REPORTS OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

The following reports were presented by David A. Fleming, MD, Chair:

1. SHORT-TERM GLOBAL HEALTH CLINICAL ENCOUNTERS

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

HOUSE ACTION: RECOMMENDATIONS ADOPTED
REMAINDER OF REPORT FILED
See Policy

Short-term global health clinical encounters deploy physicians and physicians in training from wealthy communities to provide care in under-resourced settings for a period of days or weeks. They have been promoted, in part, as a strategy for addressing global health inequities, and have unquestionably benefitted thousands of individual patients. At the same time, these trips have a problematic history and run the risk of causing harm to the patients and communities they intend to benefit [1]. To minimize harm and ensure significant benefits, participants, sponsors, and hosts must jointly prioritize activities to meet mutually agreed-on goals; navigate day-to-day collaboration across differences of culture, language, and history; and fairly allocate host and team resources.

Ethics guidance can neither redress historical wrongs nor solve the underlying structural issues that drive medical need in under-resourced settings. However, by making explicit the conditions under which short-term global health clinical encounters are ethically sound and articulating the fundamental ethical responsibilities of those who participate in and sponsor such trips, ethics guidance can promote immediate benefit to individuals and sustainable benefit for host communities. In addition, ethics guidance can highlight the ways in which power imbalances and neo-colonial assumptions can shape these practices and so may undermine their moral acceptability. This report by the Council on Ethical and Judicial Affairs (CEJA) explores the challenges of short-term global health clinical encounters and offers guidance for physicians, physicians in training, and sponsors to help them address the ethical challenges of providing clinical care in under-resourced settings. The encounters and perspective of host communities may reveal concerns not specifically addressed in this report. However, the guidance provided emphasizes the critical importance of ethical intent and collaboration with host communities, thus encouraging ongoing conversations between visiting medical teams and host communities regarding cultural, ethical, and practical concerns.

THE APPEAL OF SHORT-TERM GLOBAL HEALTH CLINICAL ENCOUNTERS

Just how many clinicians and trainees volunteer to provide medical care in under-resourced settings is difficult to estimate, but the number is large. By one estimate, in the U.S. some 21% of the nearly 3 billion dollars' worth of participant hours spent in international efforts in 2007 were medically related [2]. For trainees, in January 2015 the Consortium of Universities for Global Health identified more than 180 websites relating to global health opportunities [3]. The Association of American Medical Colleges found that among students who graduated in 2017–2018 between 25% and 31% reported having had some "global health experience" during medical school [4].

A variety of reasons motivate physicians and trainees to participate in these projects. For many, compelling motivations include the opportunities to help address health inequities, improve their diagnostic and technical skills as clinicians, or explore global health as a topic of study [2]. Global health clinical encounters may also be pursued to serve the goals of building one's resume, improving one's professional prospects, and gaining the esteem of peers and family [2].

A NOTE ON TERMINOLOGY

The literature is replete with different terms for the activity of traveling to an under-resourced community to provide medical care on a volunteer basis, including "short-term medical volunteerism" [5], "short-term medical missions" [6], "short-term medical service trips" [7,8], "short-term experience in global health" [9,10], "global health field experience" [11], "global health experience," and "international health experience"[2].

The Council on Ethical and Judicial Affairs prefers “short-term global health clinical encounters.” This identifier is generally accepted and encompasses both clinical and educational activities. It also recognizes that such encounters are not exercises in pure altruism, but a mutually beneficial collaboration between those planning and participating in these encounters and host communities. The term also highlights the fact that these activities are limited in duration, which has implications for the ethical obligations of participants and their impact on host communities.

MEDICAL CARE IN UNDER-RESOURCED SETTINGS

Traditionally, short-term global health clinical encounters focused on providing clinical care as a charitable activity, not infrequently under the auspices of faith-based institutions, whose primary goal was to address unmet medical needs [10]. Increasingly, such trips focus on the broader goal of improving the health and well-being of host communities [9]. Many also offer training opportunities for medical students, residents, and local healthcare professionals [9,10,11]. Ideally, short-term global health clinical encounters are part of larger, long-term efforts to build capacity in the health care systems being visited, and ultimately to reduce global health disparities [9,10].

The medical needs of host communities differ from those of participants’ home countries—participants may encounter patients with medical conditions they have not seen before, or who present at more advanced stages of disease, or are complicated by “conditions, such as severe malnutrition, for which medical volunteers may have limited experience” [7]. At the same time, available treatment options will often include medications, procedures or tools with which participants are not familiar. As such, the practice of medicine in under-resourced communities should be considered a unique area of expertise, requiring specific background and training in order to be effective [12].

By definition, short-term global health clinical encounters typically take place in contexts of scarce resources. The communities where these encounters take place often have limited access to health care, often lack access to food, and often lack both economic and political power [7]. As a result, they may feel unable to refuse assistance that is offered [10]. Moreover, short-term global health clinical encounters take place under the long shadow of colonialism, including medicine’s role in that [10], and have been critiqued as perpetuating the colonial legacy of racism, exploitation, and dependency [1,10,13]. To avoid reproducing these injustices, participants and sponsors should recognize that it is a privilege to practice and train in under-resourced communities, and that justice requires reciprocity and equal respect among local and visiting staff, community members, and patients in this context [9].

These realities define fundamental ethical responsibilities not only for those who volunteer, but equally for the individuals and organizations that sponsor short-term global health clinical encounters.

ETHICAL RESPONSIBILITIES IN SHORT-TERM GLOBAL HEALTH CLINICAL ENCOUNTERS

Emerging guidelines identify the following ethical duties for participants of short-term global health clinical encounters and organizations sponsoring them: (a) to produce good clinical outcomes, (b) to promote justice and sustainability, (c) to minimize burdens on host communities, and (d) to respect persons and local cultures [2,9,10,11].

Promoting Justice & Sustainability

If short-term global health clinical encounters are to achieve their goal of improving the health of local host communities, they must commit not simply to addressing immediate, concrete needs, but to helping the community build its own capacity to provide health care. To that end, the near and longer-term goals of trips should be set in collaboration with the host community, not determined in advance solely by the interests or intent of trip sponsors and participants [7,9]. Trips should seek to balance community priorities with the training interests and abilities of participants [10], but in the first instance benefits should be those desired by, and acceptable to, the host community [9]. Those involved with short-term global health clinical encounters have a responsibility to ask how they can best use a trip’s limited time and material resources to promote the long-term goal of developing local capacity. Will the trip train local health care providers? Build local infrastructure? [7]? Ideally, a short-term global health experience will be embedded in a longer-term strategy and collaboratively planned with the host community [7,10].

Minimizing Harms & Burdens in Host Communities

Just as focusing on the overarching goal of promoting justice and sustainability is foundational to ethically sound short-term global health clinical encounters, so too is identifying and minimizing the burdens such trips place on the host communities.

Beyond lodging, food, and other direct costs of short-term global health clinical encounters, which are usually reimbursed to host communities [9], such trips can place other, less visible burdens on host communities. Physicians, trainees, and others who organize or participate in short-term global health clinical encounters should be alert to possible unintended consequences that can undermine the value of a trip. Trips should not detract from or place significant burdens on local clinicians and resources, particularly in ways that negatively affect patients, jeopardize sustainability, or disrupt relationships between trainees and their home institutions [9,11]. For example, the expectation that local healthcare and support staff will be available to assist visiting clinicians in addition to (or in place of) their usual duties can disrupt care for their existing patients. It should not be assumed that host communities can absorb additional costs, even on a temporary basis [14]. Particular attention should be paid to the follow-up care that burdens local practitioners and may result in harm to patients in the aftermath of invasive procedures [15].

Sharing information beforehand as to how visiting health care professionals are expected to interact with the host community, the team's objectives, and the skill, and training they bring, can reveal potential benefits and harms, thus allowing them to be discussed and addressed before the team embarks on the experience. Likewise, selecting team members whose skills and experience map onto the needs and expectations of the host community can help minimize disruptive effects on local practice [11]. Advance preparation should include developing a plan to monitor and address ongoing costs and benefits to patients, host communities and institutions, including local trainees (when the trip includes providing training for the host community) [11].

Respecting Persons & Cultures

Physicians and trainees who participate in short-term global health clinical encounters face a host of challenges. Some of them are practical, such as resource limitations, unfamiliar medical needs, living conditions outside their experience, among many others. Others involve successfully navigating language(s) and norms they may never have encountered before, or not encountered with the same immediacy [1,2,9]. Striking a balance between Western medicine's understanding of professional ethics and the expectations of host communities rooted in other histories, traditions, and social structures calls for a level of discernment, sensitivity, and humility that may more often be seen as the skill set of an ethnographer than a clinician.

Individuals who travel to provide medical care in under-resourced settings should be aware that the interactions they will have there will inevitably be cross-cultural. They should seek to become broadly knowledgeable about the communities in which they will work, such as the primary language(s) in which encounters will occur; predominant local understandings of health and illness; local expectations for how health care professionals behave toward patients and toward one another; and salient economic, political, and social dynamics. Participants should take advantage of resources that can help them cultivate the cultural sensitivity they will need to provide safe, respectful, patient-centered care in the context of the specific host community [7,10,11]. Further, trip participants should be mindful that they bring with them their own unexamined cultural beliefs and assumptions about under-resourced communities, some of which trace back to colonialist, racialized attitudes. For instance, there is a widespread assumption that visiting physicians and trainees possess universally applicable (and perhaps superior) skills and knowledge simply by virtue of their association with Western medicine [19].

Individuals do not bear these responsibilities alone. Organizations and institutions that sponsor short-term global health clinical encounters have a responsibility to make appropriate orientation and training available to participants before they depart [11], in addition to working with host communities to put in place appropriate services, such as interpreters or local mentors, to support participants during the experience.

The ethical obligation to respect the individual patients they serve and their host communities' cultural and social traditions does not obligate physicians and trainees "to violate fundamental personal values, standards of medical care or ethical practice, or the law" [9]. Participants will likely be challenged, rather, to negotiate compromises that preserve in some reasonable measure the values of both parties whenever possible [16]. Participants should be allowed to decline to participate in activities that violate deeply held personal beliefs, but they should reflect carefully before reaching such a decision [17].

PREPARATION FOR THE EXPERIENCE

Fulfilling these fundamental ethical responsibilities requires meeting other obligations with respect to organizing and carrying out short-term global health clinical encounters. Specifically, sponsoring organizations and institutions have an obligation to ensure thoughtful, diligent preparation to promote a trip's overall goals, including appropriately preparing participants for the experience. Physicians and trainees, for their part, have an obligation to thoughtfully choose those programs with which they affiliate themselves [1,2,9,11].

Prepare Diligently

Guidelines from the American College of Physicians recognize that "predeparture preparation is itself an ethical obligation" even though this is far from a universal practice at present [9,cf. 2,12]. Collaborative planning can identify what material resources and clinical skills participants should be expected to bring to the effort. For example, what activities participants should be assigned, or whether local mentors are needed or desirable and how such relationships will be coordinated [11].

Supervision of trainees also needs to be explicitly arranged and followed up once they arrive in the host community. Studies show that 20% of participants reported inadequate supervision during their trips, and it is common for medical schools to allow "students to arrange encounters abroad without faculty supervision and support" [18,12]. Allowing students to practice in under-resourced settings without proper supervision is a clear violation of their fiduciary duty.

Thoughtful preparation includes determining what nonclinical skills and experience participants should have to contribute to the overall success of the experience. For example, the goal of supporting capacity building in the local community calls for participants who have "training and/or familiarity with principles of international development, social determinants of health, …public health systems" and in some cases, health care administration [10,12]. Without this background, interventions may result in "resource wasting and potentially poorer patient care" [12].

Adequately preparing physicians and trainees for short-term global health clinical encounters encompasses planning with respect to issues of personal safety, vaccinations, unique personal health needs, travel, malpractice insurance, and local credentialing requirements [7]. Equally important, to contribute effectively and minimize "culture shock" and distress, participants need a basic understanding of the context in which they will be working [1,2,7]. Without expecting them to become experts in local culture, participants should have access to resources that will orient them to the language(s), traditions, norms, and expectations of the host community, not simply to the resources and clinical challenges they are likely to face. Participants should have sufficient knowledge to conduct themselves appropriately, whether that is in how they dress, how they address or interact with different members of the community, or how they carry out their clinical responsibilities [7]. They also need to know to whom they can turn for guidance. If at all possible, this should be someone from outside the host community, since community members may be reluctant to "push back" against the judgments and actions of participants [19].

Preparation should also include explicit attention to the possibility that participants will encounter ethical dilemmas. Working in unfamiliar cultural settings and with limited resources introduces the real possibility that physicians and trainees will encounter situations in which they "are unable to act in ways that are consistent with ethics and their professional values" or "feel complicit in a moral wrong" [9]. In particular, participants will be required to assess "how to balance risks and benefits [for patients who have been economically marginalized and who are experiencing illnesses with which they have little clinical experience] … how to distribute limited medical resources, and when non-intervention is the appropriate choice" [15]. In addition, participants may find that local beliefs are inconsistent with their own ethical commitments. Having strategies in place to address dilemmas when they arise and to debrief after the fact can help mitigate the impact of such encounters. Physicians under stress due to difficult ethical situations experience emotional harm and this may, in turn, affect the quality of patient care [12]. In cases of

irreducible conflict with local norms, participants may withdraw from care of an individual patient or from the project after careful consideration of the effect withdrawing will have on patients, the medical team, and the larger goals of the experience, in keeping with ethics guidance on the exercise of conscience. In addition, participants should keep in mind that some care is not always better than no care, and should ensure that they are able to provide safe, respectful, patient-centered care in the context of the specific host community at all times. This context requires cultural respect and awareness on the part of participants, as well as ongoing attention to the fact that certain treatment decisions may become burdensome to the local medical community once the volunteers leave.

Choose Thoughtfully

Individual physicians and trainees who participate in short-term global health clinical encounters are not typically in a position to directly influence how such programs are organized or carried out. They can, however, choose to participate in activities carried out by organizations that fulfill the ethical and professional responsibilities discussed above [9,10,11]. Participants can select organizations and programs that demonstrate commitment to long-term, community-led efforts to build and sustain local health care resources over programs that provide episodic, stop-gap medical interventions [10]. Participants should strive to avoid working with "volunteer placement organizations" that operate primarily for their own profit and/or lack adequate on-site supervision for trainees [14]. Such organizations exploit the needs of host communities by offering them a small sum per participant and then sending participants to them without support. Physicians and trainees should also refrain from the "casual or opportunistic" treatment of patients that are not coordinated with local health care systems in advance [20].

Measure & Share Meaningful Outcomes

Organizations that sponsor short-term global health clinical encounters have a responsibility to monitor and evaluate the effectiveness of their programs, and to disseminate their findings in a transparent manner [7,9,10]. The measures used to evaluate program outcomes should be appropriate to the program's goals as defined proactively in collaboration with the host community [9]. Prospective participants should affiliate themselves with programs that demonstrate effectiveness in providing outcomes meaningful to the population they serve, rather than simple measures of process such as number of procedures performed [7]. Since the success of procedures and programs cannot reasonably be verified if even their medium-term outcomes cannot be monitored, participants should prefer programs that can track patient results over an extended timeframe, even if their own contribution is made in a short time.

RECOMMENDATION

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

Short-term global health clinical encounters, which send physicians and physicians in training from wealthier communities to provide care in under-resourced settings for a period of days or weeks, have been promoted as a strategy to provide needed care to individual patients and, increasingly, as a means to address global health inequities. To the extent that such encounters also provide training and educational opportunities, they may offer benefit both to the host communities and the medical professionals and trainees who volunteer their time and clinical skills.

Short-term global health clinical encounters typically take place in contexts of scarce resources and in the shadow of colonial histories. These realities define fundamental ethical responsibilities for participants, sponsors, and hosts to jointly prioritize activities to meet mutually agreed-on goals; navigate day-to-day collaboration across differences of culture, language, and history; and fairly allocate resources. Participants and sponsors must focus not only on enabling good health outcomes for individual patients, but on promoting justice and sustainability, minimizing burdens on host communities, and respecting persons and local cultures. Responsibly carrying out short-term global health clinical encounters requires diligent preparation on the part of participants and sponsors in collaboration with host communities.

Physicians and trainees who are involved with short-term global health clinical encounters should ensure that the trips with which they are associated:

(a) Focus prominently on promoting justice and sustainability by collaborating with the host community to define project parameters, including identifying community needs, project goals, and how the visiting medical team will integrate with local health care professionals and the local health care system. In collaboration with the host community, short-term global health clinical encounters should prioritize efforts to support the community in building health care capacity. Trips that also serve secondary goals, such as providing educational opportunities for trainees, should prioritize benefits as defined by the host community over benefits to members of the visiting medical team or the sponsoring organization.

(b) Seek to proactively identify and minimize burdens the trip places on the host community, including not only direct, material costs of hosting participants, but also possible adverse effects the presence of participants could have for beneficial local practices and local practitioners. Sponsors and participants should ensure that team members practice only within their skill sets and experience.

(c) Provide resources that help them become broadly knowledgeable about the communities in which they will work and to cultivate the cultural sensitivity they will need to provide safe, respectful, patient-centered care in the context of the specific host community. Members of the visiting medical team are expected to uphold the ethics standards of their profession and participants should insist that strategies are in place to address ethical dilemmas as they arise. In cases of irreducible conflict with local norms, participants may withdraw from care of an individual patient or from the project after careful consideration of the effect that will have on the patient, the medical team, and the project overall, in keeping with ethics guidance on the exercise of conscience. Participants should be clear that they may be ethically required to decline requests for treatment that cannot be provided safely and effectively due to resource constraints.

(d) Are organized by sponsors that embrace a mission to promote justice, patient-centered care, community welfare, and professional integrity. Physicians, as influential members of their health care systems, are well positioned to influence the selection, planning and preparation for short term encounters in global health. In addition, they can take key roles in mentoring learners and others on teams to be deployed. Physicians can also offer guidance regarding the evaluation process of the experience, in an effort to enhance and improve the outcomes of future encounters.

Sponsors of short-term global health clinical encounters should:(e) Ensure that resources needed to meet the defined goals of the trip will be in place, particularly resources that cannot be assured locally. This includes arranging for local mentors, translation services, and participants' personal health needs. It should not be assumed that host communities can absorb additional costs, even on a temporary basis.

(f) Proactively define appropriate roles and permissible range of practice for members of the visiting medical team, so that they can provide safe, high-quality care in the host community. Team members should practice only within the limits of their training and skills in keeping with professional standards they would deem acceptable in their ordinary clinical practice, even if the host community's standards are more flexible or less rigorously enforced.

(g) Ensure appropriate supervision of trainees, consistent with their training in their home communities, and make certain that they are only permitted to practice independently in ways commensurate with their level of experience in under-resourced settings.

(h) Ensure a mechanism for meaningful data collection is in place, consistent with recognized standards for the conduct of health services research and quality improvement activities in the sponsor's country.

REFERENCES

1. Bauer I. More harm than good? The questionable ethics of medical volunteering and student placements. *Tropical Diseases, Travel Medicine and Vaccines* 2017;3:5
2. Consortium of Universities for Global Health. Cough.org. Accessed January 10, 2020.
3. Association of American Medical Colleges. *Medical School Graduation Questionnaire 2018 All Schools Summary Repor*t. Available at: https://www.aamc.org/system/files/reports/1/2018gqallschoolssummaryreport.pdf. Accessed October 29, 2019.
4. DeCamp M. Ethical review of global short-term medical volunteerism. *HEC Forum.* 2011;23:91–103.

5. Roche SD, Ketheeswaran P, Wirtz VJ. International short-term medical missions: a systematic review of recommended practices. *Int J Public Health.* 2017;62:31–42.
6. Stone GS, Olson KR. The ethics of medical volunteerism. *Med Clin N Am.* 2016;100:237–246.
7. Sykes KJ. Short-term medical service trips: a systematic review of the evidence. *Am J Public Health.* 2014;104:e38–e48.
8. DeCamp M, Soleymani Lehmann L, Jaeel P, et al. Ethical obligations regarding short-term global health clinical experiences: an American College of Physicians position paper. *Ann Intern Med*. 2018;160:651–657.
9. Melby MK, Loh LC, Evert J, et al. Beyond medical "missions" to impact-driven short-term experiences in global health (STEGHs): ethical principles to optimize community benefit and learner experience. *Acad Med.* 2016;91(5):633–638.
10. Keller RC. Geographies of power, legacies of mistrust: colonial medicine in the global present. *Historical Geography* 2006;34:26-48.
11. Snyder J, Dharamsi S, Crook VA. Fly-by medical care: conceptualizing the global social responsibilities of medical tourisms and physician voluntourists. *Globalization and Health* 2011;7:6.
12. Asgary, R and Junck, E. New trends of short-term humanitarian medical volunteerism: professional and ethical considerations. J Med Ethics. 2013;39:625–31.
13. Crump JA, Sugarman J. Global health training: ethics and best practice guidelines for training experiences in global health. *Am J Trop Med Hyg.* 2010;83(6):1178–118
14. Nouvet E, Chan E, Schwartz L. Looking good but doing harm? perceptions of short-ter medical missions in Nicaragua. *Glob Public Health*. 2018;13(4):456–72.
15. Wall, A. The Context of Ethical Problems in Medical Volunteer Work. *HEC Forum.* 2011;23:79–90.
16. Freedman B. Offering truth: one ethical approach to the uninformed cancer patient. *Arch Intern Med.* 1983;153:572–576.
17. American Medical Association. *Code of Medical Ethics*, Opinion 1.1.7, Physician exercise of conscience. Available at https://www.ama-assn.org/delivering-care/ethics/physician-exercise-conscience. Accessed October 29, 2019.
18. Doobay-Persaud A, Evert J, DeCamp M et al. Extent, nature and consequences of performing outside scope of training in global health. Glob. Health. 2019; 15: 1-16.
19. Sullivan N. International clinical volunteering in Tanzania: A postcolonial analysis of global health business. *Glob Public Health*. 2018;13(3):310–24.
20. Bishop, Rachel and Litch, James. Medical tourism can do harm. BMJ. 2000;320.

2. RESEARCH HANDLING OF DE-IDENTIFIED PATIENT DATA

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

HOUSE ACTION: RECOMMENDATIONS ADOPTED
REMAINDER OF REPORT FILED
See CEJA Opinions 2.1.1, 3.1.1, 3.2.4, and 3.3.2

Policy D-315.969, "Research Handling of De-Identified Patient Data," adopted by the American Medical Association (AMA) House of Delegates in November 2021, asked the Council on Ethical and Judicial Affairs (CEJA) to examine guidance related to the use of de-identified patient data and the risks of re-identification.

In its informational report on de-identified data [CEJA 6-A-23], CEJA examined a range of challenges that health care professionals and institutions are now confronted with as technological innovations rapidly evolve both within and outside of health care, blurring the boundary distinctions between these spheres. CEJA's exploration suggested that in this dynamic environment, foundational ethical concepts of privacy and consent likely need to be revisited to better reflect that personal health information today exists in digital environments where responsibilities are distributed among multiple stakeholders.

This report expands on the previous work to articulate a series of recommendations on how best to respond to the increasing collection, sale, and use of de-identified patient data and the associated risks. The report outlines how health data exist within digital information ecosystems, how such ecosystems pose challenges to data privacy, what the *Code* says about data privacy and informed consent, how de-identified data functions as a public good for clinical research, how privacy scholars are reconceptualizing privacy as contextual integrity, and how de-identified

data derived within the context of health care institutions lead to certain ethical standards for and protections of that data.

Because CEJA recognizes both the promise of de-identified datasets for advancing health and the concerns surrounding the use of de-identified patient data including the risks of re-identification that extend from the level of individual physicians collecting clinical data to hospitals and other health care institutions as repositories and stewards of data, this report proposes a new ethics opinion in conjunction with amendments to four existing opinions to provide ethics guidance in this rapidly evolving digital health ecosystem.

HEALTH DATA & DIGITAL ECOSYSTEMS

De-identified patient data are a subset of health data that exists within larger digital health information ecosystems [1]. Such ecosystems are highly dynamic and distributed, with health information often being combined from multiple datasets and distributed among multiple stakeholders [1]. Traditionally, health data has referred to patient health information produced from patient–physician interactions and stored by health care organizations [2]. This type of data is typically recorded as identifiable patient data and entered into the patient's electronic medical record (EMR); from there, it can be de-identified and bundled together with other patent data to form an aggregated dataset. In the age of Big Data, however, where large datasets can reveal complex patterns and trends, diverse sets of information are increasingly brought together. Health data now extends to all health-relevant data, including data collected anywhere from individuals both passively and actively that can reveal information about health and health care use [2].

Within digital health ecosystems, health-related data can be generated by health care systems (e.g., EMRs, prescriptions, laboratory data, radiology), the consumer health and wellness industry (e.g., wearable fitness tracking devices, wearable medical devices such as insulin pumps, home DNA tests), digital exhaust from daily digital activities (e.g., social media posts, internet search histories, location and proximity data), as well as non-health sources of data (e.g., non-medical records of race, gender, education level, residential zip code, credit history) [2]. The ethical challenges raised by such widely distributed data ecosystems, with their vast array of data types and multiple stakeholders, require a holistic approach to the moral issues caused by digital innovation. Digital ethics has arisen as a theoretical framework to analyze these recent challenges and examine such ethical concerns from multiple levels of abstraction. The digital ethics framework takes into account the general environment in which ethical concerns arise and examines ethical dilemmas as they relate to information and data, algorithms, practices and infrastructure, and their impact on the digital world [3].

CHALLENGES TO DATA PRIVACY

In the U.S., the Health Insurance Portability and Accountability Act (HIPAA) imposes constraints on the sharing of "protected health information," including individually identifiable health information contained in the EMR, by "covered entities," including physicians, hospitals, pharmacies, and third-party payers. HIPAA's scope is narrow and does not cover other health-relevant data, such as data generated voluntarily by patients themselves, for example, through the use of commercial health-related apps or devices, or identifiable data individuals provide to municipal authorities, utilities, retailers, or on social media. Furthermore, information that began in the medical record can take on a new, independent life when linked with personal information widely available through datasets generated outside of health care. As McGraw and Mandl explain, "since HIPAA's coverage is about 'who' holds the data, but not what type of data, much of the health-relevant data collected today are collected by entities outside of HIPAA's coverage bubble and thus resides outside of HIPAA's protections" [2]. HIPAA is thus limited in its ability to protect patient data within digital health information ecosystems.

Complicating the matter is the fact that once patient health data has been de-identified, it is no longer protected by HIPAA, and can be freely bought, sold, and combined with other datasets. Hospitals now frequently sell de-identified datasets to researchers and industry. Recent developments in AI and its use within health care have similarly created new difficulties.

Patients, and patient privacy advocates, are often concerned about who has access to their data. As data ecosystems have grown larger and more distributed, this has become increasingly more difficult to ascertain. In the age of Big Data, the global sale of data has become a multibillion-dollar industry, with individuals' data viewed by industry as "new oil" [1]. The global health care data monetization market alone was valued at just over $0.4 billion in 2022 and

is expected to grow to $1.3 billion by 2030 [4]. Industry often purchases hospital datasets to improve marketing and sales, predict consumer behaviors, and to resell to other entities. Within health care and research settings, the massive datasets collected from clinical data—used initially in the care and treatment of individual patients—have created the potential for secondary use as a means for quality improvement and innovation that can be used for the benefit of future patients and patient populations [5].

The dynamic and distributed nature of today's digital health information ecosystems challenges the prevailing procedural model for protecting patient privacy: informed consent and de-identification. In a world where the secondary use of patient data within large datasets can easily enter into a global marketplace, the intended use is almost impossible to discern. Patients cannot be honestly and accurately informed about the specific terms of interactions between their collected data and the data collector and any potential risks that may emerge [1,6]. Therefore, patients are unable to truly give informed consent. Furthermore, whether de-identifying datasets truly prevents individual data subjects from being re-identified has been increasingly called into question. Removing the 18 identifiers specified in HIPAA does not ensure that the data subject cannot be re-identified by triangulation with identifying information from other readily available datasets [7]. Machine learning and AI technologies have advanced to the point that virtually all de-identified datasets risk re-identification, such that "even when individuals are not 'identifiable', they may still be 'reachable'" [6].

A final avenue to consider with respect to private health information and patient privacy is the risk of health care data breaches. Raghupathi et al note, "[h]ealthcare is a lucrative target for hackers. As a result, the healthcare industry is suffering from massive data breaches" [8]. The number of health care data breaches continues to increase every year, exposing the private health information of millions of Americans. Despite being heavily targeted by cybercriminals, health care providing institutions are widely considered by cybersecurity experts to lack sufficient security safeguards [8]. Raghupathi et al note, "healthcare entities gathering and storing individual health data have a fiduciary and regulatory duty to protect such data and, therefore, need to be proactive in understanding the nature and dimensions of health data breaches" [8].

CLINICAL DATA AND PRIVACY

Within the *Code,* Opinion 3.1.1, "Privacy in Health Care," distinguishes four aspects of privacy:

> personal space (physical privacy), personal data (informational privacy), personal choices including cultural and religious affiliations (decisional privacy), and personal relationships with family members and other intimates (associational privacy).

The *Code* does not explicitly examine whether personal medical or health information are ethically distinct from other kinds of personal information (e.g., financial records) or in what way. Current guidance treats the importance of protecting privacy in all its forms as self-evident, holding that respecting privacy in all its aspects is of fundamental importance, "an expression of respect for autonomy and a prerequisite for trust" [Opinion 3.1.1]. However, Opinion 3.3.3, "Breach of Security in Electronic Medical Records," directly acknowledges that data security breaches create potential "physical, emotional, and dignity harms" to patients. Similarly, Opinion 7.3.7, "Safeguards in the Use of DNA Databanks," states that breaches of confidential patient information "may result in discrimination or stigmatization and may carry implications for important personal choices."

Violations of privacy can result in both harm—tangible negative consequences, such as discrimination in insurance or employment or identity theft—and in wrongs that occur from the fact of personal information being known without the subject's awareness, even if the subject suffers no tangible harm [7]. Price and Cohen note that privacy issues can arise not only when data are known, but when data mining enables others to "generate knowledge about individuals through the process of inference rather than direct observation or access" [7].

CLINICAL DATA AND INFORMED CONSENT

With respect to Opinion 2.1.1, "Informed Consent," in the *Code,* successful communication is seen as essential to fostering trust that is fundamental to the patient–physician relationship and to supporting shared decision making. Opinion 2.1.1 states: "[t]he process of informed consent occurs when communication between a patient and physician results in the patient's authorization or agreement to undergo a specific medical intervention." In seeking a patient's informed consent, physicians are directed to include information about "the burdens, risks, and expected

benefits of all options, including forgoing treatment" [Opinion 2.1.1]. It should be noted, however, that no direct mention of patient data is discussed in the opinion, other than that documentation of consent should be recorded in the patient's medical record.

CLINICAL DATA, DATASETS, AND THE PUBLIC GOOD

Because aggregated clinical data has the potential for secondary use that can benefit all of society, it has been argued that such data should be treated as a form of public good [5]. When clinical data are de-identified and aggregated, the potential use for societal benefits through research and development is an emergent, secondary side effect of electronic health records that goes beyond individual benefit. Larson et al argue that not only does the public possess an interest in safeguarding and promoting clinical data for societal benefits, but all those who participate in health care systems have an ethical responsibility to treat such data as a form of public good [5]. They propose:

> all individuals and entities with access to clinical data inherently take on the same fiduciary obligations as those of medical professionals, including for-profit entities. For example, those who are granted access to the data must accept responsibility for safeguarding protected health information [5].

This entails that any entity that purchases private health information, whether or not it has been de-identified, has an ethical obligation to adhere to the ethical standards of health care where such data were produced. Hospitals thus have an ethical responsibility to ensure that their contracts of sale for datasets insist that all entities that gain access to the data adhere to the ethical standards and values of the health care industry.

This is particularly important when we recall that the wide distribution of digital health information ecosystems increasingly includes non-health-related parties from industry that may have market interests that conflict with the ethical obligations that follow health data. Within this framework, the fiduciary duty to protect patient privacy as well as to society to improve future health care follows the data and thus applies to all entities that use that data, such that all entities granted access to the data become data stewards, including for-profit parties [5]. This also includes patients, such that they bear a responsibility to allow their data to be used for the future improvement of health care for society, especially when we recognize that current health care has already benefited from past data collection [5].

While the re-identification of aggregated patient data should generally be prohibited, there are rare exceptions. There may be occasions when researchers wish to re-identify a dataset, such as sometimes occurs in the study of rare diseases that rely on international registries; in such situations, all individuals must be re-contacted, and their consent obtained in order to re-identify their data since this would represent a significant change to the initial research protocols and respective risks [9]. Re-identification of datasets for research is uncommon, however, because obtaining re-consent can be difficult and can lead to flawed research if data is lost because patients do not re-consent. The other situation in which it may be permissible, or even obligatory, to re-identify aggregated patient data is when doing so would be in the interest of the health of individual patients, such as might occur in the study of a rare genetic disorder. Even within these exceptions, the risks associated with re-identification remain and re-identified data should thus never be published. Re-identification of de-identified patient data for any other purposes, by anyone inside or outside of health care, must be avoided.

AN ALTERNATIVE APPROACH: PRIVACY AS CONTEXTUAL INTEGRITY

Within today's digital health information ecosystems, physicians and hospitals face several challenges to protecting patient privacy. Barocas and Nissenbaum contend that "even if [prevailing forms of consent and anonymization] were achievable, they would be ineffective against the novel threats to privacy posed by big data" [6]. A more effective option, Nissenbaum has argued, would understand privacy protection as a function of "contextual integrity," i.e., that in a given social domain, information flows conform to the context-specific informational norms of that domain. Whether a transmission of information is appropriate depends on "the type of information in question, about whom it is, by whom and to whom it is transmitted, and conditions or constraints under which this transmission takes place" [10]. The view of privacy as contextual integrity—that our conception of privacy is contextual and governed by various norms of information flow—recognizes that there exist different norms regarding privacy within different spheres of any distributed digital ecosystem [7,11]. The challenge within health care, as we have seen, is how to balance these various norms when they conflict and how to ensure that health care's ethical standards and values are maintained throughout the distributed use of de-identified private health information.

THE CONTEXTUAL INTEGRITY OF DE-IDENTIFIED HEALTH DATA

In handling patient data, individual physicians strive to balance supporting and respecting patient privacy while also upholding ethical obligations to the betterment of public health. Through their own actions, as well as through their membership organizations and through their health care organizations, physicians should: (1) ensure that data entered into electronic records are accurate and reliable to the best of their ability; (2) be transparent with patients regarding the limited extent to which their data can be safely protected, how their data may be used, and why the use of such data is crucial for improving health care outcomes within society; and (3) ensure that proper oversight and protections of data are in place, including contractual provisions that any data sold or shared with outside entities stay in alignment with the ethical standards of the medical profession, and that meaningful sanctions or penalties are in place and enforced against any actors that violate those ethical standards. It is critical to recognize, as is outlined in the *Code,* that the patient–physician relationship is built on trust, and that this trust relies heavily on transparency. It is important for both patient care and research that clinical data entered into the EMR be as accurate and complete as possible. Some data capture practices, such as copying-and-pasting daily progress notes from previous encounters, which may contribute to efficiency, can lead to documentation errors [12]. One avenue for improving EMR accuracy is that, under HIPAA, patients have the right to access their data and request any perceived errors be amended. While there is no one solution to improving accuracy of EMR data, further study into how to improve EMR accuracy is important. One challenge to both EMR accuracy and completeness is the limited interoperability of different EMR systems. Matching digital health records for the same patient across and within health care facilities can be a challenge, further contributing to the potential for EMR errors. Standardization of recording data elements, such as capturing patient address and last name in a consistent format, may improve matching of patient records and thus improve the accuracy of the EMR [13].

Another challenge to EMR data quality is the risk of bias, primarily due to implicit bias in EMR design and underrepresentation of patients from historically marginalized groups, low socioeconomic status, and rural areas [14,15]. Critically important for research involving data collected from EMRs, available EMR data only reflects those with access to health care in the first place. While certain study designs and tools have been developed to reduce these biases in research, physicians and health care institutions should be looking into ways to reduce bias within EMRs, such as features to optimize effective EMR use and to consistently capture patient data, especially data on race/ethnicity and social determinants of health that are often inconsistently and inaccurately captured in EMR systems [14,15,16].

Patients have a right to know how and why their data are being used. While physicians should be able to answer questions regarding patient data as they relate to HIPAA protections, it is the responsibility of health care institutions to provide more detailed information regarding expectations of data privacy, how patient data may be used, and why such use is important to improve the future of health care. Health care systems may consider fulfilling this ethical obligation by creating a patient notification of data use built into the patient registration process (using language similar to the National Institutes of Health's (NIH) Introduction-Description component, meant to provide prospective research participants with an introduction to and description of the planned storage and sharing of data and biospecimens [17]).

As stewards of health data, health care institutions have an ethical responsibility to protect data privacy. This fiduciary duty to patient data should be seen as following the data even after they are de-identified and leave the institution where they were initially captured [5,8]. While hospitals and health care organizations increasingly come under cyberattack, they consistently lag behind other industries in cybersecurity [18]. With regards to protecting the data they maintain, health care institutions have a responsibility to make more significant investments in cybersecurity.

In order to ensure that the ethical standards of health care are maintained even after data leaves health care institutions, McGraw and Mandl propose that companies collecting or using health-relevant data could be required to establish independent data ethics review boards [2]. They write that such boards could be similar to Institutional Review Boards but should focus more on privacy than on participant risk, evaluating proposed data projects for legal and ethical implications as well as their potential to improve health and/or the health care system [2]. In practice, ethics review boards involved with industry face challenges to both independence and efficacy.

Independence can be compromised by influences such as conflicts of interest, while efficacy can be compromised by the absence of authority, procedures, and systems to enact recommendations made by these review bodies. To be effective, data ethics review boards must be independent and free of conflicts of interest from the company or organization whose data research proposal(s) they are evaluating and have systems in place for both transparency and implementation of feedback for remediations of privacy and other quality and ethics concerns. Though not a comprehensive solution, independent data ethics review boards could be an effective safeguard against industry conflicts of interest and should be considered as a required part of contracts of sale of health data, with contracts stipulating that any future resale of the data also undergo review by a data ethics review board.

An additional safeguard is the implementation of regular data audits to assess the quality and use of shared data [19]. These regulatory measures could be implemented as requirements outlined in Data Use Agreements or Data Sharing Agreements (DSAs). Such agreements have the potential to establish data governance policies and practices within health care institutions regarding "what data can be shared, with whom, under what conditions, and for what purposes." In developing DSAs, hospital administrators should engage all relevant stakeholders, require a neutral entity be designated as an independent custodian of shared data, limit the types and/or characteristics of shared data to certain purposes, and apply additional safeguards to protect the data [20].

The need for more transparent disclosure to patients regarding their data use as well as the importance of building the values of medical ethics into the contracts of sale of aggregate datasets created by hospitals highlights the fact that the ethical responsibilities to respond to the risks of de-identified data should not be borne by physicians alone. Respecting patient privacy and their informed consent are responsibilities that physician member organizations and health care institutions must take on because the risks to these rights that patients face within digital health ecosystems radiate far beyond the patient–physician relationship to areas where individual physicians have little influence.

RECOMMENDATIONS

In light of the challenges considered with regard to constructing a framework for holding stakeholders accountable within digital health information ecosystems, the Council on Ethical and Judicial Affairs recommends:

1. That the following be adopted:

    Within health care systems, identifiable private health information, initially derived from and used in the care and treatment of individual patients, has led to the creation of massive de-identified datasets. As aggregate datasets, clinical data takes on a secondary promising use as a means for quality improvement and innovation that can be used for the benefit of future patients and patient populations. While de-identification of data is meant to protect the privacy of patients, there remains a risk of re-identification, so while patient anonymity can be safeguarded it cannot be guaranteed. In handling patient data, individual physicians thus strive to balance supporting and respecting patient privacy while also upholding ethical obligations to the betterment of public health.

    When clinical data are de-identified and aggregated, their potential use for societal benefits through research and development is an emergent, secondary use of electronic health records that goes beyond individual benefit. Such data, due to their potential to benefit public health, should thus be treated as a form of public good, and the ethical standards and values of health care should follow the data and be upheld and maintained even if the data are sold to entities outside of health care. The medical profession's responsibility to protect patient privacy as well as to society to improve future health care should be recognized as inherently tied to these datasets, such that all entities granted access to the data become data stewards with a duty to uphold the ethical values of health care in which the data were produced.

    As individuals or members of health care institutions, physicians should:

    (a) Follow existing and emerging regulatory safety measures to protect patient privacy;

    (b) Practice good data intake, including collecting patient data equitably to reduce bias in datasets;

(c) Answer any patient questions about data use in an honest and transparent manner to the best of their ability in accordance with current federal and state legal standards.

Health care entities, in interacting with patients, should adopt policies and practices that provide patients with transparent information regarding:

(d) The high value that health care institutions place on protecting patient data;

(e) The reality that no data can be guaranteed to be permanently anonymized, and that risk of re-identification does exist;

(f) How patient data may be used;

(g) The importance of de-identified aggregated data for improving the care of future patients.

Health care entities managing de-identified datasets, as health data stewards, should:

(h) Ensure appropriate data collection methods and practices that meet industry standards to support the creation of high-quality datasets;

(i) Ensure proper oversight of patient data is in place, including Data Use/Data Sharing Agreements for the use of de-identified datasets that may be shared, sold, or resold;

(j) Develop models for the ethical use of de-identified datasets when such provisions do not exist, such as establishing and contractually requiring independent data ethics review boards free of conflicts of interest and verifiable data audits, to evaluate the use, sale, and potential resale of clinically-derived datasets;

(k) Take appropriate cyber security measures to seek to ensure the highest level of protection is provided to patients and patient data;

(l) Develop proactive post-compromise planning strategies for use in the event of a data breach to minimize additional harm to patients;

(m) Advocate that health- and non-health entities using any health data adopt the strongest protections and seek to uphold the ethical values of the medical profession.

There is an inherent tension between the potential benefits and burdens of de-identified datasets as both sources for quality improvement to care as well as risks to patient privacy. Re-identification of data may be permissible, or even obligatory, in rare circumstances when done in the interest of the health of individual patients. Re-identification of aggregated patient data for other purposes without obtaining patients' express consent, by anyone outside or inside of health care, is impermissible; and

2. That Opinion 2.1.1, "Informed Consent"; Opinion 3.1.1, "Privacy in Health Care"; Opinion 3.2.4, "Access to Medical Records by Data Collection Companies"; and Opinion 3.3.2, "Confidentiality and Electronic Medical Records" be amended by addition as follows:

a. Opinion 2.1.1, Informed Consent

Informed consent to medical treatment is fundamental in both ethics and law. Patients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care. Successful communication in the patient-physician relationship fosters trust and supports shared decision making. <u>Transparency with patients regarding all medically appropriate options of treatment is critical to fostering trust and should extend to any discussions regarding who has access to patients' health data and how data may be used.</u>

The process of informed consent occurs when communication between a patient and physician results in the patient's authorization or agreement to undergo a specific medical intervention. In seeking a patient's informed

consent (or the consent of the patient's surrogate if the patient lacks decision-making capacity or declines to participate in making decisions), physicians should:

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

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

(i) the diagnosis (when known);

(ii) the nature and purpose of recommended interventions;

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

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

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

b. Opinion 3.1.1, Privacy in Health Care

Protecting information gathered in association with the care of the patient is a core value in health care. However, respecting patient privacy in other forms is also fundamental, as an expression of respect for patient autonomy and a prerequisite for trust.
Patient privacy encompasses a number of aspects, including personal space (physical privacy), personal data (informational privacy), personal choices including cultural and religious affiliations (decisional privacy), and personal relationships with family members and other intimates (associational privacy).

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

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

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

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

(d) Be transparent with any inquiry about existing privacy safeguards for patient data but acknowledge that anonymity cannot be guaranteed and that breaches can occur notwithstanding best data safety practices. (Modify HOD/CEJA Policy)

c. Opinion 3.2.4, Access to Medical Records by Data Collection Companies

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

Information gathered and recorded in association with the care of a patient is confidential. Patients are entitled to expect that the sensitive personal information they divulge will be used solely to enable their physician to most effectively provide needed services. Disclosing information to third parties for commercial purposes

without consent undermines trust, violates principles of informed consent and confidentiality, and may harm the integrity of the patient-physician relationship.

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

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

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

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

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

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

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

Because de-identified datasets are derived from patient data as a secondary source of data for the public good, health care professionals and/or institutions who propose to permit third-party access to such information have a responsibility to establish that any use of data derived from health care adhere to the ethical standards of the medical profession. (Modify HOD/CEJA Policy)

d. Opinion 3.3.2, Confidentiality and Electronic Medical Records

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

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

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

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

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

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

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

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

(c) Release patient information only in keeping with ethics guidance for confidentiality and privacy. (Modify HOD/CEJA Policy); and

3. That the remainder of this report be filed.

REFERENCES

1. Ruotsalainen P, Blobel B. Health information systems in the digital health ecosystem—problems and solutions for ethics, trust and privacy. Int J of Envir Res and Pub health 2020;17(9):3006.

2. McGraw D, Mandl KD. Privacy protections to encourage use of health-relevant digital data in a learning health system. NPJ dig med 2021;4(1):2.
3. Floridi L, Cath C, Taddeo M. Digital ethics: its nature and scope. *The 2018 yearbook of the digital ethics lab* 2019:9-17.
4. Data monetization in healthcare market size report, 2030. In: Data Monetization In Healthcare Market Size Report, 2030. https://www.grandviewresearch.com/industry-analysis/data-monetization-healthcare-market-report.
5. Larson DB, Magnus DC, Lungren MP, Shah NH, Langlotz CP. Ethics of using and sharing clinical imaging data for artificial intelligence: a proposed framework. Radiology 2020;295(3):675-82.
6. Barocas S, Nissenbaum H. Big data's end run around anonymity and consent. *Privacy, big data, and the public good: Frameworks for engagement* 2014;1:44-75.
7. Price WN II, Cohen IG. Privacy in the age of medical big data. Nat Med 2019;25:37–43.
8. Raghupathi W, Raghupathi V, Saharia A. Analyzing Health Data Breaches: A Visual Analytics Approach. AppliedMath 2023;3(1):175-99.
9. Hansson MG, Lochmüller H, Riess O, Schaefer F, Orth M, Rubinstein Y, Molster C, Dawkins H, Taruscio D, Posada M, Woods S. The risk of re-identification versus the need to identify individuals in rare disease research. Eur J Hum Genet 2016;24(11):1553-1558. doi:10.1038/ejhg.2016.52.
10. Nissenbaum, H. Respecting context to protect privacy: why meaning matters. Sci Eng Ethics 2018;24:831–52.
11. Nissenbaum H. Privacy as contextual integrity. Wash. L. Rev 2004;79:119-158.
12. Weng CY. Data Accuracy in Electronic Medical Record Documentation. JAMA Ophthalmol 2017;135(3):232–233. doi:10.1001/jamaophthalmol.2016.5562
13. Pew. Enhancing patient matching is critical to achieving full promise of digital health records: Accurately linking individuals with their health records essential to improving care. Pew Trust Report October 2, 2018. https://www.pewtrusts.org/en/research-and-analysis/reports/2018/10/02/enhanced-patient-matching-critical-to-achieving-full-promise-of-digital-health-records
14. Boyd AD, Gonzalez-Guarda R, Lawrence K, Patil CL, Ezenwa MO, O'Brien EC, Paek H, Braciszewski JM, Adeyemi O, Cuthel AM, Darby JE. Equity and bias in electronic health records data. Contemp Clinic Trials 2023;130:107238.
15. Boyd AD, Gonzalez-Guarda R, Lawrence K, Patil CL, Ezenwa MO, O'Brien EC, Paek H, Braciszewski JM, Adeyemi O, Cuthel AM, Darby JE. Potential bias and lack of generalizability in electronic health record data: reflections on health equity from the National Institutes of Health Pragmatic Trials Collaboratory. J of the Am Medl Informat Ass 2023:ocad115.
16. Khurshid S, Reeder C, Harrington LX, Singh P, Sarma G, Friedman SF, Di Achille P, Diamant N, Cunningham JW, Turner AC, Lau ES. Cohort design and natural language processing to reduce bias in electronic health records research. NPJ Digital Med 2022;5(1):47.
17. NIH. Informed consent for secondary research with data and biospecimens: Points to consider and sample language for future use and/or sharing. NIH Office of Science Policy Office of Extramural Research May 2020. https://osp.od.nih.gov/wp-content/uploads/Informed-Consent-Resource-for-Secondary-Research-with-Data-and-Biospecimens.pdf
18. Skahill E, West DM. Why hospitals and healthcare organizations need to take cybersecurity more seriously. Brookings August 9, 2021. https://www.brookings.edu/articles/why-hospitals-and-healthcare-organizations-need-to-take-cybersecurity-more-seriously/
19. Winter JS, Davidson E. Big Data Governance of personal health information and challenges to Contextual Integrity. The Information Society 35:36–51. doi: 10.1080/01972243.2018.1542648
20. Allen C, Des Jardins TR, Heider A, et al. Data Governance and data sharing agreements for community-wide health information exchange: Lessons from the Beacon Communities. eGEMs (Generating Evidence & Methods to improve patient outcomes) 2:5. doi: 10.13063/2327-9214.1057

3. ESTABLISHING ETHICAL PRINCIPLES FOR PHYSICIANS INVOLVED IN PRIVATE EQUITY OWNED PRACTICES

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

HOUSE ACTION: REFFERED

In response to Policy D-140.951, "Establishing Ethical Principles for Physicians Involved in Private Equity Owned Practices," which instructs our American Medical Association (AMA) to "study and clarify the ethical challenges and considerations regarding physician professionalism raised by the advent and expansion of private equity ownership", your Council on Ethical and Judicial Affairs (CEJA) presented Report 02-A-23, which offered recommendations on amending *Code* Opinion 11.2.3, "Contracts to Deliver Health Care Services." Testimony at the 2023 Annual Meeting of the House of Delegates was predominantly in opposition to the report; concerns were raised regarding the profit motives of private equity and the ethical implications of such businesses' involvement in health care. Overall, testimony expressed a desire that a stronger stance be taken against private equity's involvement in health care, and the report was referred back to CEJA.

BACKGROUND

The past several decades have seen an increase in the corporatization, financialization, and commercialization of health care [1,2]. Since 2018, more physicians now work as employees of hospitals or health care systems rather than serving in private practice [3,4]. Our AMA reports that this trend is continuing: "[e]mployed physicians were 50.2% of all patient care physicians in 2020, up from 47.4% in 2018 and 41.8% in 2012. In contrast, self-employed physicians were 44% of all patient care physicians in 2020, down from 45.9% in 2018 and 53.2% in 2012" [4]. A major factor in these trends has been the incursion of private equity into health care. It is estimated that private equity capital investment between 2000 and 2018 grew from $5 billion to $100 billion [1]. Between 2016 and 2017 alone, the global value of private equity deals in health care increased 17%, with health care deals compromising 18% of all private equity deals in 2017 [5].

Private equity firms use capital from institutional investors to purchase private practices, typically utilizing a leveraged buy-out model that finances the majority of the purchase through loans for which the physician practice serves as security, with the goal of selling the investment within 3 to 7 years and yielding a return of 20-30% [1,5,6]. However, private equity investment broadly encompasses many types of investors and strategies, including venture capital firms that primarily invest in early-stage companies for a minority ownership, growth equity firms that tend to partner with promising later-stage ventures, and traditional private equity firms that borrow money through a leveraged buyout to take a controlling stake of mature companies [7].

When ownership shifts from physicians to private equity firms, the firms typically seek to invest resources to expand market share, increase revenue, and decrease costs to make the practice more profitable before selling it to a large health care system, insurance company, another private equity firm (as a secondary buyout), or the public via an initial public offering (IPO) [8]. To expand market share, private equity typically employs a "platform and add-on" or "roll-up" approach in which smaller add-ons are acquired after the initial purchase of a large, established practice, allowing private equity firms to gain market power in a specific health care segment or sub-segment [1,9]. These practices by private equity appear to be driving mergers and acquisitions within health care, significantly contributing to the consolidation of the health care industry that has dramatically increased over the past decade [9].

Proponents of private equity investments in health care claim that private equity provides access to capital infusions, which may facilitate practice innovation and aid in the adoption of new technological infrastructure [6,8]. Proponents also advocate that private equity can bring "valuable managerial expertise, reduce operational inefficiencies, leverage economies of scale, and increase healthcare access by synergistically aligning profit incentives with high quality care provision" [10].

Critics argue that private equity's focus on generating large, short-term profits likely establishes an emphasis on profitability over patient care, which creates dual loyalties for physicians working as employees at private equity-owned practices [5,6]. Critics further assert that prioritizing profits likely jeopardizes patient outcomes, overburdens health care companies with debt, leads to an over-emphasis on profitable services, limits access to care for certain patient populations (such as uninsured individuals or individuals with lower rates of reimbursement such as Medicaid or Medicare patients), and fundamentally limits physician control over the practice and clinical decision making [5,8,10].

Despite strong opinions regarding private equity's incursion into medicine, empirical research on the effects of private equity investments in health care, and the impacts on patient outcomes, is currently limited [8]. Zhu and Polsky explain that this lack of research is primarily because "[p]rivate equity firms aren't required to publicly disclose acquisitions or sales, and the widespread use of nondisclosure agreements further contributes to opacity

about practice ownership and the nature of transactions" [6]. Private equity firms are emerging to be major employers of physicians. Currently, it is estimated that 8% of all private hospitals in the U.S. and 22% of all proprietary for-profit hospitals are owned by private equity firms [11].

Ethical Issue

Private equity firms' commitment to ensuring high returns on their investments creates a potential ethical dilemma when investing in health care. Whether or not it may be ethically permissible for physicians to sell their practices to private equity firms or for physicians to work as employees for such acquisitions largely depends on how private equity investments impact patient care and outcomes. This report will examine how private equity investments in health care may be ethical, the circumstance and factors to be weighed, as well as how physicians may ethically navigate private equity buyouts and employment.

Relevant Practical Matters for Clinical Practice

A major concern of physicians regarding private equity investments in health care is the potential loss of autonomy, which physicians worry could translate into hospital policies designed for profitability and that limit physicians' decision-making and their ability to care for patients [9]. Loss of autonomy is also associated with increased physician burnout [12]. There are also valid concerns that private equity ownership leads to increased patient volumes and more expensive and potentially unnecessary procedures [9].

Review of Relevant Literature

Empirical Evidence in Medical Literature

More research is needed on the effects of private equity investments in the health care sector, as little empirical evidence exists on how private equity impacts utilization, spending, or patient outcomes. There is widespread concern among physicians that private equity-controlled practices result in worse patient outcomes.

The best evidence that private equity acquisition of hospitals harms patients is a recent difference-in differences study by Kannan et al of hospital-acquired adverse events and hospitalization outcomes associated with private equity acquisitions of U.S. hospitals [13]. Data from 100% Medicare Part A claims at 51 private equity-acquired hospitals were compared with data from 259 matched control hospitals (not acquired by private equity) for hospital stays between 2009 and 2019. While there was no differential change in mortality 30 days after hospital discharge, the researchers did find that after private equity acquisition, Medicare beneficiaries admitted to private equity-owned hospitals experienced a 25.4% increase in hospital-acquired conditions compared with those treated at control hospitals. This increase in hospital-acquired conditions, which are established measures of inpatient quality and are considered preventable, was largely driven by a 27.3% increase in falls and a 37.7% increase in central line-associated bloodstream infections at private equity-acquired hospitals [13]. The increase in central-line associated infections after private equity acquisition occurred even as these hospitals saw a 16% reduction in percutaneous central line placement. Kannan et al hypothesize that such increases in hospital-acquired infections could result from decreases in staffing, as such adverse events have been shown to be correlated with staffing ratios among nurses and that private equity often will reduce staffing and change the clinician labor mix at acquired hospitals as a cost-cutting strategy [13].

In another difference-in-differences study of 578 private equity-acquired practices in dermatology, gastroenterology, and ophthalmology matched with a control group of 2,874 non-private equity-acquired practices, Singh et al found a mean increase of 20.2% in charges per claim and a consistent increase in patient utilization over the first eight quarters after acquisition, with the increase in patient utilization primarily driven by a 37.9% increase in visits by new patients [14]. Overall, the researchers found that "private equity acquisition was associated with increases in health care spending and several measures of utilization, and some evidence of greater intensity of care" [14]. They also found increased coding intensity, and posit that this finding could be due to either changes in coding and billing practices that have more efficient charge capture or, conversely, could reflect upcoding to increase revenues [14]. The motivating factors behind this impact on coding deserves further study.

In a systematic review of 55 studies evaluating trends in private equity ownership in health care and the impacts on outcomes, costs, and quality, Borsa et al found that private equity ownership was associated with an increase in cost to patients or payers, primarily from increased charges and rates for services as well as inconclusive, mixed results on how private equity impacts quality of care [10]. The majority of the studies (n=47) evaluated private equity ownership of health care operations in the US, but represented a range of settings, the most common of which were nursing homes (n=17), hospitals (n=9), dermatology (n=9), and ophthalmology (n=7). Only eight studies included health outcomes, with two finding beneficial impacts, three findings harmful impacts, and three finding neutral impacts; the three that found harmful impacts were all studies of nursing homes [10]. These results suggest that private equity may impact segments of the health care industry differently.

In their analysis of 281 private equity acquisitions involving 610 unique target hospitals, Gao et al found that over an eight-year window, acquisitions were associated with increased profitability, no change in the rate of closures, no statistically significant changes in mortality or readmission rates, and that the percentage of Medicare and Medicaid patients stayed relatively the same [15]. Over the eight year window, private equity-acquired hospitals increased their operating income by 7.4%. Compared to their matched control groups, private equity-acquired hospitals were equally or more likely to survive, contrary to the prevailing narrative. Private equity-acquired hospitals initially experienced a 14% decrease in the number of core workers (medical workers that include physicians, nurses, and pharmacists) over the first four years but over the next four years this difference dissipates to only 2% and is not statistically significant. In contrast, the decline in administrative workers is significant and persistent, with a reduction of 18% within the first four years of acquisition and a 22% reduction by the end of eight years. This reduction in administrative workers was most profound at nonprofit hospitals. Core workers' wages were not found to change, while administrative workers' wages declined by 7%. No changes to patient mortality rates or readmission were found, except for a 0.9% increase in readmission following pneumonia. In looking at rates of stroke, complications and infections during hospitalization as measure of patient outcomes, no statistically significant differences were found between private equity-acquired hospitals, the control group, or non-private equity acquired hospitals. Private equity-acquired hospitals appear to treat a higher number of resource-intensive patients and decrease their outpatient ratio. Gao et al conclude: "[o]verall, our evidence suggests that PE acquirers improve the operating efficiency of target hospitals without a compromise in healthcare quality" [15].

Normative and Substantive Views in Ethics and Medical Literature

The debate over private equity's incursion into health care often regards private equity acquisitions through a lens of exceptionalism—either negatively or positively. However, although private equity owned hospitals are different in their ownership structure and oversight compared to other traditional health care investors, private equity-acquired hospitals may not be substantively different from other for profit and non-profit hospitals in terms of their stated goals of both solvency and patient care. Zhu and Polsky argue that private equity is not inherently unethical and that there are likely good and bad actors as is the case in many sectors [6]. They add: "physicians should be aware that private equity's growth is emblematic of broader disruptions in the physician-practice ecosystem and is a symptom of medicine's transformation into a corporate enterprise" [6].

The corporatization of medicine is not without ethical and professional risks, of course. In their ethical analysis of orthopaedic surgery practices owned by non-physicians, Moses et al note that the incentives and goals of surgeons might be misaligned with those of the investors, pitting patient care against profits; profit maximization might also lead to wasteful overtreatment as well as a loss of physician autonomy within the practice as well as patient autonomy if physicians are encouraged to be more paternalistic to achieve financial goals [3].

Veatch notes that business ethics and medical ethics are not inherently at odds but admits that differences do exist [16]. Veatch highlights that physicians are uncomfortable with any removal of professional control that may accompany the increasing commercialization of the physician's role. Veatch points out that paradoxically, despite being open to the profit motive in the practice of medicine, the practice as a whole has shown strong resistance to the commercialization of medical practice. For Veatch, the crux of the issue is whether people perceive health care as a fundamental right or a commodity like any other, adding that the notion of health care as a right jeopardizes any profit motive in health care including traditional private practitioner fee-for-service models [16].

Pellegrino offers a similar analysis, arguing that health care is not a commodity but rather a human good that society has an obligation to provide in some measure to all citizens [17]. Pellegrino argues that health care is substantively different from traditional market goods—it is not fungible, cannot be proprietary because medical knowledge is

possible only due to collective achievements, is realized in part through the patient's own body, and requires an intensely personal relationship—and thus cannot be a commodity. Pellegrino warns that the commodification of health and medicine turns any interaction between the patient and physician into a commercial transaction subject to the laws and ethics of business rather than to medical and professional ethics. "In this view," Pellegrino writes, "inequities are unfortunate but not unjust […]. In this view of health care, physicians and patients become commodities too" [17]. Rather than claiming that health care is a fundamental right, Pellegrino takes a position of distributive justice to argue that health care is a collective good. Because a good society is one in which each citizen is enabled to flourish, and good health is a condition of human flourishing, society has a moral responsibility to provide health care to all citizens. In this light, health care is both an individual and a social good. Pellegrino also refers to this view as one of "beneficent justice" and explains, "[t]reating health care as a common good implies a notion of solidarity of humanity, i.e., the linkage of humans to each other as social beings" [17]. Pellegrino concludes:

> Understanding health care to be a commodity takes one down one arm of a bifurcating pathway to the ethic of the marketplace and instrumental resolution of injustices. Taking health care as a human good takes us down a divergent pathway to the resolution of injustice through a moral ordering of societal and individual priorities [17].

Whether health care is understood as a commodity or a human good is of course not always so clear in policy and in practice. What is evident, however, is that as health care has become increasingly commodified, the ethical risks to patients and physicians are being realized as physicians find themselves increasingly working as employees and worrying about the impact that commercial enterprises—such as private equity investments—may be having on patients.

Private equity represents the latest and most extreme form of health care commercialization that has escalated over the past few decades. This is the very reason why private equity firms became interested in health care in the first place—they recognized that health care as a market was already ripe for investment and future profitability. Private equity firms use the same investment models in health care that they do in other industries—invest in fragmented markets, acquire the most promising targets as a platform, expand through add-on acquisitions, and exit the market once a significant consolidation of market share can secure a sale, secondary buyout, or IPO [9]. Each individual acquisition is typically too small to require review by anti-trust regulators at the Federal Trade Commission (FTC); at the same time, however, this practice is driving the trend of mergers and acquisitions in the health care sector [9].

Fuse Brown and Hall explain, "[private equity] functions as a divining rod for finding market failures—where PE has penetrated, there is likely a profit motive ripe for exploitation" [1]. They continue that private equity investments pose three primary risks:

> First, PE investment spurs health care consolidation, which increases prices and potentially reduces quality and access. Second, the pressure from PE investors to increase revenue can lead to exploitation of billing loopholes, overutilization, upcoding, aggressive risk-coding, harming patients through unnecessary care, excessive bills, and increasing overall health spending. Third, physicians acquired by PE companies may be subject to onerous employment terms and lose autonomy over clinical decisions [1].

While the profit motive of private equity firms may drive them to take part in less than scrupulous practices, such as private equity's exploitation of out-of-network surprise billing, there is also potential for private equity to play a more positive role in transforming health care practices [1,18]. Powers et al write:

> Ultimately, private equity—a financing mechanism—is not inherently good or bad. Instead, it acts to amplify the response to extant financial incentives. Within a fee-for-service construct, this is intrinsically problematic. But value-based payment models can serve as an important guardrail, helping to ensure that financial return to private equity investors are appropriately aligned with system goals of access, quality, equity, and affordability [18].

Private equity firms could help accelerate changes in health care payment and delivery towards value-based models. With such models, where financial performance is tied to quality and value, private equity may be incentivized to invest in changes that support better health and lower costs [18].

While more research is needed on the impacts of private equity investments in health care, private equity firms' involvement in health care does not appear to be exceptional within the current corporate transformation of the profession and thus is inherently no more or less ethical than this current trend that has penetrated health care and the practice of medicine far beyond interactions with private equity. As Fuse Brown and Hall point out, "PE investment in health care is just the latest manifestation of the long trend of increasing commercialization of medicine. And so long as the U.S. treats health care as a market commodity, profit-seeking will persist" [1]. Ikrum et al provide a balanced view of the situation and offer some recommendations for partnering with private equity in health care:

> While PE involvement in health care delivery invokes inherent concerns, it has provided much-needed capital for many primary care practices to mitigate the effects of the pandemic and to potentially undertake care delivery innovations such as population health management under value-based payment models. To make partnerships with private investors work, providers need to select the right investors, establish strategies upfront to address misaligned objectives, and define a successful partnership by setting goals for and transparently reporting on indicators that reflect both financial and clinical performance. Safeguards and regulations on sales may also protect patients and providers [7].

Relevant Laws

Fuse Brown and Hall write that despite the market consolidation that results from private equity acquisitions within health care, these acquisitions generally go unreported and unreviewed since they do not exceed the mandatory reporting threshold under the Hart-Scott-Rodino (HSR) Act and that there are currently no legal guidelines for assessing the collective market effects of add-on acquisitions. However, they do note:

> Under Section 7 of the Clayton Act, federal antitrust authorities—the Federal Trade Commission (FTC) and the Department of Justice (DOJ)—can sue to block mergers and acquisitions where the effect of the transaction may be "substantially to lessen competition, or to tend to create a monopoly." To determine whether a transaction may threaten competition, antitrust agencies analyze whether the transaction will enhance the market power of the transacting parties in a given geographic and product market. […] Typically, the FTC oversees health care acquisitions (other than insurance) [1].

To protect patients from harmful billing practices, the federal government has passed the No Surprise Act, the False Claims Act, Anti-Kickback Statute, and Stark Law. Additionally, most states have similar laws, such as those barring fee-splitting and self-referral, and several states have passed laws regulating or restricting the use of gag clauses in physician contracts. The FTC has also recently proposed a rule banning noncompete clauses in all employment contracts [1].

The federal Emergency Medical Treatment and Labor Act (EMTALA) ensures that hospitals with an emergency department provide all patients access to emergency services regardless of their ability to pay. Similarly, federal law requires nonprofit hospitals, which account for 58% of community hospitals, provide some level of charity care as a condition for their tax-exempt status, which the Internal Revenue Service (IRS) defines as "free or discounted health services provided to persons who meet the organization's eligibility criteria for financial assistance and are unable to pay for all or a portion of the services" [19].

Relevant AMA Policy Provisions

Council on Medical Service Report 11-A-10 reviewed the scope and impact of private equity and venture capital investment in health care, and its recommendations were adopted as Policy H-160.891, "Corporate Investors." This policy delineates 11 factors that physicians should consider before entering into partnership with corporate investors, including alignment of mission, vision, and goals; the degree to which corporate partners may require physicians to cede control over practice decision making; process for staff representation on the board of directors and medical leadership selection; and retaining medical authority in patient care and supervision of nonphysician practitioners.

Our AMA further developed and published materials to assist physicians contemplating partnering with private equity and venture capital firms:

- Venture Capital and Private Equity: How to Evaluate Contractual Agreements

- Model Checklist: Venture Capital and Private Equity Investments
- Snapshot: Venture Capital and Private Equity Investments

Policy H-310.901, "The Impact of Private Equity on Medical Training," encourages GME training institutions and programs to "demonstrate transparency on mergers and closures, especially as it relates to private equity acquisition" and asserts that our AMA will "[s]upport publicly funded independent research on the impact that private equity has on graduate medical education."

RELEVANT *CODE* PROVISIONS

The AMA *Code of Medical Ethics* Opinion 11.2.1, "Professionalism in Health Care Systems," acknowledges that "[p]ayment models and financial incentives can create conflicts of interest among patients, health care organizations, and physicians" and offers recommendations for physicians within leadership positions regarding the ethical use of payment models that influence where and by whom care is delivered. Key elements include the need for transparency, fairness, a primary commitment to patient care, and avoiding overreliance on financial incentives that may undermine physician professionalism.

Opinion 11.2.2, "Conflicts of Interest in Patient Care," clearly states: "[t]he primary objective of the medical profession is to render service to humanity; reward or financial gain is a subordinate consideration. […] When the economic interests of the hospital, health care organization, or other entity are in conflict with patient welfare, patient welfare takes priority."

Opinion 11.2.3, "Contracts to Deliver Health Care Services," stipulates that physicians' fundamental ethical obligation to patient welfare requires physicians to carefully consider any contract to deliver health care services they may enter into to ensure they do not create untenable conflicts of interest. The opinion states that physicians should negotiate or remove "any terms that unduly compromise physicians' ability to uphold ethical standards." However, it should be acknowledged that physicians have little leverage in changing entire payment structures or reimbursement mechanisms when negotiating their contracts with hospitals. Similarly, physicians in private practice often feel that they have little leverage in negotiating the sale of their practice; they simply receive an offer and are told they can take it or leave it.

Opinion 11.2.3.1, "Restrictive Covenants," states: "[c]ovenants-not-to-compete restrict competition, can disrupt patient care, and may limit access to care" and that physicians should not enter into covenants that "[u]nreasonably restrict the right of a physician to practice medicine for a specified period of time or in a specified geographic area on termination of a contractual relationship". However, many hospitals and hospital systems today now routinely include noncompete clauses as part of their physician contracts. These clauses put physicians at risk of violation of professional obligations and their widespread use has the potential to undermine the integrity of the profession as a whole.

ETHICAL ANALYSIS

The ethical concerns raised by private equity investments in health care are not unique but instead represent ethical dilemmas that exist due to the very nature of treating health care as a commodity. While private equity firms may choose to pursue financial incentives that are counter to the physicians' ethical and professional responsibilities, private equity's investment in health care is not inherently unethical. However, caution is warranted so it is crucial that policy guidelines be developed to ensure that private equity-acquired hospitals, hospital systems, and physician practices continue to function in an ethical manner that prioritizes patients and patient care over profits. Policies that require greater transparency and disclosure of data on private equity ownership, greater state regulatory control over private equity acquisitions, closing payment and billing loopholes, rules requiring an independent clinical director on the Board of private equity firms engaged in health care, and means for physicians to help set goals and measure outcomes to ensure the alignment of corporate and clinical values should be considered [7].

Though the current literature is conflicting, there are valid concerns that private equity investment in health care might negatively impact patient outcomes. Since serious potential risks and conflicts of interest do exist, it is essential for physicians considering entering into partnership with private equity firms to evaluate their contracts and require that the agreements are consistent with the norms of medical ethics. Likewise, physicians considering entering into a contractual relation as an employee of a private equity-owned hospital should ensure that their

contract does not place them in an untenable conflict of interest or compromise their ability to fulfill their ethical and professional obligations to patients [8].

It is the conclusion of the Council on Ethical and Judicial Affairs (CEJA) that new ethics guidance specifically addressing private equity investment in health care is not needed. There already exists rich House policy and AMA published materials addressing private equity investments in health care. Furthermore, the ethical issues that private equity involvement raise are not limited to that specific sphere of health care investment. In light of the fact that private equity is not unique in the ethical concerns it raises, the Council finds that existing guidance in Opinion 11.2.2, "Conflicts of Interest in Patient Care," and Opinion 11.2.3, "Contracts to Deliver Health Care Services," are sufficient at the present time to address the concerns raised by the increasing investment by private equity in health care; however, it may be appropriate to amend current guidance to more clearly encompass partnerships with private equity firms and the ethical concerns that they raise for both physicians seeking capital to support their private practice as well as physicians entering into employment contracts with private equity-owned hospitals.

RECOMMENDATIONS

In view of these deliberations, the Council on Ethical and Judicial Affairs recommends that Opinion 11.2.3, "Contracts to Deliver Health Care Services," be amended by addition and deletion as follows and the remainder of this report be filed:

> Physicians have a fundamental ethical obligation to put the welfare of patients ahead of other considerations, including personal financial interests. This obligation requires ~~them to~~ that before entering into contracts to deliver health care services, physicians consider carefully the proposed contract to assure themselves that its terms and conditions ~~of contracts to deliver health care services before entering into such contracts to ensure that those contracts~~ do not create untenable conflicts of interest or compromise their ability to fulfill their ethical and professional obligations to patients.
>
> Ongoing evolution in the health care system continues to bring changes to medicine, including changes in reimbursement mechanisms, models for health care delivery, restrictions on referral and use of services, clinical practice guidelines, and limitations on benefits packages. While these changes are intended to enhance quality, efficiency, and safety in health care, they can also put at risk physicians' ability to uphold professional ethical standards ~~of informed consent and fidelity to patients~~ and can impede physicians' freedom to exercise independent professional judgment and tailor care to meet the needs of individual patients.
>
> As physicians seek capital to support their practices or enter into various differently structured contracts to deliver health care services—with group practices, hospitals, health plans, investment firms, or other entities—they should be mindful that while ~~many~~ some arrangements have the potential to promote desired improvements in care, ~~some~~ other arrangements ~~also~~ have the potential to ~~impede~~ put patients' interests at risk and to interfere with physician autonomy.
>
> When ~~contracting~~ partnering with entities, or having a representative do so on their behalf, to provide health care services, physicians should:
>
> (a) Carefully review the terms of proposed contracts, preferably with the advice of legal and ethics counsel, ~~or have a representative do so on their behalf~~ to assure themselves that the arrangement:
>
> (i) minimizes conflict of interest with respect to proposed reimbursement mechanisms, financial or performance incentives, restrictions on care, or other mechanisms intended to influence physicians' treatment recommendations or direct what care patients receive, in keeping with ethics guidance;
>
> (ii) does not compromise the physician's own financial well-being or ability to provide high-quality care through unrealistic expectations regarding utilization of services or terms that expose the physician to excessive financial risk;
>
> (iii) ~~allows~~ ensures the physician can ~~to~~ appropriately exercise professional judgment;
>
> (iv) includes a mechanism to address grievances and supports advocacy on behalf of individual patients;

(v) is transparent and permits disclosure to patients.

(vi) enables physicians to have significant influence on, or preferably outright control of, decisions that impact practice staffing.

(b) Negotiate modification or removal of any terms that unduly compromise physicians' ability to uphold ethical or professional standards.

When entering into contracts as employees, preferably with the advice of legal and ethics counsel, physicians must:

(c) Advocate for contract provisions to specifically address and uphold physician ethics and professionalism.

(d) Advocate that contract provisions affecting practice align with the professional and ethical obligations of physicians and negotiate to ensure that alignment.

(e) Advocate that contracts do not require the physician to practice beyond their professional capacity and provide contractual avenues for addressing concerns related to good practice, including burnout or related issues.

REFERENCES

1. Fuse Brown EC, Hall MA. Private Equity and the Corporatization of Health Care. Stanford Law Review 2024;76.
2. Crowley R, Atiq O, Hilden D, Health and Public Policy Committee of the American College of Physicians. Financial profit in medicine: A position paper from the American College of Physicians. Annals of Internal Medicine 2021;174(10):1447-9.
3. Moses MJ, Weiser LG, Bosco III JA. The corporate practice of medicine: Ethical implications of orthopaedic surgery practice ownership by non-physicians. JBJS 2020;102(11):e53.
4. AMA analysis shows most physicians work outside of private practice. In: American Medical Association. https://www.ama-assn.org/press-center/press-releases/ama-analysis-shows-most-physicians-work-outside-private-practice#:~:text=Employment%20status,2018%20and%2053.2%25%20in%202012.
5. Gondi S, Song Z. Potential implications of private equity investments in health care delivery. JAMA 2019;321(11):1047-8.
6. Zhu JM, Polsky D. Private equity and physician medical practices-navigating a changing ecosystem. NEJM 2021;384(11):981-3.
7. Ikram U, Aung KK, Song Z. Private equity and primary care: Lessons from the field. NEJM Catalyst Innovations in Care Delivery 2021;2(6).
8. DeCamp M, Snyder Sulmasy L, American College of Physicians Ethics, Professionalism and Human Rights Committee. Ethical and professionalism implications of physician employment and health care business practices: a policy paper from the American College of Physicians. Ann of Intern Med 2021;174(6):844-51.
9. Appelbaum E, Batt R. Private equity buyouts in healthcare: who wins, who loses? Institute for New Economic Thinking Working Paper Series 2020(118). doi.org/10.36687/inetwp118
10. Borsa A, Bejarano G, Ellen M, Bruch JD. Evaluating trends in private equity ownership and impacts on health outcomes, costs, and quality: systematic review. BMJ 2023;382.
11. PESP Private Equity Hospital tracker. In: Private Equity Stakeholder Project PESP. https://pestakeholder.org/private-equity-hospital-tracker/.
12. Dillon EC, Tai-Seale M, Meehan A, Martin V, Nordgren R, Lee T, Nauenberg T, Frosch DL. Frontline perspectives on physician burnout and strategies to improve well-being: interviews with physicians and health system leaders. Journal of General Internal Medicine 2020;35:261-7.
13. Kannan S, Bruch JD, Song Z. Changes in Hospital Adverse Events and Patient Outcomes Associated With Private Equity Acquisition. JAMA. 2023;330(24):2365–2375. doi:10.1001/jama.2023.23147
14. Singh Y, Song Z, Polsky D, Bruch JD, Zhu JM. Association of private equity acquisition of physician practices with changes in health care spending and utilization. JAMA Health Forum 2022;3(9):e222886-e222886.
15. Gao J, Sevilir M, Kim YS. Private equity in the hospital industry. European Corporate Governance Institute–Finance Working Paper 2021;787.

16. Veatch RM. Ethical dilemmas of for-profit enterprise in health care. In *The New Health Care for Profit: Doctors and Hospitals in a Competitive Environment.* Gray BH, ed. National Academy Press, Washington DC, 1983.
17. Pellegrino ED. The commodification of medical and health care: the moral consequences of a paradigm shift from a professional to a market ethic. J Med Philos 1999;24(3):243-266. doi:10.1076/jmep.24.3.243.2523
18. Powers BW, Shrank WH, Navathe AS. Private equity and health care delivery: value-based payment as a guardrail?. JAMA 2021;326(10):907-8.
19. Levinson Z, Hulver S, Neuman T. Hospital charity care: how it works and why it matters. KFF 2022 Nov 3. https://www.kff.org/health-costs/issue-brief/hospital-charity-care-how-it-works-and-why-it-matters/

4. PHYSICIANS' USE OF SOCIAL MEDIA FOR PRODUCT PROMOTION AND COMPENSATION

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

HOUSE ACTION: RECOMMENDATIONS ADOPTED
REMAINDER OF REPORT FILED
See CEJA Opinion 2.3.2

At the 2022 Annual Meeting, the House of Delegates referred Resolution 025-A-22 (Resolution 025), "Use of Social Media for Product Promotion and Compensation" which asked that the American Medical Association (AMA) "study the ethical issues of medical students, residents, fellows, and physicians endorsing non-health related products through social and mainstream media for personal or financial gain."

This report by the Council on Ethical and Judicial Affairs (CEJA) explores ethical issues posed by this use of social media and reviews existing guidance in the AMA *Code of Medical Ethics* (*Code*).

BACKGROUND

Resolution 025 details the recent phenomenon of physicians' involvement in promotions and endorsements on social media. While Resolution 025 is limited to the context of physicians promoting non-health related products through social media, this report encompasses the issue broadly in the contexts of promoting both non-health related and/or health related products. The concept of social media has changed dramatically in the last couple of decades and has altered how consumer goods and services are advertised, promoted, and sold. Social media now accounts for a broad range of communication—e.g., Tik Tok, Instagram, Facebook, X (formerly Twitter), YouTube—that can reach millions of people, and now often involves "influencing", where individuals promote or sell goods and services or promote themselves (e.g. their personality or lifestyle) as a financial venture.

ETHICAL CONCERNS

Physicians' and medical students' sale and promotion of products or services and use of social media raises several ethical concerns. (1) These practices may damage the patient-physician relationship. If patients feel pressured to purchase products or services, this may undermine the trust that grounds patient-physician relationships, since it raises questions about whether physicians are fulfilling their fiduciary duty to put patients' interests above their own financial interests. (2) If inappropriate pressure is applied, then selling and promotion of products may result in the exploitation of patient vulnerability. (3) If physicians lend their credibility as medical professionals to products or services that are not supported by peer-reviewed evidence or are of questionable value, then they may put patient well-being and the integrity of the profession in jeopardy in the interest of profit-making.

Welfare of the Patient and the Patient-Physician Relationship

The sale and promotion of goods and services by physicians has the potential to negatively affect the welfare of patients. If a physician puts their financial interests above the interests of the patients, then this undercuts the foundational ethical principle that physicians must regard their "responsibility to the patient as paramount. [Principle VIII]. In addition, since patients are "vulnerable and dependent on the doctor's expertise" and there is an "asymmetry of knowledge" between patients and physicians, there is a risk that patients may be exploited and this, in turn, can "undermine a patient's trust" [1]. Further, if patients find out about a physician's financial incentive to recommend certain products or services after the fact, they may feel that they have been purposefully deceived, and

so have reason to distrust both that individual physician and the profession as a whole. It is therefore imperative that physicians conscientiously distinguish when they are acting in their professional capacity by recommending products or services intended for patient benefit or public health, and when they are acting as commercial agents independent of their professional identity.

Integrity of the Profession

Physician sales and promotion of products and services may also damage the integrity of the profession. Physicians have an ethical duty to uphold professional standards in their role as physician in all areas of life. A key principle of professional integrity is that physicians should recognize that they carry the authority of their professional role with them into other social spheres. Physicians "engage in a number or roles" which include conveyors of information, advocates, experts, and commentators on medically related issues [2]. For many physicians, "navigating successfully among the potentially overlapping roles …poses challenges." [2] Physicians "carry with them heightened expectations as trusted…representatives of the medical profession." [2] Physicians should be aware that these expectations cannot be entirely separated from their personal identity either online or elsewhere and should take care to curate their social media presence accordingly.

PROFESSIONALISM IN THE USE OF SOCIAL MEDIA

The concept of social media has changed since the technology's first appearance and widespread adoption. Today, social media platforms are broadly internet-enabled technologies that enable individuals to have a presence online and ability to share opinions and self-generated media content to a wide audience.

Opinion 2.3.2 "Professionalism in Social Media" reflects an outdated understanding of the types and uses of social media, modeling its guidance on traditional sites such as Facebook, where the primary purposes are social networking among friends and colleagues, and perhaps also disseminating beneficial public health messages. While guidance that addresses these uses is still necessary (and so should be retained), modifications are required to reflect the fact that social media can now be used as a form of marketing intended to financially benefit individuals and corporations. The ethical concerns that arise in this context mirror those that arise in other situations where physicians are selling and promoting goods and services, that is, use of social media by medical professionals can undermine trust and damage the integrity of patient-physician relationships and the profession as a whole when physicians inappropriately use their social media presence to promote personal interests.

CONCLUSION

Updating 2.3.2 "Professionalism in the Use of Social Media" so that it includes guidance on using social media to sell and promote products makes it clear that the consolidated guidance clearly applies to the concerns raised in Resolution 025. Revising this also provides an opportunity to update language to reflect the current realities of technology and contemporary business practices.

RECOMMENDATION

In consideration of the foregoing, the Council on Ethical and Judicial Affairs recommends that: Opinion 2.3.2, "Professionalism in the Use of Social Media" be amended by substitution to read as follows and the remainder of this report be filed:

> Social media—internet-enabled communication platforms—enable individual medical students and physicians to have both a personal and a professional presence online. Social media can foster collegiality and camaraderie within the profession as well as provide opportunities to widely disseminate public health messages and other health communications. However, use of social media by medical professionals can also undermine trust and damage the integrity of patient-physician relationships and the profession as a whole, especially when medical students and physicians use their social media presence to promote personal interests.
>
> Physicians and medical students should be aware that they cannot realistically separate their personal and professional personas entirely online and should curate their social media presence accordingly. Physicians and medical students therefore should:

(a) When publishing any content, consider that even personal social media posts have the potential to damage their professional reputation or even impugn the integrity of the profession.

(b) Respect professional standards of patient privacy and confidentiality and refrain from publishing patient information online without appropriate consent.

(c) Maintain appropriate boundaries of the patient-physician relationship in accordance with ethics guidance if they interact with their patients through social media, just as they would in any other context.

(d) Use privacy settings to safeguard personal information and content, but be aware that once on the Internet, content is likely there permanently. They should routinely monitor their social media presence to ensure that their personal and professional information and content published about them by others is accurate and appropriate.

(e) Publicly disclose any financial interests related to their social media content, including, but not limited to, paid partnerships and corporate sponsorships.

(f) When using social media platforms to disseminate medical health care information, ensure that such information is useful and accurate based on professional medical judgment.

REFERENCES

1. Council on Ethical and Judicial Affairs, CEJA Report 5-I-97, "Sale of Non-Health Related Goods." https://code-medical-ethics.ama-assn.org/sites/default/files/2022-08/9.6.5%20Sale%20of%20non-health-related%20goods%20--%20background%20reports.pdf.
2. Council on Ethical and Judicial Affairs, CEJA Report 2-I-17, "Ethical Physician Conduct in the Media." https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/about-ama/councils/Council%20Reports/council-on-ethics-and-judicial-affairs/ceja-report-2-i17.pdf.

Council on Ethical and Judicial Affairs, CEJA Report 1-A-99, "Sale of Health-Related Products form Physician's Offices." https://code-medical-ethics.ama-assn.org/sites/default/files/2022-08/9.6.4%20Sale%20of%20health-related%20products%20--%20background%20reports.pdf

5. CEJA'S SUNSET REVIEW OF 2014 HOUSE POLICIES

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

HOUSE ACTION: RECOMMENDATIONS ADOPTED
REMAINDER OF REPORT FILED

Policy G-600.110, "Sunset Mechanism for AMA Policy," calls for the decennial review of American Medical Association (AMA) policies to ensure that our AMA's policy database is current, coherent, and relevant. This policy reads as follows, laying out the parameters for review and specifying the needed procedures:

1. As the House of Delegates adopts policies, a maximum ten-year time horizon shall exist. A policy will typically sunset after ten years unless action is taken by the House of Delegates to retain it. Any action of our AMA House that reaffirms or amends an existing policy position shall reset the sunset "clock," making the reaffirmed or amended policy viable for another 10 years.

2. In the implementation and ongoing operation of our AMA policy sunset mechanism, the following procedures shall be followed: (a) Each year, the Speakers shall provide a list of policies that are subject to review under the policy sunset mechanism; (b) Such policies shall be assigned to the appropriate AMA councils for review; (c) Each AMA council that has been asked to review policies shall develop and submit a report to the House of Delegates identifying policies that are scheduled to sunset; (d) For each policy under review, the reviewing council can recommend one of the following actions: (i) retain the policy; (ii) sunset the policy; (iii) retain part of the policy; or (iv) reconcile the policy with more recent and like policy; (e) For each recommendation that it makes to retain a policy in any fashion, the reviewing council shall

provide a succinct, but cogent justification (f) The Speakers shall determine the best way for the House of Delegates to handle the sunset reports.

3. Nothing in this policy shall prohibit a report to the HOD or resolution to sunset a policy earlier than its 10-year horizon if it is no longer relevant, has been superseded by a more current policy, or has been accomplished.

4. The AMA councils and the House of Delegates should conform to the following guidelines for sunset: (a) when a policy is no longer relevant or necessary; (b) when a policy or directive has been accomplished; or (c) when the policy or directive is part of an established AMA practice that is transparent to the House and codified elsewhere such as the AMA Bylaws or the AMA House of Delegates Reference Manual: Procedures, Policies and Practices.

5. The most recent policy shall be deemed to supersede contradictory past AMA policies.

6. Sunset policies will be retained in the AMA historical archives.

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. (Directive to Take Action)

APPENDIX – RECOMMENDED ACTIONS

Policy Number	**Title**	**Text**	**Recommendation**
H-140.898	Medical Profession Opposition to Physician Participation in Execution	Our AMA strongly reaffirms its opposition to physician participation in execution.	Retain; remains relevant.
H-140.950	Physician Participation in Capital Punishment	Evaluations of Prisoner Competence to be Executed; Treatment to Restore Competence to be Executed: Our AMA endorses the following: (1) Physician participation in evaluations of a prisoner's competence to be executed is ethical only when certain safeguards are in place. A physician can render a medical opinion regarding competency which should be merely one aspect of the information taken into account by the ultimate decision maker, a role that legally should be assumed by a judge or hearing officer. Prisoners' rights to due process at the competency hearings should be carefully observed. (2) When a condemned prisoner has been declared incompetent to be executed, physicians should not treat the prisoner to restore competence unless a commutation order is issued before treatment begins. (3) If the incompetent prisoner is undergoing extreme suffering as a result of psychosis or any other illness, medical intervention intended to mitigate the level of suffering is ethically permissible. It will not always be easy to	Retain; remains relevant.

		distinguish these situations from treatment for the purpose of restoring the prisoner's competence, and in particular, to determine when treatment initiated to reduce suffering should be stopped. However, there is no alternative at this time other than to rely upon the treating physician to exercise judgment in deciding when and to what extent treatment is necessary to reduce extreme suffering. The cumulative experience of physicians applying these principles over time may lead to future refinements. Treatment should be provided in a properly-secured, general medical or psychiatric facility, not in a cell block. The task of re-evaluating the prisoner's competence to be executed should be performed by an independent physician examiner. (4) Given the ethical conflicts involved, no physician, even if employed by the state, should be compelled to participate in the process of establishing a prisoner's competence to be executed if such activity is contrary to the physician's personal beliefs. Similarly, physicians who would prefer not to be involved with treatment of an incompetent, condemned prisoner should be excused or permitted to transfer care of the prisoner to another physician.	
H-140.963	Secrecy and Physician Participation in State Executions	The AMA opposes any and all attempts either in state laws or in rules and regulations that seek to enable or require physician participation in legal executions and/or which protect from disclosure the identity of physicians participating or performing direct or ancillary functions in an execution.	Retain; remains relevant.
H-140.999	Our AMA and Bioethics	Our AMA requests official representation on any federal advisory committee or commission dealing with ethical issues of interest to medicine.	Retain; remains relevant.
H-140.963	Secrecy and Physician Participation in State Executions	The AMA opposes any and all attempts either in state laws or in rules and regulations that seek to enable or require physician participation in legal executions and/or which protect from disclosure the identity of physicians participating or performing direct or ancillary functions in an execution.	Retain; remains relevant.
H-265.992	Expert Witness Testimony	Our AMA: (1) encourages each state medical society to work with its state licensing board toward the development of effective disciplinary measures for physicians who provide fraudulent testimony; (2) provides legal and advocacy support to those medical and specialty organizations who seek to devise programs designed to discipline physicians for unprofessional conduct relative to expert witness testimony; (3) continues to study and work with interested organizations to address the inherent difficulties	Retain; remains relevant.

		in conducting the peer review of physicians who provide expert witness testimony; (4) continues to educate physicians about ethical guidelines and professional responsibility regarding the provision of expert witness testimony; (5) encourages each state medical society to work with its state licensing board to grant any out-of-state expert witness physician a temporary license at a nominal fee or at no cost for the express purpose of expert testimony on a per case basis, such that the expert witness is subject to the peer review process. (6) encourages each state medical society to assist its state licensing board in the peer review process of expert witnesses by providing an expert witness committee program similar to the one in the state of Florida; (7) works with the Federation of State Medical Boards to address problems regarding out-of-state expert witnesses; and (8) acts as a clearinghouse for advice and support as the state medical associations develop their own expert witness committee programs.	
H-270.961	Medical Care Must Stay Confidential	Our AMA will strongly oppose any federal legislation requiring physicians to establish the immigration status of their patients.	Retain; remains relevant.
H-405.958	Physician Right to Conscience	Our AMA supports high standards of civility and respect among physicians amidst differing political beliefs, aspects of conscience and ethical views because debate and expression of disagreement is healthy and essential to the improvement of medicine, and physicians should communicate any differences in a civil and professional manner.	Retain; remains relevant.
H-65.997	Human Rights	Our AMA endorses the World Medical Association's Declaration of Tokyo which are guidelines for medical doctors concerning torture and other cruel, inhuman or degrading treatment or punishment in relation to detention and imprisonment.	Retain; remains relevant.

6. 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 https://www.ama-assn.org/governing-rules.

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.

APPENDIX – CEJA *Judicial Function Statistics* - APRIL 1, 2023 – MARCH 31, 2024

Physicians Reviewed	SUMMARY OF CEJA ACTIVITIES
14	Determinations of no probable cause
22	Determinations following a plenary hearing
18	Determinations after a finding of probable cause, based only on the written record, after the physician waived the plenary hearing

Physicians Reviewed	*FINAL DETERMINATIONS FOLLOWING INITIAL REVIEWS*
14	No sanction or other type of action
3	Monitoring
17	Probation
4	Revocation
5	Suspension
1	Denied
1	Suspension lifted
0	Censure

7	Reprimand
3	Admonish

Physicians Reviewed	PROBATION/MONITORING STATUS
20	Members placed on Probation/Monitoring during reporting interval
15	Members placed on Probation without reporting to Data Bank
10	Probation/Monitoring concluded satisfactorily during reporting interval
0	Memberships suspended due to non-compliance with the terms of probation
10	Physicians on Probation/Monitoring at any time during reporting interval who paid their AMA membership dues
7	Physicians on Probation/Monitoring at any time during reporting interval who did not pay their AMA membership dues