relevant to the practice and its patient population.
- (e) Provide samples of prescription medications on a long-term basis to treat a chronic medical condition only after inquiring about the patient's ability to obtain the preferred medication and determining that the patient would not otherwise have access to the needed medication.

Collectively, physicians should advocate for:

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

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### 3. MODERNIZED CODE OF MEDICAL ETHICS

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

#### HOUSE ACTION: REFERRED

As the Council on Ethical and Judicial Affairs has previously reported [1], in 2008 it began a project to comprehensively review the AMA's foundational document, the *Code of Medical Ethics*, and update the Opinions that interpret *AMA Principles of Medical Ethics*. The Council's goal was to ensure that the *Code's* ethical guidance keeps pace with the demands of a changing world of medical practice. This project represents the first such thoroughgoing review in more than 50 years.

With assistance from the Federation of Medicine and AMA Councils and Sections, the Council reviewed each individual Opinion for clarity, timeliness and ongoing relevance in today's health care environment, and consistency within the *Code*. The Council reorganized Opinions into a more intuitive chapter structure to ensure that guidance is easy to find and adopted a uniform format for Opinions to ensure that guidance is easy to read and easy to apply. In modernizing Opinions, the Council looked for opportunities to consolidate guidance into a single, comprehensive statement on a topic; to harmonize guidance on related issues; and to identify and update or retire guidance that has become significantly outdated over time. Throughout, the Council strove to preserve the accumulated wisdom of the House of Delegates represented in the Opinions of the *Code*.

#### OPPORTUNITIES FOR STAKEHOLDER INPUT

Over the course of the project, the Council has turned to the member organizations of the Federation of Medicine, as well as to AMA Councils and Sections, to help inform its work. Input from stakeholders early in the process in 2010 helped the Council identify outdated content and revealed points where the guidance of the *Code* may be differently interpreted by different stakeholders. This information guided the Council as it painstakingly reviewed each of the more than 200 Opinions that had accrued to the *Code* over time.

The Council's deliberative work process involved close scrutiny of existing Opinions by subcommittees focused on individual chapters under the new taxonomy to develop proposals for updating each chapter's constituent Opinions, which were then reviewed and revised by the Council as a whole as a prelude to the subcommittees drafting modernized Opinions. Draft Opinions were in their turn reviewed by the Council as whole and refined in an iterative process over multiple meetings. At the conclusion of that process, the Council on Ethical and Judicial Affairs devoted its Open Forum at the 2013 Interim Meeting to updating the House of Delegates on the status of the project. Following I-13 the Council created a special online discussion forum to which it posted the draft chapters to enable delegates, alternates, and members of the AMA to review and comment on the material as well as soliciting feedback through online continuing medical education modules that focused on draft chapters. During the 2014 Annual Meeting, the Council invited delegates and other interested stakeholders to provide feedback in person at its Open Forum. The Council extended the opportunity to provide feedback—via the online forum, letters, and emails—through the end of June 2014.

In summer 2014, the Council on Ethical and Judicial Affairs reviewed input and devoted its September 2014 meeting to finalizing a revised draft of the modernized *Code* to present to the House at the 2014 Interim Meeting. The Council posted the revised draft to its online forum in late September, ahead of publication in the I-14 Delegates Handbook. The Council was available to answer questions about the project and the document at a special "open house" session on the first day of I-14 and subsequently heard comments about the draft modernized *Code* in testimony offered to the I-14 Reference Committee on Amendments to Constitution and Bylaws.

In response to concerns that the House needed additional time to consider these materials and that it would find it very helpful to have substantive changes more clearly indicated, the Council updated posted documents to highlight new or significantly revised content and reposted the materials for an extended comment period, which ended January 15, 2015.

## INTERPRETING THE *CODE*

The issue that emerged most clearly through comments received, testimony heard, comments on CME modules relating to modernizing the *Code*, and other, less formal channels was that the language of the draft modernized *Code* was open to potential misinterpretation that could have adverse consequences for physicians. Specifically, the Council heard that it was essential to clarify the intended meaning of the terms *must* and *should*.

### *Must, Should & May*

Consistent with the practice of the US Department of Health and Human Services[2], the Food and Drug Administration[3], and other entities, throughout the Opinions of the draft modernized *Code* the Council uses the words *must*, *should*, and *may* in their common understandings to distinguish different levels of ethical obligation. Use of the word *must* indicates that an action is ethically required of physicians. From the perspective of ethics and professionalism, such actions are not matters about which physicians may use judgment or discretion. Thus, for example, “Physicians who testify as fact witnesses in legal claims **must** deliver honest testimony.”

The Council uses the word *should* to indicate an action or obligation that is strongly recommended as a matter of professional ethics, but which may have some exceptions. *Should* is used to indicate what is expected of a physician in most instances, absent special circumstances or considerations. *Should* indicates that ethically there is some latitude for physician judgment and discretion. Thus, for example, “Physicians **should** routinely inquire about physical, sexual, and psychological abuse as part of the medical history.” Some Opinions set out conditions under which physicians may deviate from primary guidance—for example, “In general, physicians **should not** treat themselves or members of their own families. However, it may be acceptable to do so in limited circumstances in emergency settings ... or for short-term, minor problems.”

The Council uses *may* to indicate that an action is ethically permissible when qualifying conditions set out in the Opinion are met. Thus, “Physicians **may** disclose personal health information without the specific consent of the patient to other health care personnel for purposes of providing care or for health care operations.”

The Council recognizes that circumstances at times impinge on physicians’ ability or opportunity to follow the guidance of the *Code* strictly as written. Recognizing when such circumstances exist and determining how best to adhere to the goals and spirit, if not the absolute letter, of guidance requires physicians to use skills of ethical discernment and reflection. Physicians are expected to have compelling reasons to deviate from guidance when, in their best judgment, they determine that it is ethically appropriate or even necessary to do so.

The more stringent the ethical obligation, the stronger the justification required to deviate from it in any specific instance. Obligations indicated by *must* can be reversed or violated only in very rare circumstances. An example could include, when two or more core ethical values conflict in such a way that it is not possible for the physician to uphold both or all and the physician must decide which value will prevail. Guidance introduced by *should* sets a general expectation for conduct, but permits more latitude for discerning alternative ways to meet the expectation. Obligations indicated by *may* call on the physician to confirm that qualifying conditions are met sufficiently to warrant taking the action addressed in guidance.

The Council also recognizes that guidance is not always equally applicable to every individual physician. For example, depending on the nature of his or her practice not every physician will be in a position to inquire about abuse. All physicians should nonetheless be sensitive to signs of possible abuse and find some way to address the situation if the concern arises. In this respect too, then, the *Code* relies on the reasonable exercise of judgment.

A key goal of the project to modernize the *Code* has been to enhance the clarity of guidance for physicians and promote consistency in interpretation. To this end, the Council restructured Opinions into a format that articulates salient ethical values or concerns, clearly defines the primary context of concern, and identifies key responsibilities in the form of recommendations for action that best uphold core values or address the ethical concerns at issue. To map the existing guidance of the *Code* into this uniform format, the Council recast content into simpler, more direct constructions to minimize ambiguity and so reduce the likelihood of unintended interpretations. The Council likewise strove to use consistent terminology throughout the updated Opinions to promote the same ends. As a result, the use of language in the guidance of the draft modernized *Code* is significantly more consistent than in

existing Opinions. This will help ensure that not only physicians, but also others who turn to the *Code* to understand professional ethical responsibilities in medicine understand guidance in the same way.

#### *Further Aids to Interpretation*

The Council has long believed that it is important to provide resources to aid interpretation of the *Code*. The Council has posted the full text of reports that set out the rationale for ethical guidance to its pages on the AMA website [4]. These reports will continue to be available online and, because the Council has tried to preserve existing guidance to the greatest extent possible, these reports will continue to assist users in interpreting physicians' ethical responsibilities. As new Opinions are developed going forward, the Council's reports will continue to be posted.

At the beginning of 2013, the Council launched an effort to make additional interpretive resources available to users of the current *Code* in the form of online ethics CME focused on selected Opinions [5]. New modules are now in development for each updated Opinion in the modernized *Code*.

The Council has the further goal of developing illustrative case vignettes for each Opinion that will be available online and in print, and looks forward to working with the Federation and other stakeholders to create this resource.

### OVERVIEW OF MODERNIZATION

After reviewing all Opinions in the *Code*, the Council determined that ten existing opinions were so significantly outdated as to warrant withdrawal. The Council reviewed the remaining guidance for opportunities to consolidate or reorganize content across Opinions, which resulted in a total of 160 individual Opinions included in the draft modernized *Code*. All of these Opinions were reformatted to conform to the template for Opinions the Council developed in 2009.

Where needed, the Council introduced new language in the opening paragraph or paragraphs of an Opinion to articulate the key ethical values at stake or to clarify the context and scope of guidance. The Council also incorporated new guidance where doing so would address a gap identified during the review process, clarify guidance, amend guidance in light of significant changes in medical science or the health care environment since an Opinion was last updated, or ensure consistency across Opinions. Overall, Opinions of the draft *Code* have been modernized as follows:

- Reformatted only, no new language or content incorporated – 42 Opinions
- New language and/or content incorporated – 118 Opinions
  - To articulate key ethical values (89)
  - To address a gap in current guidance (50)
  - To clarify content/scope of current guidance (34)
  - To clarify current guidance (25)
  - To ensure consistency across guidance on related topics (10)
  - To replace outdated guidance (5)

Each Opinion in the draft modernized *Code* indicates the source passage in the Opinions of the current *Code* and new language or content when that has been incorporated.

In some topic areas the Council found that Opinions required more significant updating than in other areas. For example, Opinions that address decision making for pediatric patients (Chapter 2B, section 2), genetics and reproductive medicine (Chapter 4), and end-of-life care (Chapter 5). Notably, these areas have seen rapid evolution in science, medical practice, and social values in recent decades and the Council did not find it surprising that guidance has become outdated or more challenging to interpret and apply. The Council believes that the new language or content incorporated in these and all modernized Opinions reflects widely held consensus in ethics and medicine and should not be controversial.

## RECOMMENDATION

The Council on Ethical and Judicial Affairs recommends that the individual Opinions of the *AMA Code of Medical Ethics* be amended by substitution as follows and that the remainder of this report be filed:

The full text of the modernized Code of Medical Ethics is posted online at [ama-assn.org/go/cejaforum](http://ama-assn.org/go/cejaforum).

## REFERENCES

1. Council on Ethical and Judicial Affairs. *Modernizing the Code of Medical Ethics*. Available at <http://www.ama-assn.org/ama/pub/about-ama/our-people/ama-councils/council-ethical-judicial-affairs.page>. Accessed February 6, 2015.
2. Office of Human Research Protections. E.g., *Guidance on Written IRB Procedures*. Available at <http://www.hhs.gov/ohrp/policy/irbgd107.html>. Accessed February 6, 2015.
3. U.S. Food and Drug Administration. E.g., *Guidance for Industry: Using a Centralized IRB Review Process in Multicenter Clinical Trials*. Available at <http://www.fda.gov/RegulatoryInformation/Guidances/ucm127004.htm>. Accessed February 6, 2015.
4. Council on Ethical and Judicial Affairs. CEJA Reports. Available at <http://www.ama-assn.org/ama/pub/about-ama/our-people/ama-councils/council-ethical-judicial-affairs/ceja-reports.page?>. Accessed February 6, 2015.
5. American Medical Association. Continuing Medical Education by Topic–Ethics. Available at <http://www.ama-assn.org/ama/pub/education-careers/continuing-medical-education.page?>. Accessed February 6, 2015.

## 4. JUDICIAL FUNCTION OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS: ANNUAL REPORT

*Informational report; no reference committee hearing.*

### HOUSE ACTION: FILED

At the 2003 Annual Meeting, the Council on Ethical and Judicial Affairs (CEJA) presented a detailed explanation of its judicial function. This undertaking was motivated in part by the considerable attention professionalism has received in many areas of medicine, including the concept of professional self-regulation.

CEJA has authority under the Bylaws of the American Medical Association (AMA) to disapprove a membership application or to take action against a member. The disciplinary process begins when a possible violation of the [Principles of Medical Ethics](#) or illegal or other unethical conduct by an applicant or member is reported to the AMA. This information most often comes from statements made in the membership application form, a report of disciplinary action taken by state licensing authorities or other membership organizations, or a report of action taken by a government tribunal.

The Council rarely re-examines determinations of liability or sanctions imposed by other entities. However, it also does not impose its own sanctions without first offering a hearing to the physician. CEJA can impose the following sanctions: applicants can be accepted into membership without any condition, placed under monitoring, or placed on probation. They also may be accepted but be the object of an admonishment, a reprimand, or censure. In some cases, their application can be rejected. Existing members similarly may be placed under monitoring or on probation, and can be admonished, reprimanded or censured. Additionally, their membership may be suspended or they may be expelled. Updated rules for review of membership can be found at [ama-assn.org/ama/pub/about-ama/our-people/ama-councils/council-ethical-judicial-affairs/governing-rules/rules-review-membership.page](http://ama-assn.org/ama/pub/about-ama/our-people/ama-councils/council-ethical-judicial-affairs/governing-rules/rules-review-membership.page).

Beginning with the 2003 report, the Council has provided an annual tabulation of its judicial activities to the House of Delegates. In the appendix to this report, a tabulation of CEJA's activities during the most recent reporting period is presented.

## CEJA Judicial Function Statistics, April 1, 2014 ~ March 31, 2015

Physicians Reviewed	SUMMARY OF CEJA ACTIVITIES
3	Determinations of no probable cause
51	Determinations following a plenary hearing
45	Determinations after a finding of probable cause, but without a plenary hearing

Physicians Reviewed	DETERMINATIONS (by type of action taken)
16	No sanction or other type of action
4	Monitoring
29	Probation
24	Revocation
10	Suspension
1	Resignation accepted
2	Application denied
13	Censure/Admonishment/Reprimand

Physicians Reviewed	PROBATION/MONITORING STATUS
23	Members placed on Probation/Monitoring during reporting interval
10	Members placed on Probation without reporting to Data Bank
10	Probation/Monitoring concluded satisfactorily during reporting interval
58	Number of physicians on Probation/Monitoring at any time during reporting interval who have paid AMA membership dues
43	Number of physicians on Probation/Monitoring at any time during reporting interval who have not paid AMA membership dues

### 5. CEJA'S SUNSET REVIEW OF 2005 HOUSE POLICIES

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

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

At its 1984 Interim Meeting, the House of Delegates (HOD) established a sunset mechanism for House policies (Policy G-600.110). Under this mechanism, a policy established by the House ceases to be viable after 10 years unless action is taken by the House to retain it.

The objective of the sunset mechanism is to help ensure that the American Medical Association (AMA) policy database is current, coherent, and relevant. By eliminating outmoded, duplicative, and inconsistent policies, the sunset mechanism contributes to the ability of the AMA to communicate and promote its policy positions. It also contributes to the efficiency and effectiveness of HOD deliberations.

At its 2012 Annual Meeting, the House modified Policy G-600.110 to change the process through which the policy sunset review is conducted. The process now includes the following steps:

- Each year the House policies that are subject to review under the policy sunset mechanism are identified.
- Policies are assigned to appropriate Councils for review.
- For the Annual Meeting of the House, each Council develops a separate policy sunset report that recommends how each policy assigned to it should be handled. For each policy it reviews, a Council may recommend one of the following actions: (a) retain the policy; (b) sunset the policy; (c) retain part of the policy; (d) reconcile the policy with more recent and like policy. A justification must be provided for the recommended action to retain a policy.

- A policy will typically sunset after ten years unless action is taken by the House of Delegates to retain it. A reaffirmation or amendment to policy by the House of Delegates resets the sunset clock, making the reaffirmed or amended policy viable for another 10 years.

Although the policy sunset review mechanism may not be used to change the meaning of AMA policies, minor editorial changes can be accomplished through the sunset review process.

## 2005 POLICIES

In this report, the Council on Ethical and Judicial Affairs presents its recommendations regarding the disposition of 2005 House policies that were assigned to or originated from CEJA.

## DUPLICATIVE POLICIES

On the model of the Council on Long Range Planning & Development (CLRPD)/CEJA Joint Report I-01 and of subsequent reports of CEJA's sunset review of House policies, this report recommends the rescission of House policies that originate from CEJA Reports and duplicate current opinions issued since June 2006. As noted previously, the intent of this process is the elimination of duplicative ethics policies from PolicyFinder. The process does not diminish the substance of AMA policy in any sense. Indeed, CEJA Opinions are a category of AMA policy.

## MECHANISM TO ELIMINATE DUPLICATIVE ETHICS POLICIES

The Council continues to present reports to the HOD. If adopted, the recommendations of these reports continue to be recorded in PolicyFinder as House policy. After the corresponding CEJA Opinion is issued, CEJA utilizes its annual sunset report to rescind the duplicative House policy.

For example, at the 2007 Interim Meeting, the HOD adopted the recommendations of CEJA Report 8-I-07, "Pediatric Decision-Making." It was recorded in PolicyFinder as Policy H-140.865. At the 2008 Annual Meeting, CEJA filed the corresponding Opinion E-2.026, thereby generating a duplicative policy. Under the mechanism to eliminate duplicative ethics policies, CEJA recommended the rescission of Policy H-140.865 as part of the Council's 2009 sunset report.

The Appendix provides recommended actions and their rationale on House policies from 2005, as well as on duplicate policies.

## RECOMMENDATION

The Council on Ethical and Judicial Affairs recommends that the House of Delegates policies that are listed in the Appendix to this report be acted upon in the manner indicated and the remainder of this report be filed.

## APPENDIX

Policy No.	Title	Recommended Action & Rationale
D-270.994	Universal Out-of-Hospital DNR Systems	Rescind: Policy no longer relevant
H-065.981	Human Rights and Health Professionals	Retain: Policy remains relevant
H-065.991	Persecution of Physicians for Political Reasons and Participation by Doctors in Violations of Human Rights	Retain: Policy remains relevant
H-065.993	Abuse of Medicine for Political Purposes	Retain: Policy remains relevant
H-065.994	Medical Care in Countries in Turmoil	Retain: Policy remains relevant
H-140.874	Opposition to Legislation that Presumes to Prescribe Patients' Preferences for Artificial Hydration and Nutrition	Retain: Policy remains relevant
H-140.997	Patient Advocacy	Retain: Policy remains relevant
H-225.992	Right to Relevant Information	Retain: Policy remains relevant
H-405.963	Political Diploma Mills	Rescind: Policy no longer relevant