OPINIONS OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

The following opinions were presented by Jeremy A. Lazarus, MD, Chair:

1. RESEARCH HANDLING OF DE-IDENTIFIED PATIENT DATA

CEJA Opinion; no reference committee hearing.

HOUSE ACTION: FILED

INTRODUCTION

At the 2024 Annual Meeting, the American Medical Association House of Delegates adopted the recommendations of Council on Ethical and Judicial Affairs Report 2-A-24, "Research Handling of De-Identified Patient Data." The Council issues this Opinion, which will appear in the next version of AMA PolicyFinder and the online edition of the *Code of Medical Ethics*.

E-3.3.4 Research Handling of De-Identified Patient Data

> 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.
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> 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.
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> 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.
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> Health care entities, in interacting with patients, should adopt policies and practices that provide patients with transparent information regarding:
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> (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. (IV)

2. AMENDMENT TO E-2.1.1, "INFORMED CONSENT"

CEJA Opinion; no reference committee hearing.

HOUSE ACTION: FILED

INTRODUCTION

At the 2024 Annual Meeting, the American Medical Association House of Delegates adopted the recommendations of Council on Ethical and Judicial Affairs Report 2-A-24, "Research Handling of De-Identified Patient Data." The Council issues this Opinion, which will appear in the next version of AMA PolicyFinder and the online edition of the *Code of Medical Ethics*.

E-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. 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.
>
> 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. (I, II, V, VIII)

3. AMENDMENT TO E-3.1.1, "PRIVACY IN HEALTH CARE"

CEJA Opinion; no reference committee hearing.

HOUSE ACTION: FILED

INTRODUCTION

At the 2024 Annual Meeting, the American Medical Association House of Delegates adopted the recommendations of Council on Ethical and Judicial Affairs Report 2-A-24, "Research Handling of De-Identified Patient Data." The Council issues this Opinion, which will appear in the next version of AMA PolicyFinder and the online edition of the *Code of Medical Ethics*.

E-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:
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> (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. (I, IV)

4. AMENDMENT TO E-3.2.4 "ACCESS TO MEDICAL RECORDS BY DATA COLLECTION COMPANIES"

CEJA Opinion; no reference committee hearing.

HOUSE ACTION: FILED

INTRODUCTION

At the 2024 Annual Meeting, the American Medical Association House of Delegates adopted the recommendations of Council on Ethical and Judicial Affairs Report 2-A-24, "Research Handling of De-Identified Patient Data." The Council issues this Opinion, which will appear in the next version of AMA PolicyFinder and the online edition of the *Code of Medical Ethics*.

E-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. (I, II, IV)

5. AMENDMENT TO E-3.3.2, "CONFIDENTIALITY AND ELECTRONIC MEDICAL RECORDS"

CEJA Opinion; no reference committee hearing.

HOUSE ACTION: FILED

INTRODUCTION

At the 2024 Annual Meeting, the American Medical Association House of Delegates adopted the recommendations of Council on Ethical and Judicial Affairs Report 2-A-24, "Research Handling of De-Identified Patient Data." The Council issues this Opinion, which will appear in the next version of AMA PolicyFinder and the online edition of the *Code of Medical Ethics*.

E-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;
  (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. (V)

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

CEJA Opinion; no reference committee hearing.

HOUSE ACTION: FILED

INTRODUCTION

At the 2024 Annual Meeting, the American Medical Association House of Delegates adopted the recommendations of Council on Ethical and Judicial Affairs Report 4-A-24, "A Physicians' Use of Social Media for Product Promotion and Compensation." The Council issues this Opinion, which will appear in the next version of AMA PolicyFinder and the online edition of the *Code of Medical Ethics*.

E-2.3.2– Physicians' Use of Social Media for Product Promotion and Compensation

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. (I, II, IV)

7. SHORT-TERM GLOBAL HEALTH CLINICAL ENCOUNTERS

CEJA Opinion; no reference committee hearing.

HOUSE ACTION: FILED

INTRODUCTION

At the 2024 Annual Meeting, the American Medical Association House of Delegates adopted the recommendations of Council on Ethical and Judicial Affairs Report 1-A- 24, "Short-Term Global Health Clinical Encounters." The Council issues this Opinion, which will appear in the next version of AMA PolicyFinder and the online edition of the *Code of Medical Ethics*.

E-8.1.4 Short-Term Global Health Clinical Encounters

> 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. (I, V, VII, IX)

REPORTS OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

The following reports were presented by Jeremy A. Lazarus, MD, Chair:

1. EXPANDING ACCESS TO PALLIATIVE CARE

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

HOUSE ACTION: RECOMMENDATION ADOPTED
REMAINDER OF REPORT FILED

BACKGROUND

The majority of deaths in the United States result after months to years of treating complications of underlying chronic illness and comorbidities, including cancer, heart disease, and stroke [1]. Although many deaths in America are anticipated, patient preferences, values, and goals for medical treatment during serious and critical illness are not often elicited prior to the initiation of life sustaining interventions including mechanical ventilation, artificial nutrition and hydration, and cardiopulmonary resuscitation [2]. The stress and uncertainty surrounding medical decisions during serious illness often results in patients and their families experiencing needless physical and emotional suffering such as anxiety, depression, and the prolonged use of unwanted or likely to be ineffective mechanical and pharmacological life sustaining interventions that cannot restore the patient to an acceptable level of health and function [3]. The patient and their family's experience of suffering during their serious illness is often avoidable or mitigatable by physicians through palliative care [3].

Palliative care focuses on improving quality of life by providing physical and emotional support to the patient and their family during serious and critical illness [4]. Palliative care can be provided at any point in the illness trajectory by any physician, in any specialty (a.k.a. primary palliative care) [5]. When the patient's and/or their family's needs are more complex, specialty palliative care can be consulted [5]. Opinion 5.3 of the *Code of Medical Ethics* (*Code*) calls for the provision of palliative care, which is appropriate when patient or family distress, physical and psychological symptom burden, uncertainty about what to expect in the future, or spiritual/existential distress is identified. Failure to provide palliative care is in direct conflict with the well-established ethical duty for physicians to address the pain and suffering of their patients [6]. Furthermore, American Medical Association (AMA) policy H-70.915 encourages the provision of "good palliative care" and "encourages all physicians to become skilled in palliative medicine." Opinion 5.3, "Withholding and Withdrawing Life-Sustaining Treatment," calls for the provision of palliative care when such transitions in care are considered. Additionally, a 1991 Council on Ethical and Judicial Affairs (CEJA) Report was adopted entitled "Decisions Near End of Life" which advocated for the use of palliative care [7].

Although there is a strong basis supporting the provision of palliative care for patients facing serious illness, the *Code* does not address the ethical provision of palliative care for serious or critical illness. This gap should be filled by the creation of a new opinion which describes the ethical provision of "good palliative care" and provides ethical guidelines for implementing palliative care during clinical practice.

RELEVANT LAW(S)

There are several definitions of palliative care from the Centers for Medicare and Medicaid Services (CMS), the World Health Organization, the World Medical Association, and the Center to Advance Palliative Care. Common elements include physical and psychological symptom management, focusing on the patient and caregivers as the unit of care, provision throughout the course of the illness, and continuity of care across settings and over time. Reimbursement for palliative care is funded through the CMS as well as other insurers [8]. Also, the Palliative Care and Hospice Education Training Act (PCHETA) is under consideration in the Senate and has been introduced with bipartisan support and the official support of over 90 national and state organizations [9]. PCHETA would create and promote education programs, research programs, and public education programs to support and expand the palliative care workforce, delivery of palliative care, and public awareness about palliative care. In support of furthering the evidence base for palliative medicine, the National Institutes of Health recently established a Consortium for Palliative Care Research Across the Lifespan, a cross-institute funding initiative with an annual commitment of approximately $12 million [10].

RELEVANT POLICY PROVISION(S)

Numerous AMA policies support the provision of palliative care for patients and the education of palliative care for physicians. AMA policy H-140.966 states that "physicians have an obligation to relieve pain and suffering and to promote the dignity and autonomy of patients in their care. Furthermore, policy encourages the provision of "good palliative care" and "encourages all physicians to become skilled in palliative medicine." H-295.875 encourages "the inclusion of palliative medicine in the core curriculum of undergraduate and graduate medical education" and the "use of palliative care techniques and interdisciplinary team care." D-295.969 "encourages palliative training for physicians caring for elderly and terminally ill patients in long-term care facilities." H-85.949 supports "increased access to comprehensive interdisciplinary palliative care services by Medicare patients." H-55.999 "supports palliative care procedures for cancer patients."

RELEVANT *CODE* PROVISION(S)

The *Code* references and supports the provision of palliative care numerous times. For example, Opinions 5.3 and 6.1.2 both require physicians to "ensure that relevant standards for good clinical practice and palliative care are followed when implementing any decision to withdraw a life-sustaining intervention" and Opinion 5.6 requires physicians to consult "an expert in the field of palliative care, to ensure that symptom-specific treatments have been sufficiently employed" prior to engaging in palliative sedation to unconsciousness. Additionally, Opinions 2.2.5 and 5.2 mention palliative interventions; however, the *Code* does not directly address what qualifies as palliative care, nor does it provide ethical guidance on the delivery of palliative care.

ETHICAL ISSUES

Delivering palliative care during clinical practice is inextricably linked with navigating ethical dilemmas. For example, physicians must balance the often-competing values, preferences, and goals of the patient, the health care entity, the clinical care team, the payer, and their surrogate or support persons while making complex medical decisions such as when to withhold or withdraw life sustaining interventions or when to counsel cessation of 'curative' treatments that become ineffective or harmful [3,11]. These competing values, preferences, and goals arise from many sources including the profession itself, society, community, family, religious beliefs, and personal desires and experience. While navigating various perspectives and competing values during palliative care delivery, physicians must also balance complex ethical questions such as when it is ethically appropriate to withhold or withdrawal life sustaining interventions or provide sedation or analgesia to relieve symptom distress when the unintended potential effect is hastened death. The concept of double effect permits, under appropriate conditions medical treatments or interventions that could have the effect of hastening death so long as the primary intention of providing the medical treatment or intervention is not to hasten death but is for some other clinically and ethically appropriate reason such as pain and symptom management.

Many of the ethical complexities of palliative care are discussed in detail within the 1991 CEJA report entitled "Decisions Near End of Life"; however, guidance regarding ethical palliative care is absent within the *Code* [7]. This is problematic for several reasons. Importantly, palliative care as a discipline has substantially evolved since 1991 when it was first recognized as a medical specialty. Despite the rapid evolution of palliative care as a medical specialty, the ethical issues highlighted in the 1991 report remain; however, the understanding of palliative care and the role palliative care plays in resolving ethical dilemmas has evolved. Additionally, palliative care is often misunderstood as being limited to comfort care for patients imminently facing end of life. This misunderstanding often results in palliative care being initiated late in the disease course and typically only after the decision to discontinue curative or life prolonging interventions [12]. Additionally, this misunderstanding often results in palliative care not being offered concurrently with curative treatments, even for patients with substantial distress during a serious or complex critical illness. Furthermore, due to the underutilization of palliative care throughout the full course of the patient's illness trajectory, patients are too often referred for palliative care consultation prior to imminent death, and thus, often receive high burden life sustaining interventions where burden outweighs benefit [13,8]. This is problematic because delaying the provision of palliative care results in patients and their families facing unnecessary suffering which is in direct conflict with a physician's ethical duty to relieve pain and suffering. Providing ethical guidance in the *Code* will help alleviate misnomers and barriers to implementing and practicing ethical palliative care during clinical practice.

RELEVANT PRACTICAL MATTERS FOR CLINICAL PRACTICE

Amending the *Code* to include ethical guidance on providing palliative care for patients facing serious, chronic, complex, or critical illness will positively affect clinical practice. First, the benefits of palliative care have been well studied and include improved quality of life, decreased symptom burden, increased goal-concordant care, increased caregiver support, reduced anxiety, decreased hospital mortality, and reductions in unnecessary medical costs [14]. In some cases, it may even result in longer survival than those treated with chemotherapy [15]. Second, palliative care improves the quality of care the patient (and their care partners) receives, while providing support for the physician and their team and has been associated with both improved physician satisfaction and patient satisfaction. Third, serious and critical illness care is often a source of stress for physicians and has been associated with physician burn out [13]. Palliative care provides support to physicians in four important ways through the provision of: 1) dedicated time for intensive family meetings and goals of care conversations; 2) skilled communication over time to help patients and their families determine the medical treatment options that match their preferences, values, and goals as illness evolves; 3) expert pain and symptom management of both physical, emotional, social, and spiritual distress; and 4) comprehensive coordination of communication among all providers involved in the patients care [5,14,11].

REVIEW OF RELEVANT LITERATURE

Most people will experience death in a hospital or health care facility after suffering from a chronic serious illness, and one-in-three of the deaths that occur in the hospital will result from a decision to withdraw life-sustaining interventions [12,16-19]. Although it is common for Americans to die in a hospital or health care facility and receive life prolonging interventions at the end of life, this is not how most healthy Americans report that they want their lives to end. This is likely related to multiple factors: the aim of preserving life; the rational assumption that patients and families hold that doctors would not recommend treatments they did not believe to be helpful to the patient so they accede to the doctor's recommendations; and the fact that when death is imminent, patient (and caregiver) desire to hold on often strengthens (this is evident in the observation that despite presence of advance directives specifying comfort measures when recovery is not possible, they are seldom honored) [20]. Evidence is clear that regardless of prognosis and treatments, patients and caregivers living with serious, chronic, complex, and critical illness experience anxiety, depression, and physical and spiritual/existential suffering [11]. One way to remediate this experience is through the provision of palliative care, which is associated with improved quality of life, reduced suffering, and reduced hospital mortality [5,14].

Palliative care is the comprehensive management and coordination of care for pain and other distressing symptoms including physical, psychological, intellectual, social, psychosocial, spiritual, and existential consequences of a serious illness that improves the quality of life of patients and their families/caregivers [5]. The evaluation and treatment are patient-centered, with a focus on the central role of the family unit in decision-making according to the needs, values, beliefs, and culture of the patient and his or her family [14]. Palliative care can be offered in all care settings, by any physician, and at any stage in a serious illness. The provision of palliative care by physicians without subspecialty training in palliative medicine is known as primary palliative care [5]. When a patient and/or their family's needs become complex, specialty palliative care can be delivered through a collaborative team approach involving all disciplines optimally including physicians, nurses, social workers, spiritual care providers, therapists, and pharmacists. Specialist level palliative care teams work alongside the primary treating team as an added layer of support for all- patient, caregivers, and clinicians.

Hospice is a mode of palliative care for patients in their homes or long-term care facilities provided in the U.S. with a specific Medicare payment model. Eligible U.S. patients must have an expected prognostic life-expectancy of six months or less and agree to give up regular Medicare insurance coverage. Most private insurers in the U.S. follow the Medicare model for patients not on Medicare. Hospice care is predominantly provided at home or in nursing homes. In contrast, palliative care has no prognosis or treatment restrictions (delivered at any age, any stage, any setting and whether the illness is curable chronic or progressive) and is provided (depending on local capacity) in any setting- hospital, office, cancer center, dialysis unit, home, or long-term care facility [8]. While patients usually receive palliative care concurrently with traditional medical treatments, hospice care focuses on comfort measures for the patient and their family near the end of life. Comfort measures focus on relieving the stress, anxiety, and physical pain which often occurs during the dying process.

The use of complex disease-specific interventions at the end of life is associated with stress and uncertainty and often results in patients and their families experiencing physical and existential suffering such as intractable pain, anxiety, and depression [13]. The patients and their families' experience of suffering is often avoidable or mitigatable through palliative care [5,14,13]. Although the provision of palliative care is associated with improved quality of life, more days at home, and reduced suffering, palliative care is too often initiated as a last resort, after disease-specific interventions have become ineffective (i.e. futile or unable to result in a beneficial outcome), and the decision to withdraw life sustaining interventions either needs to be made or has already been made [13]. Due to the underutilization of palliative care throughout the full course of the patient's illness trajectory, patients are too often referred for palliative care consultation prior to imminent death, and thus, often receive high burden life sustaining interventions where burden outweighs benefit [13,8].

ETHICAL ANALYSIS

Palliative Care is the Evidence Based Standard of Care for Patients with Serious and Critical Illness

The need to address palliative care in the *Code* is not a novel concept. At the 1991 Annual Meeting of the House of Delegates (HOD), CEJA Report was adopted entitled "Decisions Near End of Life" which addressed palliative care as an ethical medical intervention [7]. Since the adoption of the CEJA report "Decisions Near End of Life", the HOD passed policy H-70.915 entitled "Good Palliative Care" in 2014. This policy "encourages all physicians to become skilled in palliative medicine" and "encourages education programs . . . in care of the dying patient." Additionally, this policy advocates for reimbursement of palliative care services and research to improve the field of palliative medicine. This policy has been reaffirmed three times since it was originally passed showing the continued interest and support of palliative care in the AMA HOD. In addition to the HOD policy on Good Palliative Care, the HOD has passed eight other policies which have affirmatively advocated for providing palliative care.

The AMA HOD is not alone in its support of palliative care. The World Health Assembly (WHA) declared that providing palliative care should be considered an ethical duty for health organizations. Additionally, the World Health Organization declared that palliative care is an ethical duty of health professionals and, in 2012, the United Nations Office of the High Commissioner for Human Rights recognized that the failure to provide palliative care and end of life care to older persons is a human rights violation. Furthermore, in 2011, the World Medical Association (WMA) adopted the Declaration on End-of-Life Medical Care which declared that "The objective of palliative care is to achieve the best possible quality of life through appropriate palliation of pain and other distressing physical symptoms, and attention to the social, psychological and spiritual needs of the patient and is part of good medical care" [10]. Three years later, the WMA further expanded their support of palliative care with the adoption of a resolution which called for the integration of palliative care in global disease control and health system plans. Additionally, major world religions also endorse palliative care [21].

Despite the continued support for palliative care within the AMA HOD and from medical organizations across the globe, the *Code* remains silent on what constitutes the ethical provision of palliative care. Providing guidance on the ethical practice of palliative care in the *Code* is important because there is not one standard definition of palliative care and what it entails. Additionally, palliative care is often misattributed as being connected to physician assisted suicide or euthanasia. Misattribution and confusion about the scope of palliative care may be contributing to the underutilization of this high quality, evidence based, medical intervention. As there is an established ethical duty within the *Code* to provide palliative care and HOD policies which encourage the provision of palliative care, it is imperative to offer clinicians guidance on what the ethical delivery of high-quality palliative care entails. Additionally, it is imperative to distinguish palliative care, which is an ethical duty, from other practices which either straddle the line of ethical acceptability or are considered by the *Code* as unethical in the practice of medicine (e.g., knowingly and intentionally hastening death, physician assisted suicide, and euthanasia). Lastly, given the rapid and vast evolution of palliative care as a medical discipline, it is important to update the 1991 CEJA report's understanding of the scope and way in which palliative care is ethically implemented during clinical practice.

The Aim of Palliative Care is Not Hastening Death

Providing palliative care is ethically distinguishable from physician assisted suicide and euthanasia, both of which are intended to cause death. It is important, however, to recognize that treatments for the relief of intractable pain/agitation/dyspnea may theoretically (and very rarely if the clinician is well trained in symptom management) result in the unintended consequence of hastening death. To the contrary, uncontrolled symptom distress, including moderate to severe pain, agitation, depression, and dyspnea, are all associated with a higher risk of death [21-25]. The ethical concept of "double effect" hinges on the intention of the medical intervention. It stipulates that an intervention is ethically permissible if it is provided with the intention of relieving pain or treating symptoms, even if the intervention has the foreseen but unintended side effect of hastening death, provided that the benefits outweigh the burdens and the relief of symptoms or suffering is not achieved by means of causing death [26]. Conversely, this same intervention would be deemed unethical if the primary intention was to hasten death. Patients and/or their surrogate medical decision makers should be provided informed consent which allows them to determine if the risk of intentionally hastening death is worth the relief of pain and/or suffering.

Palliative Care is Offered Concurrently with Curative Treatments

The *Code* contains many ethical opinions permitting the withholding or withdrawing of medical interventions for life-prolonging purposes. For example, patients with decision making capacity have the ethical right to decline or stop any medical intervention, even if this decision will result in their death (Opinion 5.3). Additionally, patients have the ethical right to refuse cardiopulmonary resuscitation attempts through the execution of a Do Not Resuscitate Order (Opinion 5.4). In addition to patients having the ethical right to determine if they want to start or continue an offered medical treatment, physicians also have an ethical duty to not provide interventions that, "in their best medical judgement, cannot reasonably be expected to yield the intended clinical benefit or achieve agreed-on goals for care" (Opinion 5.5).

Although there is a well-established ethical basis for medical interventions to be withheld or withdrawn from both the patient and physicians' perspective, there is also a well-established ethical "duty to relieve pain and suffering" that is "central to the physician's role as healer and is an obligation physicians have to their patients" (Opinion 5.6). Further, as noted above, symptom distress is consistently associated with a higher risk of death, adding to the professional obligation to ameliorate it. Additionally, physicians have an ethical duty to "respond to the needs of patients at the end of life", and they "should not abandon a patient once it is determined that a cure is impossible" (Opinion 5.8).

The provision of palliative care bridges these ethical obligations by providing physical and emotional support to patients and their family/ care partners during the entire illness trajectory. Palliative care is offered to patients concurrently with disease-directed treatments and interventions and, therefore, it is not necessary to decide between continued treatment and palliative care intervention because they are provided simultaneously. As the illness progresses and the patient's medical goals transition from cure or prolonging life towards making the life that remains as peaceful and functional as possible, hospice should be offered to the patient and their family. Although life prolonging interventions (for the terminal condition) are not offered as a Medicare Condition of Participation in hospice during the provision of comfort care, the patient and their family are provided physical, emotional, spiritual, and practical support during the dying process.

CONCLUSION

Although our AMA adopted a CEJA report in 1991 which recommend "providing effective palliative treatment . . ." a *Code* opinion speaking to what it means to practice ethical and effective palliative care has never been adopted [7]. This is problematic because palliative care is an essential part of a patient's serious illness experience and provides beneficial outcomes in terms of symptom distress, patient and family understanding of what to expect and how to prepare for it, and reduction in use of Emergency Department and hospital admission for symptom crises. This is further problematic because the term "palliative treatment" is referred to in both the *Code* and numerous HOD policies; however, the ethical provision of this medical practice is neither discussed nor defined in house policies or in the *Code*.

RECOMMENDATION

Given both the AMA Policy and CEJA's historical support of addressing the palliative needs of patients and the duty of clinicians to provide optimal palliative care to patients, it is recommended that the *Code of Medical Ethics* be amended to include a new opinion on Palliative Care.

Physicians have clinical ethical responsibilities to address the pain and suffering occasioned by illness and injury and to respect their patients as whole persons. These duties require physicians to assure the provision of effective palliative care whenever a patient is experiencing serious, chronic, complex, or critical illness, regardless of prognosis. Palliative care is sound medical treatment that includes the comprehensive management and coordination of care for pain and other distressing symptoms including physical, psychological, intellectual, social, spiritual, and existential distress from serious illness. Evaluation and treatment are patient-centered but with an additional focus on the needs, values, beliefs, and culture of patients and those who love and care for them in decision-making accordingly.

Palliative care is widely acknowledged to be appropriate for patients who are close to death, but persons who have chronic, progressive, and/or eventually fatal illnesses often have symptoms and experience suffering early in the disease course. The clinical ethical responsibilities to address symptoms and suffering may therefore sometimes entail a need for palliative care before the terminal phase of disease. Moreover, the duty to respect patients as whole persons should lead physicians to encourage patients with chronic, progressive, and/or eventually fatal conditions to identify surrogate medical decision makers, given the likelihood of a loss of decisional capacity during medical treatment.

When caring for patients' physicians should:

(a) Integrate palliative care into treatment.
(b) Seek and/or provide palliative care, as necessary, for the management of symptoms and suffering occasioned by any serious illness or condition, at any stage, and at any age throughout the course of illness.
(c) Offer palliative care simultaneously with disease modifying interventions, including attempts for cure or remission.
(d) Be aware of, and where needed, engage palliative care expertise in care.

Physician as a profession should:

(e) Advocate that palliative care be accessible for all patients, as necessary, for the management of symptoms and suffering occasioned by any serious illness or condition, at any stage, and at any age throughout the course of illness.

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2. PROTECTING PHYSICIANS WHO ENGAGE IN CONTRACTS TO DELIVER HEALTH CARE SERVICES

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

HOUSE ACTION: REFERRED

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", the Council on Ethical and Judicial Affairs (CEJA) presented Report 02-A-23, and later a revised Report 03-A-24, which offered recommendations on amending Opinion 11.2.3, "Contracts to Deliver Health Care Services." The 2024 report was referred back to CEJA, with testimony expressing a desire that a stronger stance be taken against private equity's involvement in health care.

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 in private practice [3,4]. Our AMA reports that this trend is continuing: "[e]mployed physicians were 50.2 percent of all patient care physicians in 2020, up from 47.4 percent in 2018 and 41.8 percent in 2012. In contrast, self-employed physicians were 44 percent of all patient care physicians in 2020, down from 45.9 percent in 2018 and 53.2 percent 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 percent, with health care deals compromising 18 percent 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 percent [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]. More research is needed on the effects of private equity investment in the health care sector, as little empirical evidence exists on how private equity impacts utilization, spending, or patient outcomes. Of the empirical research that has been done, evidence on the effects of private equity acquisition of health care entities on patient outcomes has been mixed [10,13-15].

Regardless, there is widespread concern among physicians that private equity-controlled practices result in worse patient outcomes. This is particularly worrisome as private equity firms are emerging to be major employers of physicians. Currently, it is estimated that eight percent of all private hospitals in the U.S. and 22 percent of all proprietary for-profit hospitals are owned by private equity firms [11].

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 Surprises 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 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 percent of community hospitals, provide some level of charity care as a condition for their tax-exempt status, which the Internal Revenue Service 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” [16].

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 AMA *Code Provisions*

Opinion 10.1.1, “Ethical Obligations of Medical Directors,” states that physicians in administrative positions must uphold their core professional obligations to patients. The opinion mandates that physicians in their role as medical directors should help develop guidelines and policies that are fair and equitable, and that they should always “[p]ut patient interests over personal interests (financial or other) created by the nonclinical role.”

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. While the FTC issued a rule in April 2024 banning most noncompete agreements, a Texas District Judge issued a preliminary injunction on July 3, 2024, halting the enforcement of the ban, with a final order on the merits due by August 30, 2024.

ETHICAL ANALYSIS

The increasing corporatization and financialization of health care have generated legitimate concerns over ethical dilemmas they raise regarding a focus on profits at the expense of patient care. Because it is unethical to place profit motives above commitments to patient care and well-being, private equity firms’ commitment to ensuring short-term, high returns on their investments creates a potential ethical dilemma when investing in health care. This report examines whether private equity investments in health care may be ethical, as well as how physicians may ethically navigate private equity buyouts and employment in today’s rapidly evolving financial health care landscape.

A major concern of physicians regarding private equity investments in health care is the potential loss of autonomy, which physicians worry could translate into practice 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]. 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 health care entities are different in their ownership structure and oversight compared to other traditional health care investors, private equity-acquired health care entities may not be substantively different from other for profit and non-profit health care entities 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 comes with ethical and professional risks that are perhaps best exemplified by private equity but are not unique to private equity alone. One only needs to turn to the systemic failure of nonprofit hospitals to provide adequate charity care or how for-profit hospitals often reduce access to care (particularly for

Medicaid recipients) to see examples of how the corporatization and financialization of medicine has increasingly come to treat health care as a mere commodity [17,18]. This is despite the fact that health care is inherently different from normal market goods because the demand for health care is substantially inelastic and nonfungible, and medical knowledge is a social good collectively produced by the work of generations of physicians, researchers, and patients. The real problem with private equity's involvement in health care is that it blatantly reveals that as a society, we have increasingly moved towards treating health care as a commodity when as a profession, we know this should not be the case.

While business ethics and medical ethics are not inherently antithetical, differences do clearly exist [19]. Many physicians are thus justly concerned about 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 profession 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 [19].

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 [20]. 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" [20].

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" [20]. 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 [20].

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 [1,21]. 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 [21].

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 [21].

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]. Any financing model of health care that ignores patient care or puts profits over patient care should be considered unethical by physicians and the public.

Concerns over private equity's incursion into health care are clearly warranted. However, the financial and investment landscape of health care continues to evolve, and while private equity may be the latest trend it will not be the last version that emerges within the health care marketplace. Health care spending in the US continues to rise each year, with health spending increasing by 4.1percent in 2022 for a total of $4.5 trillion and accounting for roughly 17 percent of total gross domestic product [22]. With so much money involved in health care, it is bound to draw in investors; the involvement of investors from outside of health care, who may treat it as merely a market commodity and do not share physicians' overriding commitment to patient care and well-being, should be concerning. Such involvement by outside investors is likely to further transform health care, driving consolidation, commercialization, and de-professionalization.

In a practical approach to the current financial health care landscape, Ikrum et al offer some realistic 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].

While private equity's overriding profit motive may be unethical in many instances, the reality is that private equity is already a large player in health care and physicians urgently need guidance on how to interact with private equity firms and private equity-owned health care entities. Keeping within its purview, the *Code* should offer guidance to physicians and to the practice of medicine on how to best interact with private equity and other outside forces that increasingly impact health care today. To support physicians as private equity continues to increase its market share of health care entities, practical guidance is needed related to both the sale of physician-owned practices to private equity as well as to those seeking employment by private equity-owned health care entities to help physicians navigate today's evolving financial health care landscape.

CONCLUSION

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. Any decision to pursue financial incentives over and above patient care is unethical, and physicians' concerns regarding private equity's focus on short-term profits at the expense of patients' and their own well-being are justly warranted. Due to such concerns, physicians should strongly consider whether they can sell their practice to private equity investors while also upholding their ethical and professional obligations to patients and to the profession as a whole.

It is therefore crucial that policy guidelines be developed to ensure that private equity-acquired hospitals, hospital systems, and physician practices 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]. The growth of private equity investment within the health care marketplace is clearly concerning and is an urgent issue that needs greater regulatory oversight. Beyond established ethical and professional norms, new regulations must be developed to prevent private equity from negatively impacting patient care and the medical profession [6].

Though the current literature is conflicting, there are valid concerns that private equity investment in health care might negatively impact patient outcomes. Significantly, since serious potential risks and conflicts of interest do exist, it is essential for physicians considering entering into partnership with private equity firms to first reflect on their ethical and professional obligations. If they do decide to proceed, however, physicians have a duty 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—whether with a private equity-owned hospital or otherwise—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]. While we must acknowledge that physicians often have little power in contract negotiations, their ethical obligation remains nonetheless to try to negotiate when contractual agreements are likely to lead to ethical dilemmas.

The Preamble to the *Code* stipulates that "[o]pinions of the AMA Council on Ethical and Judicial Affairs lay out the ethical responsibilities of physicians as members of the profession of medicine." Although some areas of concern therefore extend beyond what the *Code* may speak to, CEJA is currently studying the ethical obligations of health care entities that interact with physicians and is considering entering a report in the near future regarding the potential need for a new opinion to address additional stakeholders involved in our evolving health care landscape.

It is the conclusion of the Council on Ethical and Judicial Affairs that increasing investment by private equity firms in health care raises ethical concerns regarding dual loyalties of physicians and competing interests between profits and patients. To respond to these issues, CEJA recommends amending Opinion 11.2.3, "Contracts to Deliver Health Care Services," to more clearly address concerns raised by entering into partnerships with private equity firms and the ethical risks that may arise for both physicians seeking capital to support their private practice as well as physicians entering into employment contracts with private equity-owned health care entities.

RECOMMENDATION

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:

> While profitmaking is not inherently unethical, no part of the health care system that supports or delivers patient care should place profits over such care. 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 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 should:

(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.

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