

REPORTS OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

The following reports, 1–3, were presented by Stephen L. Brotherton, 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 the 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 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 may 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 to 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 the ability to use telecommunications technologies effectively. These may 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 Opinions E-5.025, "Physician Advisory or Referral Services by Telecommunication," and 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) When the physician would otherwise be expected to obtain informed consent, 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 both positive and negative 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, e.g., when the individual does not have access to 24-hour pharmacy services [6].

Assessing Medications for Efficacy, Tolerability, Patient Preference

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

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

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

Overcoming Cost-Related Obstacles to Care

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

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

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

CHALLENGES FOR PHYSICIANS: SAFETY, QUALITY & PROFESSIONALISM

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

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

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

ACCESS TO MEDICATION: ALTERNATIVES TO SAMPLES

Sample medications distributed directly to patients by physicians are only one means for making medications available to patients who have limited ability to pay. Medication assistance programs sponsored by pharmaceutical companies, publicly subsidized medication programs (such as the Public Health Service [340B] Drug Pricing Program), or other mechanisms also offer access to free or low-cost medications.

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

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

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

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

CONCLUSION

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.

RECOMMENDATIONS

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

Used appropriately, 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 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 medication preferred by the patient and physician 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 Code Modernization](#).

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*.

MODERNIZING THE CODE

As part of this process, the Council has sought input from stakeholders through several channels. (See Appendix A: Timeline.) In addition to soliciting initial feedback on the existing *Code* from the member organizations of the Federation of Medicine and AMA Councils and Sections, the Council has posted iterations of the draft modernized *Code* for review by AMA members on its online discussion forum (www.ama-assn.org/go/cejaforum). The Council also held special Open Forum sessions devoted to the project at the 2013 Interim Meeting of the House of Delegates and the 2014 Annual Meeting, in addition to hosting informal "open house" discussions at the 2014 Interim and 2015 Annual meetings and receiving testimony in reference committee at those meetings.

Over the past two years, the Council has made changes in the draft materials in response to feedback. For example, at the suggestion of readers, the Council simplified the layout of the document and color-coded new language wherever it was introduced to make it easier for readers to identify new passages. As the Council previously noted, most such new language is found in the preamble to updated opinions to set out explicitly ethical values and issues central to the opinion. This practice is continued in the present draft, which was revised in light of the most recent feedback received at AMA's 2015 Annual Meeting.

The Council incorporated a new preface into the draft modernized *Code* in May 2015 to clarify the use of *must*, *should*, and *may* in updated guidance. Throughout the *Code* CEJA uses the words *must*, *should*, and *may* in their common understandings to distinguish different levels of ethical obligation. From the perspective of ethics and professionalism, *must* indicates that an action is a near-absolute obligation. The Council uses the word *should* to indicate an action or obligation that is strongly recommended as a matter of professional ethics, but to which some exceptions can be possible. Thus *should* is used to indicate what is expected of a physician in most instances, absent special circumstances or considerations in which there is some latitude for physician judgment and discretion. The Council uses *may* to indicate that an action is ethically permissible when qualifying conditions set out in the Opinion are met.

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, for example, 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 is forced to decide which value will prevail. Guidance introduced by *should* sets a general expectation for physician conduct, but permits greater 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.

As the Council noted in its A-15 report, the new preface will become a permanent feature of the *Code* as an aid to interpretation going forward.

A UNITARY DOCUMENT

At the 2015 Annual Meeting testimony suggested that the draft modernized *Code of Medical Ethics* be discussed and adopted chapter by chapter rather than as a unitary whole. This approach would be disruptive and untenable in that it would make guidance more difficult to find than in the present *Code* and would perpetuate, or potentially exacerbate, discrepancies in guidance across the *Code*.

The overarching goal of modernizing the *Code* has been to ensure that guidance is clear, easy to find, logically organized and easy to use, and internally consistent. To that end, CEJA has reorganized opinions into intuitively clear chapters and ordered opinions within each chapter to provide general guidance in an area first, followed by guidance in narrower contexts or situations.

Importantly, during its review of existing guidance, the council closely reviewed each individual opinion against the backdrop of the entire *Code* to identify potential discrepancies in guidance so that differences could be resolved in the corresponding modernized opinions. As a result, although each modernized opinion can be read and interpreted on its own, the modernized *Code* as a whole is a closely integrated, cross-referenced ethics compendium for physicians. This revised organization of the modernized *Code* will help minimize the possibility that discrepancies will arise in the future as new guidance is developed.

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/cejforum.

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.