OPINIONS OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

The following opinions, 1–5, were presented by John W. McMahon, Sr., MD, Chair:

1. AMENDMENT TO E-10.016, “PEDIATRIC DECISION-MAKING”

CEJA Opinion; no reference committee hearing.

HOUSE ACTION: FILED

INTRODUCTION

At the 2010 Interim Meeting, the American Medical Association House of Delegates adopted the recommendations of Council on Ethical and Judicial Affairs Report 1-1-10, “Amendment to E-10.016, ‘Pediatric Decision-Making.’” The Council issues this Opinion, which will appear in the next version of AMA PolicyFinder and the next print edition of the Code of Medical Ethics.

E-10.016 Pediatric Decision-Making

Medical decision making for pediatric patients should be based on the child’s best interest, which is determined by weighing many factors, including effectiveness of appropriate medical therapies, the patient’s psychological and emotional welfare, and the family situation. When there is legitimate inability to reach consensus about what is in the best interest of the child, the wishes of the parents should generally receive preference.

Physicians treating pediatric patients generally must obtain informed consent from a parent or a legal guardian. Certain classes of children, such as emancipated or mature minors, may provide consent to their own medical care. Physicians should give pediatric patients the opportunity to participate in decision making at a developmentally appropriate level. The physician should seek the patient’s assent, or agreement, by explaining the medical condition, its clinical implications, and the treatment plan in ways that take into account the child’s cognitive and emotional maturity and social circumstances. The physician should provide a supportive environment and encourage reluctant parents to discuss their child’s health status with the patient, in private themselves or with the physician. For HIV-infected children in particular, the physician should be sensitive to the fact that disclosure of health status can have implications for the child’s relationships with biological relatives, household members, and peers; adherence to a complex medical regimen; and participation in behaviors that put the child or others at risk. Physicians should also be sensitive that disclosure of HIV and other conditions (e.g., some inherited conditions) can also have implications for family members other than the child. If the patient does not or cannot assent, physicians should still explain the plan of care and tell him or her what to expect, without deception. In the case of an adolescent patient who has decision making capacity, the physician should encourage the patient’s active participation in decision making. The use of force such as with using physical restraints to carry out a medical intervention in adolescent patients who do not assent should be a last resort.

Parents and physicians may disagree about the course of action that best serves the pediatric patient’s interests, including how much to tell the child about his or her health status, when and how to do so, and who should lead the discussion. When disagreements occur, institutional policies for timely conflict resolution should be followed, including consultation with an ethics committee, pastoral service, or other counseling resource. If a health care facility does not have policies for resolving conflicts in a timely manner, physicians should encourage their development. Physicians should treat reversible life-threatening conditions regardless of any persistent disagreement. Resolution of disagreements in the courts should be pursued only as a last resort. (IV, VIII)
2. ADVANCE CARE PLANNING

CEJA Opinion; no reference committee hearing.

HOUSE ACTION: FILED

INTRODUCTION

At the 2010 Interim Meeting, the American Medical Association House of Delegates adopted the recommendations of Council on Ethical and Judicial Affairs Report 4-I-10, “Advance Care Planning.” The Council issues this Opinion, which will appear in the next version of AMA PolicyFinder and the next print edition of the Code of Medical Ethics.

E-2.191 Advance Care Planning

The process of advance care planning is widely recognized as a way to support patient self-determination, facilitate decision making, and promote better care at the end of life. Although often thought of primarily for terminally ill patients or those with chronic medical conditions, advance care planning is valuable for everyone, regardless of age or current health status. Planning in advance for decisions about care in the event of a life-threatening illness or injury gives individuals the opportunity to reflect on and express the values they want to have govern their care, to articulate the factors that are important to them for quality of life, and to make clear any preferences they have with respect to specific interventions. Importantly, these discussions also give individuals the opportunity to identify who they would want to make decisions for them should they not have decision-making capacity.

Proactively discussing with patients what they would or would not want if recovery from illness or injury is improbable also gives physicians opportunity to address patients’ concerns and expectations and clarify misunderstandings individuals may have about specific medical conditions or interventions. Encouraging patients to share their views with their families or other intimates and record them in advance directives, and to name a surrogate decision maker, helps to ensure that patients’ own values, goals, and preferences will inform care decisions even when they cannot speak for themselves.

Physicians should routinely engage their patients in advance care planning in keeping with the following guidelines:

(a) Regularly encourage all patients, regardless of age or health status to:

   (i) Think about their values and perspectives on quality of life and articulate what goals they would have for care if they faced a life-threatening illness or injury, including any preferences they may have about specific medical interventions (such as pain management, medically administered nutrition and hydration, mechanical ventilation, use of antibiotics, dialysis, or cardiopulmonary resuscitation);

   (ii) Identify someone they would want to have make decisions on their behalf if they did not have decision-making capacity;

   (iii) Make their views known to their designated surrogate and to (other) family members or intimates.

(b) Be prepared to answer questions about advance care planning, to help patients formulate their views, and to help them articulate their preferences for care (including their wishes regarding time-limited trials of interventions and surrogate decision maker). Physicians should also be prepared to refer patients to additional resources for further information and guidance if appropriate.

(c) Explain how advance directives, as written articulations of their preferences, are used as tools to help guide treatment decisions in collaboration with patients themselves when they have decision-making capacity, or with surrogates when they do not, and explain the surrogate’s responsibilities in decision making. Involve the patient’s surrogate in this conversation whenever possible.
(d) Incorporate notes from the advance care planning discussion in the medical record. Patient values, preferences for treatment, and designation of surrogate decision maker should be included in the notes to be used as guidance when the patient is unable to express his or her own decisions. If the patient has an advance directive document or written designation of proxy, include a copy (or note the existence of the directive) in the medical record and encourage the patient to give a copy to his or her surrogate and others to help ensure it will be available when needed.

(e) Periodically review with the patient his or her goals, preferences and chosen decision maker, which often change over time or with changes in health status. Update the patient’s medical records accordingly when preferences have changed to ensure that these continue to reflect the individual’s current wishes. If applicable, assist the patient with updating his or her advance directive or designation of proxy forms. Involve the patient’s surrogate in these reviews whenever possible. (I, IV)

3. ROUTINE UNIVERSAL IMMUNIZATION OF PHYSICIANS FOR VACCINE-PREVENTABLE DISEASE

CEJA Opinion; no reference committee hearing.

HOUSE ACTION: FILED

INTRODUCTION

At the 2010 Interim Meeting, the American Medical Association House of Delegates adopted the recommendations of Council on Ethical and Judicial Affairs Report 5-I-10, “Routine Universal Immunization of Physicians for Vaccine-Preventable Disease.” The Council issues this Opinion, which will appear in the next version of AMA PolicyFinder and the next print edition of the Code of Medical Ethics.

E-9.133 Routine Universal Immunization of Physicians for Vaccine-Preventable Disease

As professionals committed to promoting the welfare of individual patients and the health of the public and to safeguarding their own and their colleagues’ well-being, physicians have an ethical responsibility to take appropriate measures to prevent the spread of infectious disease in health care settings. Conscientious participation in routine infection control practices, such as hand washing and respiratory precautions is a basic expectation of the profession. In some situations, however, routine infection control is not sufficient to protect the interests of patients, the public, and fellow health care workers.

In the context of a highly transmissible disease that poses significant medical risk for vulnerable patients or colleagues, or threatens the availability of the health care workforce, particularly a disease that has potential to become epidemic or pandemic, and for which there is an available, safe, and effective vaccine, physicians have an obligation to:

(a) Accept immunization absent a recognized medical, religious, or philosophic reason to not be immunized.

(b) Accept a decision of the medical staff leadership or health care institution, or other appropriate authority to adjust practice activities if not immunized (e.g., wear masks or refrain from direct patient care). It may be appropriate in some circumstances to inform patients about immunization status. (I, II)
4. AMENDMENT TO E-2.15, “TRANSPLANTATION OF ORGANS FROM LIVING DONORS”

CEJA Opinion; no reference committee hearing.

HOUSE ACTION: FILED

INTRODUCTION

At the 2010 Interim Meeting, the American Medical Association House of Delegates adopted the recommendations of Council on Ethical and Judicial Affairs Report 6-I-10, “Nonsimultaneous, Altruistic Organ Donation.” The Council issues this Opinion, which will appear in the next version of AMA PolicyFinder and the next print edition of the Code of Medical Ethics.

E-2.15 Transplantation of Organs from Living Donors

Living organ donors are exposed to surgical procedures that pose risks but offer no physical benefits. The medical profession has pursued living donation because the lives and quality of life of patients with end-stage organ failure depend on the availability of transplantable organs and some individuals are willing to donate the needed organs. This practice is consistent with the goals of the profession—treating illness and alleviating suffering—only insofar as the benefits to both donor and recipient outweigh the risks to both.

(1) Because donors are initially healthy and then are exposed to potential harms, they require special safeguards. Accordingly, every donor should be assigned an advocate team that includes a physician. This team is primarily concerned with the well-being of the donor. Though some individuals on the donor advocate team may participate in the care of the recipient, this team ideally should be as independent as possible from those caring for the recipient. This can help avoid actual or perceived conflicts of interest between donors and recipients.

(a) To determine whether a potential living donor is an appropriate candidate, the advocate team must provide a complete medical evaluation to identify any serious risk to the potential donor’s life or health. This includes a psychosocial evaluation of the potential donor to identify disqualifying factors, address specific needs and explore potential motivations to donate.

(b) Before the potential donor agrees to donate, the advocate team should provide information regarding the donation procedure and its indications, as well as the risks and potential complications to both donor and recipient. Informed consent for donation is distinct from informed consent for the actual surgery to remove the organ.

(i) The potential donor must have decision-making capacity, and the decision to donate must be free from undue pressure. The potential donor must demonstrate adequate understanding of the disclosed information.

(ii) Unemancipated minors and legally incompetent adults ordinarily should not be accepted as living donors because of their inability to fully understand and decide voluntarily. However, in exceptional circumstances, minors with substantial decision making capability who agree to serve as donors, with the informed consent of their legal guardians, may be considered for donation to recipients with whom they are emotionally connected. Since minors’ guardians may be emotionally connected to the organ recipient, when an unemancipated minor agrees to donate, it may be appropriate to seek advice from another adult trusted by the minor or an independent body, such as consultation with an ethics committee, pastoral service, or other counseling resource.

(iii) Potential donors must be informed that they may withdraw from donation at any time before undergoing the operation and that, should this occur, the health care team is committed to protect the potential donor from pressures to reveal the reasons for withdrawal. If the potential donor withdraws, the health care team should report simply that the individual was unsuitable for donation. From the outset, all involved parties must agree that the reasons why any potential donor does not donate will remain confidential for the potential donor’s protection.
paired, domino, or chain donation withdrawal must still be permitted. Physicians should make
special efforts to present a clear and comprehensive description of the commitment being made by
the donor and the implications for other parties to the paired donation during the informed consent
process.

(c) Living donation should never be considered if the best medical judgment indicates that transplantation
cannot reasonably be expected to yield the intended clinical benefit or achieve agreed on goals for care
for the intended recipient.

(2) Living donors should not receive payment for any of their solid organs. However, donors should be treated
fairly; reimbursement for travel, lodging, meals, lost wages, and the medical care associated with donation
is ethically appropriate.

(3) The distribution of organs from living donors may take several different forms:

(a) It is ethically acceptable for donors to designate a recipient, whether a close relative or a known,
unrelated recipient.

(b) Designation of a stranger as the intended recipient is ethical if it produces a net gain of organs in the
organ pool without unreasonably disadvantaging others on the waiting list. Variations involve potential
donors who respond to public solicitation for organs or who wish to participate in a paired donation or
“organ swap” (e.g., blood type incompatible donor-recipient pairs Y and Z are recombined to make
compatible pairs: donor-Y with recipient-Z and donor-Z with recipient-Y) domino paired donation,
and nonsimultaneous extended altruistic donation (also known as chain donation).

(c) Organs donated by living donors who do not designate a recipient should be allocated according to the
algorithm that governs the distribution of deceased donor organs.

(4) Novel variants of living donation call for special attention to protect both donors and recipients:

(a) Physicians must ensure utmost respect the privacy and confidentiality of donors and recipients, which
may be more difficult when many patients are involved and when donation-transplantation cycles may
be extended over time (as in domino or chain donation)

(b) Physicians should monitor prospective donors and recipients in a proposed nontraditional donation for
signs of psychological distress during screening and after the transplant is complete.

(c) Physicians must protect the donor’s right to withdraw in living paired-donations and ensure that the
individual is not pressured to donate.

(5) To enhance the safety of living organ donation through better understanding of the harms and benefits
associated with living organ donation, physicians should support the development and maintenance of a
national database of living donor outcomes, similar to that of deceased donation. (I, V, VII, VIII)
5. PROFESSIONALISM IN THE USE OF SOCIAL MEDIA

CEJA Opinion; no reference committee hearing.

HOUSE ACTION: FILED

INTRODUCTION

At the 2010 Interim Meeting, the American Medical Association House of Delegates adopted the recommendations of Council on Ethical and Judicial Affairs Report 8-I-10, “Professionalism in the Use of Social Media.” The Council issues this Opinion, which will appear in the next version of AMA PolicyFinder and the next print edition of the Code of Medical Ethics.

E-9.124 Professionalism in the Use of Social Media

The Internet has created the ability for medical students and physicians to communicate and share information quickly and to reach millions of people easily. Participating in social networking and other similar Internet opportunities can support physicians’ personal expression, enable individual physicians to have a professional presence online, foster collegiality and camaraderie within the profession, provide opportunity to widely disseminate public health messages and other health communication. Social networks, blogs, and other forms of communication online also create new challenges to the patient-physician relationship. Physicians should weigh a number of considerations when maintaining a presence online:

(a) Physicians should be cognizant of standards of patient privacy and confidentiality that must be maintained in all environments, including online, and must refrain from posting identifiable patient information online.

(b) When using the Internet for social networking, physicians should use privacy settings to safeguard personal information and content to the extent possible, but should realize that privacy settings are not absolute and that once on the Internet, content is likely there permanently. Thus, physicians should routinely monitor their own Internet presence to ensure that the personal and professional information on their own sites and, to the extent possible, content posted about them by others, is accurate and appropriate.

(c) If they interact with patients on the Internet, physicians must maintain appropriate boundaries of the patient-physician relationship in accordance with professional ethical guidelines just, as they would in any other context.

(d) To maintain appropriate professional boundaries physicians should consider separating personal and professional content online.

(e) When physicians see content posted by colleagues that appears unprofessional they have a responsibility to bring that content to the attention of the individual, so that he or she can remove it and/or take other appropriate actions. If the behavior significantly violates professional norms and the individual does not take appropriate action to resolve the situation, the physician should report the matter to appropriate authorities.

(f) Physicians must recognize that actions online and content posted may negatively affect their reputations among patients and colleagues, may have consequences for their medical careers (particularly for physicians-in-training and medical students), and can undermine public trust in the medical profession. (I, II, IV)
REPORTS OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

The following reports, 1–8, were presented by John W. McMahon, Sr., MD, Chair:

1. FINANCIAL RELATIONSHIPS WITH INDUSTRY IN CONTINUING MEDICAL EDUCATION

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

HOUSE ACTION: RECOMMENDATION ADOPTED AND REMAINDER OF REPORT FILED

See Policy H-140.849.

Relationships between medicine and industry—such as pharmaceutical, biotechnology, and medical device companies—have driven innovation in patient care, contributed to the economic well-being of the community, and provided significant resources (financial and otherwise) for professional education, to the ultimate benefit of patients and the public.[1,2] The interests and obligations of medicine and industry diverge in important ways, however. An increasingly urgent challenge for both partners is to devise ways to preserve strong, productive collaborations for the benefit of patients and the public at the same time they each take clear, effective action to avoid relationships that could undermine public trust.

As relationships between medicine and industry have evolved, major national organizations, such as the Institute of Medicine (IOM)[3] and the Association of American Medical Colleges (AAMC)[4,5,6] have explored the challenges that these relationships can pose in research, clinical care, education, and beyond. Key stakeholders, including (among others) the Accreditation Council for Continuing Medical Education (ACCME),[7] the Council of Medical Specialty Societies (CMSS),[8] and the Pharmaceutical Research and Manufacturers Association (PhRMA)[9] have developed guidance to help their constituents sustain appropriate, productive, and professional interactions.

The American Medical Association was founded on the vision that as medical professionals, physicians should represent the highest standards of competence, integrity, and professionalism. This report carries that vision forward. It examines ethical aspects of medicine-industry relationships in continuing medical education (CME), explores ethical challenges that can be posed by financial relationships from the perspective of physicians, and provides guidance for members of the medical profession who attend or who organize, teach in, or serve other roles in CME.

The Council on Ethical and Judicial Affairs recognizes that pharmaceutical, biotechnology, and medical device companies are not the only entities with which financial relationships can raise concerns. CEJA likewise recognizes that CME is not the only domain of potential concern. However, narrowing our focus to CME allows us to explore the complex considerations at stake in a manageable context and to provide practical ethical guidance on issues that increasingly challenge physicians as professionals.

LIFELONG LEARNING & MEDICINE’S DUTY TO EDUCATE

Publicly in his oath and privately in his encounter with the patient, the physician professes two things—to be competent to help and to help with the patient’s best interests in mind.

Edmund Pellegrino[10]

The practice of medicine is inherently a moral activity, founded in a “covenant of trust” between patient and physician.[10,11,12] The respect and autonomy that medicine enjoys rest on the profession’s commitment to fidelity and service in the patient-physician relationship. To sustain that commitment, medicine must ensure that physicians acquire and maintain the knowledge, skills, and values that are central to the healing profession. In return, society grants medicine considerable authority to set the ethical and professional standards of practice and the autonomy to educate practitioners.[13,14]

The special moral character of the interaction between patient and physician arises from the need—illness or the prevention of illness—that brings the patient into the relationship. Physicians are granted extraordinary privileges to intervene in patients’ lives. Patients entrust to physicians the care of their bodies and the protection of sensitive...
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information revealed in confidence for the purpose of seeking healing. Educating current and future generations of physicians to fulfill the responsibilities that flow from the patient-physician relationship is the foundation of medicine’s status as a caring and competent profession. Thus medicine’s ethical duty to educate cannot be delegated to others.

Individual physicians have an ethical obligation to dedicate themselves to “continue to study, apply, and advance scientific knowledge” and to “maintain a commitment to medical education.”[15] As professionals, practicing physicians are expected to commit themselves to lifelong learning and to maintain their clinical knowledge and skills through CME and other professional development activities.[16] That commitment is reflected not only in ethical expectations and standards, but also in requirements for licensure and specialty certification, as well as hospital credentialing.

Physicians and the patients who rely on them must be confident that treatment recommendations and clinical decisions are well informed and reflect up-to-date knowledge and practice. CME activities that are pedagogically sound, scientifically grounded, and clinically relevant are essential to ensure that physicians can provide the high quality of care their patients deserve. To achieve these goals, medicine has an ethical obligation to ensure that the profession independently sets the agenda and defines the goals of physician education; controls what subject matter is taught; determines physicians’ educational needs; and takes steps to ensure the independence of educational content and of those who teach it. The importance of doing so may extend well beyond continuing education—as one commentary noted, “[w]hat is at stake is nothing less than the privilege of autonomy in our interactions with patients, self-regulation, public esteem, and a rewarding and well-compensated career.”[17]

CONTINUING MEDICAL EDUCATION

Continuing medical education today takes place in an environment that includes “promotional” activities, “certified CME,” and noncertified CME. Promotional activities lie outside the scope of the present analysis and recommendations. As defined by the Food and Drug Administration (FDA), these are activities developed by or on behalf of a commercial entity and under the substantive influence of that entity to provide information on the therapeutic use of a product or service. They are governed by the labeling and advertising provisions of the Food, Drug, and Cosmetic Act,[18,19] and may constitute protected commercial speech.

“Certified CME” refers to educational activities developed and implemented in compliance with the certification requirements of the American Medical Association Physician Recognition Award (PRA) CME Credit System or the accrediting policies of the American Academy of Family Physicians or American Osteopathic Association.[20] Certified CME meets the requirements for Category 1 credit under AMA’s PRA program, including compliance with Accreditation Council for Continuing Medical Education (ACCME) standards and with relevant AMA ethics policy.[21]

Beyond these formal categories lie activities designed to inform and educate practicing physicians that are neither promotion nor certified CME. These other activities may or may not be commercially supported, may or may not voluntarily adhere to AMA policy or ACCME Standards for Commercial SupportSM (even if they are not formally certified or offered by formally accredited providers), and may or may not be recognized by licensing bodies or credentialing boards as fulfilling CME requirements.

Physician involvement is critical in CME. Individually and collectively, physicians play key roles in educating their peers, as teachers, content developers, organizers of CME, or in other capacities.

Financial Relationships with Industry in CME

In the context of continuing medical education, relationships with industry that may pose challenges for the independence and objectivity of physician education include not only direct industry support of CME activities, but also financial relationships between industry and individual physicians involved in CME as faculty, content developers, or in other capacities.

Industry support for CME has declined in recent years, but commercial funding still accounts for approximately 40 percent of overall CME-related revenue, ranging from less than one percent to just over 60 percent across accredited
A growing number of accredited providers—20 percent as of July 2009—no longer accepts any commercial support at all.[23]

Industry support helps to meet the costs of CME activities in the face of uncertain funding from other sources[24] and may help make CME more accessible, especially for physicians in resource-poor communities.[25] Industry engagement and support can be especially helpful in ensuring affordable CME when educational activities need high cost, sophisticated, rapidly evolving technology or devices. Along with lower costs, industry support may encourage greater participation than would otherwise be the case by providing amenities. As yet there is no peer-reviewed evidence to support or to refute the effect of industry funding on accessibility of or participation in CME activities.[26]

However, there is growing concern within and outside medicine that industry funding for CME could have undesirable effects, including potentially biasing content toward funders’ products and influencing the overall range of topics covered.[27,28,29,30] Importantly, where patients’ health and public trust are concerned, the perception of bias, even if mistaken, can be as potentially damaging as the existence of actual bias.

Influence, Evidence & Ethics

Whether or how financial relationships influence CME activities or the overall CME curriculum is an important question. But answering this empirical question cannot resolve the core ethical challenge, no matter what the evidence should prove to be. Physicians are entrusted with the interests of patients. Where trust is central, the appearance of influence or bias can be as damaging as actual influence. Empirical evidence alone is not enough to overcome public skepticism. Even evidence that undesired consequences have not occurred cannot be expected by itself to restore confidence when trust has been compromised.

The available data neither support nor disprove that financial relationships influence CME. Standards have been established to address concerns about possible influence in CME, such as the ACCME Standards for Commercial Support.[SM] The efficacy of those standards or other processes to address the potential for industry influence on content or the overall range of CME topics is difficult to determine. Several recent studies have suggested that the great majority of physicians attending CME activities do not perceive bias in the content of those activities, based on their responses to questions about bias on standard evaluations of CME activities.[31,32,33] As the authors themselves note, these studies are subject to limitations, such as the “insensitivity of simple ‘yes/no’ questions to assess learners’ perceptions of bias.”[33, cf. 32, cp., 34]

Other research indicates that individual physicians, like everyone else, are subject to influence, even if they are not aware of how industry support of a CME activity could affect their clinical decisions.[35,36,37,38,39] Further, a recent review of the relevant literature found that although there is clear evidence that CME influences physicians’ prescribing practices, the question of what effect changes in prescribing have on actual patient outcomes has not specifically been studied.[39]

To maintain productive relationships with industry that benefit patients and to sustain the trust on which the patient-physician relationship and public confidence in the profession depend, medicine must take steps to safeguard the independence and integrity of physician education.

ENSURING THE INDEPENDENCE & INTEGRITY OF CME

CEJA recognizes that competing interests are a fact of life for everyone, including but not limited to physicians. For physicians, however, even very modest potential or perceived competing interests can put trust at risk. As individuals and as a profession, physicians have a responsibility to protect the quality of professional education and the reputation of medicine. While competing interests cannot be eliminated entirely, prudent judgments can be made about how to minimize potential influence and prevent or reduce undesired consequences.

Minimizing the Opportunity for Influence

Physicians should aspire to avoid the potential for influence or the chance that confidence in the integrity and independence of their professional education could be diminished. Avoiding entirely situations in which there is potential for influence has the virtue of ethical clarity and practical simplicity. CME that is free of financial
relationships with companies that have direct interests in physicians’ recommendations strongly underscores medicine’s defining professional commitment to independence and fidelity to patients. Avoiding such relationships also has the practical advantage of eliminating the administrative and resource costs that must otherwise be devoted to mitigating influence.[40] costs that may be particularly challenging for smaller CME providers.[25]

In their roles as CME providers, content developers, and faculty, physicians should strive to avoid financial relationships with industry. The Institute of Medicine has called for development of a new system of funding CME that is free of industry influence.[3] Medicine should cultivate alternative sources of support, should design and conduct educational activities so as to reduce costs, and should insist that content developers and faculty members not have problematic ties with industry to ensure independent, unbiased, high quality educational programming that best meets physicians’ needs and is accessible and affordable for all practitioners.

Changing the terms of financial relationships likewise can help minimize the potential for influence. For example, physicians who have decision-making authority in organizations that provide CME could set an upper limit on how great a proportion of the organization’s income derives from industry support to ensure that the organization does not become overly reliant on commercial funding. Asking physicians who teach in or develop content for a CME activity to refrain from accepting compensation (honoraria, consulting fees, etc.) for a defined period before and after the activity from a commercial supporter that has an interest in the educational subject matter could similarly promote independence. Decisions to require that physicians involved in CME as faculty members or in other roles change the terms of their relationships with industry must, of course, be made fairly and consistently across individual cases.

That said, it is not always feasible, or necessarily desirable, for professional education to disengage from industry completely. In some situations financial relationships with industry can be ethically justifiable. When not accepting support from a commercial source or not permitting participation by individuals who have financial interests in the educational subject matter would significantly undermine medicine’s capacity to ensure that physicians have access to appropriate, high-quality CME, it can be acceptable to permit such support or participation. In these situations, vigorous efforts must be made to mitigate the potential influence of financial relationships.

Mitigating Potential Influence

While there should be a presumption that physicians who organize, design, develop content, or teach in CME should not have concurrent financial ties to industry related to their CME responsibilities, it is important to recognize that not all relationships with industry are equally problematic. A relationship that is only indirectly related to an educational activity, modest in scope, or distant in time is not likely to adversely affect—or be perceived to affect—the activity in question. For example, having once conducted sponsored research or accepted a modest honorarium for speaking on behalf of a company would not necessarily create such clear potential for bias as to preclude an individual with the appropriate expertise from developing content or serving as a faculty member for a given CME activity.[41]

Financial relationships that are direct or substantial, however, have significant potential to undermine confidence in educational activities, even if they do not actually compromise those activities. Examples of a direct or substantial financial interest include ownership or equity interest in a company that has an interest in the educational subject matter of a CME activity or royalties or ongoing compensated relationships (e.g., consulting arrangements or service on scientific advisory bodies or speakers bureaus).[4] Relationships that involve fiduciary responsibilities on behalf of the funder (such as service on a corporate board of directors) or decision-making authority in financial matters can be similarly problematic.[42] In such situations, ethically strong practice requires that steps be taken to mitigate the possible influence of financial relationships on educational activities.

PRINCIPLES FOR SUSTAINING TRUST

The goal of mitigation is to promote—and enhance confidence in—the integrity of continuing professional education. Commitment to transparency, independence, and accountability enables physicians to achieve that goal, whatever role they may play in CME. Moreover, being transparent about financial relationships that have the potential to influence CME and forthcoming about what steps have been taken to minimize possible influence supports physician-learners in exercising critical judgment individually as “consumers” of CME.
Transparency

As the ACCME Standards for Commercial SupportSM recognize, transparency—i.e., disclosing the existence of a financial relationship—is a necessary first step in mitigating the potential of financial relationships to create bias (or the appearance of bias),[7] but it is not sufficient and may even have perverse effects. Disclosure places the burden on learners themselves to determine how skeptical they should be about possible bias in an educational activity.[43] To the extent that disclosure fosters the impression that the presenter is particularly honest and trustworthy, it can encourage false confidence in the activity. To the extent that the presenter believes disclosing a financial relationship is adequate to mitigate its potential influence, he or she may be less circumspect in ensuring content is free of such influence.

While transparency is essential, disclosing financial relationships is necessary but not sufficient to mitigate the potential for influence in CME.

Independence

Taking concrete steps to ensure that CME is independent and objective is equally important. Creating a “firewall” between funders and decisions about educational goals, content, faculty, pedagogical methods and materials, and other substantive dimensions of CME activities can help protect the independence of professional education. Both ACCME and the Inspector General of the Department of Health and Human Services have recommended clearly separating decisions about funding from substantive decisions about CME activities,[7,19] and many organizations are developing models, such as “blind trusts,” to do so.[e.g.,44,45] Support of individual CME activities by multiple, competing funders may also help diffuse the potential influence of any one funder. Carrying out educational needs assessments prior to seeking or accepting commercial support or identifying faculty can similarly enhance the independence of the planning process and resulting CME programming. Likewise, having prospective peer review of a presentation (review of slides or other forms of communication in advance of the presentation by an objective and independent expert who has the power to require changes prior to the public showing) can help ensure that the presentation is free of commercial bias.

Accountability

Physician-learners, patients, the public, and the medical community as a whole should be able to be confident that physicians who organize, design, develop content, or teach in CME will uphold principles of transparency and independence. The expectation that physicians involved in CME will hold themselves accountable to address the potential that financial relationships with industry have to influence professional education is a cornerstone of self-regulation. That responsibility can be greatly enhanced by the efforts of accrediting and certifying bodies, but it cannot be supplanted by them. In particular, physician leaders in CME should be able and willing to discuss how the principles of transparency and independence have been applied in the educational activities with which they are involved or over which they have decision-making authority.

Exceptional Cases

At times it may be impossible to avoid a financial interest or extraordinarily difficult or even impossible to mitigate its potential impact on an educational activity. For the most part, accepting support from a company or permitting participation by an individual when there is an irreducible financial interest would not be ethically acceptable. However, in certain circumstances, it may be justifiable.

Such circumstances include instances when accessible, high-quality CME cannot reasonably be carried out without support from sources that have a direct financial interest in physicians’ clinical recommendations, such as activities that require cadavers or high-cost, sophisticated equipment to train physicians in new procedures or the use of new technologies. Similarly, in the earliest stage of adoption of a new medical device, technique, or technology the only individuals truly qualified to train physicians in its use are often those who developed the innovation. These individuals may have the most substantial and direct interests at stake, whether through employment, royalties, equity interests or other direct financial interests in the adoption and dissemination of the new technology. Physicians who organize CME should be transparent about what considerations led them to decide to permit an individual with a problematic financial interest to participate in a particular CME activity to ensure that such decisions are justifiable and persuasive to the professional community at large.
Putting Principles into Practice – The Exercise of Judgment

Inevitably, putting principles of transparency, independence, and accountability into practice calls for the exercise of judgment. It requires knowledge of the particular circumstances and thoughtful deliberation. Yet this is no different from the kinds of judgments physicians routinely make in the context of caring for patients and applying other portions of the Code of Medical Ethics to their daily practice.

One approach is to reflect on what “consumers” of CME (which arguably includes patients and the broader professional community, as well as individual physician-learners) would want to know to exercise their skills of critical judgment; that is, to make well-considered judgments for themselves about the objectivity and quality of a CME activity, its faculty, and its educational content. Such factors might include not only the existence of a financial interest(s), but equally the source of that interest, the type of interest (such as honoraria, consulting fees, equity, stock options, royalties), and the magnitude of the interest, e.g., dollar amount to the nearest $1,000, as currently required by the North American Spine Society.[46]

Similarly, consumers of CME could reasonably want to know how the potential influence of a financial interest has been addressed to protect the independence of the activity; or consumers may want to know on what grounds an individual who has a direct, substantial, and unavoidable financial interest has been permitted to participate in a CME activity. In the latter case, for example, reasonable decision-making criteria might include that the dissemination of the device, technique or technology will be of significant benefit to patients and to the public and the professional community; that the individual is uniquely qualified as an expert in the relevant body of knowledge or skills; that the individual discloses the source, nature, and magnitude of the specific financial interest at stake; that there is demonstrated, compelling need for the specific CME activity; that all feasible steps are taken to mitigate influence; and that this expert’s participation in dissemination will, eventually, enable those without such financial interests to take on the educational role. An individual might be considered “uniquely qualified” when he or she is the only expert (or one of a few) who has significant knowledge about or experience in treating a rare disease or was involved in the early development or testing of a new treatment, device, or technology. A “compelling need” for a particular educational activity may be present when a new therapy becomes available to treat a disease present in the local community for which the new treatment represents a substantial improvement.

The need to rely on “conflicted expertise” can be affected by local conditions—CME in small or rural communities, for example, may not always have ready access to experts who are free of problematic ties to industry. In any event, when a substantial body of peer-reviewed evidence has evolved in a given subject area, or when a cohort of individuals without direct, substantial interests has become experienced in using a new medication, device, or technology and is available to teach, using a “uniquely qualified” expert becomes less justifiable.

As the professional community gains experience, it is to be expected that consensus will coalesce around core interpretations. As Harvard Medical School notes in its conflict of interest policy:

These classifications are not intended to serve as a rigid or comprehensive code of conduct or to define “black letter” rules with respect to conflict of interest. It is expected that the guidelines will be applied in accordance with the spirit of the mission of Harvard Medical School in education, research and patient care. By this process, it is expected that a common institutional experience in the application of these guidelines will gradually evolve.[47]

We expect that a similar shared understanding of how principles of transparency, independence, and accountability should apply to financial relationships with industry in continuing medical education will evolve for the medical profession.

RECOMMENDATION

The Council on Ethical and Judicial Affairs recommends that the following be adopted and the remainder of this report be filed:

In an environment of rapidly changing information and emerging technology, physicians must maintain the knowledge, skills, and values central to a healing profession. They must protect the independence and commitment to fidelity and service that define the medical profession.
Financial or in-kind support from pharmaceutical, biotechnology or medical device companies that have a direct interest in physicians’ recommendations creates conditions in which external interests could influence the availability and/or content of continuing medical education (CME). Financial relationships between such sources and individual physicians who organize CME, teach in CME, or have other roles in continuing professional education can carry similar potential to influence CME in undesired ways.

CME that is independent of funding or in-kind support from sources that have financial interests in physicians’ recommendations promotes confidence in the independence and integrity of professional education, as does CME in which organizers, teachers, and others involved in educating physicians do not have financial relationships with industry that could influence their participation. When possible, CME should be provided without such support or the participation of individuals who have financial interests in the educational subject matter.

In some circumstances, support from industry or participation by individuals who have financial interests in the subject matter may be needed to enable access to appropriate, high-quality CME. In these circumstances, physician-learners should be confident that vigorous efforts will be made to maintain the independence and integrity of educational activities.

Individually and collectively physicians must ensure that the profession independently defines the goals of physician education, determines educational needs, and sets its own priorities for CME. Physicians who attend CME activities should expect that, in addition to complying with all applicable professional standards for accreditation and certification, their colleagues who organize, teach, or have other roles in CME will:

(a) be transparent about financial relationships that could potentially influence educational activities.

(b) provide the information physician-learners need to make critical judgments about an educational activity, including:

(i) the source(s) and nature of commercial support for the activity; and/or
(ii) the source(s) and nature of any individual financial relationships with industry related to the subject matter of the activity; and
(iii) what steps have been taken to mitigate the potential influence of financial relationships.

(c) protect the independence of educational activities by:

(i) ensuring independent, prospective assessment of educational needs and priorities;
(ii) adhering to a transparent process for prospectively determining when industry support is needed;
(iii) giving preference in selecting faculty or content developers to similarly qualified experts who do not have financial interests in the educational subject matter;
(iv) ensuring a transparent process for making decisions about participation by physicians who may have a financial interest in the educational subject matter;
(v) permitting individuals who have a substantial financial interest in the educational subject matter to participate in CME only when their participation is central to the success of the educational activity; the activity meets a demonstrated need in the professional community; and the source, nature, and magnitude of the individual’s specific financial interest is disclosed; and
(vi) taking steps to mitigate potential influence commensurate with the nature of the financial interest(s) at issue, such as prospective peer review.

REFERENCES

2. PHYSICIAN RESPONSIBILITIES FOR SAFE PATIENT DISCHARGE FROM HEALTH CARE FACILITIES

(RESOLUTION 4-I-08)

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

HOUSE ACTION: NOT ADOPTED

Resolution 4-I-08, “Forced Repatriation of Immigrants by Hospitals,” which was introduced by the California Delegation and referred, asked the Council on Ethical and Judicial Affairs (CEJA) to address the ethical concerns surrounding “the forced repatriation” of patients who are not citizens or legal residents of the United States from hospitals in the US to facilities in the patients’ countries of citizenship. Incidents of “forced repatriation” of such patients have been a consequence, in large part, of the limited insurance and treatment options available in the United States to patients with long-term health care needs who are not citizens or legal residents. These circumstances can test a physician’s ability to carry out his or her duty to discharge patients safely. For physicians, this is fundamentally an issue of the ethics of safe patient discharge. Therefore, this report first addresses physicians’ ethical responsibilities for discharging patients safely, and then explores implications for discharge practices in contexts of severely limited options.

PHYSICIANS’ ETHICAL RESPONSIBILITIES IN DISCHARGING PATIENTS

When a patient discharge from a health care facility is planned, the physician must evaluate its appropriateness. Therefore, a patient discharge should not occur without the physician’s prior order. In patient discharge, the following statement by Pellegrino holds true: “No order can be carried out, no policy observed, and no regulation imposed without the physician’s assent…. The physician is therefore de facto a moral accomplice in whatever is done for good or ill to patients.”[1]

In considering and making discharge decisions, physicians should be guided by a framework that prioritizes the well-being of patients. The physician’s fundamental purpose is to help alleviate the impact of illness on human
persons.[2] Therefore, dedication to patients’ well-being is not only a basic tenet of a physician’s professional ethic,[3-6] it is a physician’s primary ethic. Principle VIII of the AMA Principles of Medical Ethics affirms, “A physician shall, while caring for a patient, regard responsibility to the patient as paramount.”[5]

With regard to a patient discharge decision, this primary ethic requires that the physician be satisfied that the discharge plan appropriately meets the individual patient’s medical needs and is safe for the patient. A safe patient discharge is an ethical standard which acknowledges that discharge arrangements are often complex,[7] involving numerous stakeholders and concerns that are beyond a physician’s control.[8,9] By way of example, a model discharge may favor a professional caretaker who is available 24 hours a day, but in reality the only available caretaker may be obligated elsewhere, and be able to only meet the patient’s minimum needs for having a caregiver available. Safe discharge requires that physicians, together with the assistance of institutional support staff if needed, weigh such practical realities in light of the patient’s best interests, and take reasonable steps to prevent foreseeable harm to the patient during and after the discharge.

The safety of patients depends on physicians (and supporting staff) anticipating and addressing (or delegating others to address) risks before authorizing a discharge, which is when physicians have some control over the process. Many risks will be clinical in nature, but physicians may be able to anticipate and address psychosocial and situational risks as well.[10] Regardless of clinical stability at the time of discharge, risks of harm can escalate if patients are, for instance, socially isolated, left without appropriate caretakers, or forced to live in an unsuitable environment after discharge.[8,9] Therefore, to ensure safety, physicians, in partnership with other health care professionals,[10] should: confirm the patient’s clinical readiness for discharge, confirm the receiving environment’s appropriateness to meet the patient’s needs, respect caretakers’ concerns and patients’ preferences, and be sensitive to societal interests to the extent possible.

**Confirm the Patient’s Clinical Readiness for Discharge**

According to standard practice and consistent with his or her expertise, the physician should carefully assess the patient and confirm that the individual is medically stable enough to leave the hospital setting and to travel distances (if the planning anticipates this) before authorizing a discharge.[11] Whether a patient is medically stable for discharge may depend on specific discharge arrangements. Physicians should be satisfied that aspects of discharge arrangements—such as transportation, care during transportation and appropriate, sustainable care at the destination—have been reasonably verified either by themselves or by other available hospital professionals who specialize in this area. While discharge coordinators or others may be better equipped to make these arrangements,[7,12] the physician should always clarify to all involved parties the expectations regarding a patient’s needs, the minimum technological capabilities and the provider expertise necessary to deliver an appropriate level of care. Expectations regarding accountability for execution of the plan should also be stipulated.

**Confirm the Receiving Environment’s Ability to Meet the Patient’s Needs**

A physician’s responsibility for safe patient discharge is recognized as standard practice, and the responsibility has been affirmed through several formal means. As a condition of participation in Medicare and Medicaid services, hospitals are required to discharge patients to “appropriate facilities” that can sufficiently meet the patient’s medical needs.[13] The AMA Council on Scientific Affairs (now Council on Science and Public Health) in its 1996 report on evidence-based discharge practices affirmed as a primary principle that a patient’s needs “be matched to an environment with the ability to meet those needs.”[10]

Physicians should not discharge a patient to an environment in which the patient’s health could reasonably be expected to deteriorate simply because of inadequate resources at the intended destination. Before discharging a patient, the physician should be assured that both the professional and material resources at the receiving facility are adequate to address the patient’s medical needs.[7,12] While a discharging physician may have no control over the care provided at the destination, he or she is nonetheless well placed to decide whether the described standard of care at the destination is likely to be appropriate for the patient’s post-discharge care needs. To do so, the physician (or assigned discharge professionals) should work cooperatively with discharge planning staff at the transferring facility to coordinate with caretakers at the receiving facility.

In an effort to secure appropriate continuity of patient care, physicians may also request that discharge plans stipulate follow-up progress reports on a discharged patient. Such follow-up may be effective in preventing
unplanned rehospitalizations.[17] It may also allow the physician and others to consider corrective steps when the new care setting belatedly proves to be unsafe for the patient. At the very least, such follow-up may help prevent harm to future patients who may be discharged to the same facility under similar conditions.

Respect Caretakers’ Concerns and Patients’ Preferences

Physicians should actively seek the input of the patient’s future caretakers and respect their concerns when possible. Discharge is by nature a complex process that involves multiple concerned individuals making negotiated arrangements for the patient’s care.[8] Not only are future caretakers, such as family members, significantly affected by the changes that a patient’s discharge often entails,[8] but their availability to provide care is vital to the patient’s long-term safety. A discharge is more likely to serve the future well-being of the patient if it accounts for others’ ability, availability and willingness to provide long-term care. Future caretakers’ knowledge of the financial and community resources may also be helpful to physicians as they consider the patient’s post-discharge care needs.

Similarly, individual patient’s own informed preferences regarding discharge and post-discharge care arrangements should be respected by physicians whenever possible. In so doing, physicians help to mitigate harms that arise from an undue constraint on one’s ability to exercise self determination. This respect is, in fact, a physician responsibility that is widely affirmed in various opinions of the AMA’s [16,18,19] Code of Medical Ethics.

The physician’s responsibility to respect a patient’s right to self-determination acknowledges that the right is not absolute,[20] but that it is appropriately constrained, in some measure, by the options afforded by a multiplicity of other social factors. Physicians should consider the wishes of the patient to the extent that respecting a patient’s right to self-determination contributes to a safe discharge. Discharge often marks a significant medical and social transition for patients. While some patients fully recover and return to the normalcy of home, many with ongoing care needs enter a new phase of care at home or another health care facility. For this group in particular, discharge is often marked by the stresses of adjusting to new care and living arrangements.[8] By providing patients with a degree of control over this process, physicians can help patients better prepare for a safer transition.

Be Sensitive to Societal Interests

Physicians should be sensitive to the interests of society in discharge practices, but without compromising the individual patient’s safety, which must remain a physician’s primary commitment. The patient-physician interaction necessarily exists within a nexus of specific policies and limited resources. This reality shapes what a physician is or is not able to do in regard to patient discharge. For example, the unsustainable costs of health care in the US have made the prudent use of health care resources increasingly important. Many health care institutions incentivize reducing a patient’s length of stay, for instance, in an effort to constrain costs.[21] Such incentives, while legitimate, may increase the risk of patients being discharged before they are clinically ready or before post-discharge care can be adequately arranged. Physicians should be wary of such possibilities and should avoid the influence of nonclinical elements during discharge planning, because nonclinical factors can compromise the safety of patients.

IMPLICATIONS FOR DISCHARGE TO RESOURCE POOR SETTINGS ABROAD

Ensuring a safe discharge for patients can be extremely challenging for physicians when adequate post-discharge options are severely limited. For instance, homeless patients may have limited options due to a lack of insurance or caretakers,[22] while a patient in a rural setting may be limited by logistic barriers. The issue of limited options is starkly illustrated by recent reports alleging forced discharge of noncitizen immigrant patients from US hospitals to resource poor facilities in their countries of origin.

These practices usually involve noncitizen immigrants who are residing in the US illegally or have legally resided in the country for less than five years. When such noncitizen immigrants experience a major illness or injury, their initial emergency medical needs are met regardless of their immigration or insurance status under the provisions of the Emergency Medical Treatment and Active Labor Act (EMTALA).[23-25] However, uninsured noncitizen immigrant patients, who have been stabilized, but require long-term care, often cannot access appropriate facilities or caregivers in the United States.[25,26] They frequently lack the financial means to purchase private insurance for long-term care, and their immigration status disqualifies them from Medicaid or Medicare. Such patients may alternatively qualify for a patchwork of local resources or allowances from Immigration and Naturalization Services (INS), but these plans apply to only a few qualified groups.[26,27]
Millions of legal and illegal noncitizen immigrants are potentially at risk of being unsafely discharged across US borders. As of March 2007, an estimated 37.9 million noncitizen immigrants were living and working in the US.[28] Of these, more than 33.8 percent (or 12.8 million) lacked any public or private health insurance for the entire year of 2006.[28] The risks are particularly high among certain immigrant groups, such as those from Mexico, 56.9 percent of whom did not have any insurance in 2006.[28] According to preliminary inquiries made by journalists, this risk has translated into physician authorizations for hundreds of patient discharges to facilities in other countries each year, with little formal oversight.[23,26,29]

Immigration status is clearly a reality that can limit the options available to patients and their physicians.[30,31] However, these limitations should not diminish the physician’s ethical commitment to seek a safe discharge for all patients. Physicians should not discriminate in the care that they provide.[32] “The existence of a genuine medical need,” and not the patient’s immigration or social status, “constitutes a moral claim on those equipped to help.”[1] Physicians should negotiate even difficult limitations with the patient’s safety in mind.

Physicians should, of course, assess the patient’s medical stability and readiness for discharge to another care environment and for a long international trip (during which patients may be prone to dehydration or respiratory illness[33]). Relative to a local discharge, an international discharge may require additional efforts to coordinate care effectively, such as speaking with the receiving physician through an interpreter or seeking reliable information about the standard of care at the facility in question. For patients with extensive care needs, the physician should keep in mind that many countries throughout the world are struggling to provide even basic medical care for their citizens, and are unlikely to be able to provide resource intensive care with public funds.[26] Regardless of whether or not the discharging hospital itself is the best environment for the patient’s needs,[25] the physician should not discharge the patient to care conditions that are inadequate to his or her needs.

Throughout the discharge process, physicians should listen to the concerns of future caretakers and to the preferences of a patient who is not a citizen or legal resident just as they would when planning the discharge of a citizen patient. The physician should consider the caretakers’ and patients’ understanding of the standards of care in their country of citizenship and the social attachments (such as employment or other support systems) that the patient may have in the US, for example. These considerations may be important when physicians assess the adequacy of future care arrangements for the patient. Moreover, the caretakers’ and patient’s involvement in the discussions may very well lead to a helpful consensus about what ought to be done.

Consular offices of the patient’s country of origin may be able to assist in this challenging process. While the resources available to staff vary from consulate to consulate, engaging the consulate early in the process may reveal resources of which health care professionals, patients, and families were not aware. The Consulate of Mexico, for example, maintains “health stations” in 17 states in the US to assist in providing health care and other resources for Mexican nationals in this country and to help coordinate discharge planning or resources at a receiving facility.[41]

Addressing tension between the needs of an individual patient and broader societal needs to ensure that resources are used prudently can be particularly challenging when discharge decisions involve a noncitizen who will be returned to his or her country of origin. To the extent that uncompensated care is at issue, physicians may need to be sensitive to administrators’ concerns about the hospital’s financial viability. The costs for hospitals to provide uncompensated long-term care for even “a few” patients can be significant, reaching up to $2 million a year according to one New York City hospital.[25] Hospital administrators have used such costs and their duties to stewardship to justify potentially unsafe discharge practices in the past.[25,26] To be sure, physicians should consider that the hospital’s existence benefits other patients and the economy of an entire community[34] and thus should not prescribe: (1) medically unnecessary interventions;[35,36] or (2) interventions that would unfairly deny care to other patients.[37] However, unless an uninsured noncitizen immigrant’s care at the hospital meets either criterion, a physician should maintain the primacy of the patient’s safety over the hospital’s resource concerns.

Therefore, when asked by hospital administrators to discharge an uninsured, noncitizen immigrant patient to an inadequate facility on the basis of limited resources, physicians should carefully examine the arguments for potential harm to the hospital and in turn, other patients. Ideally, physicians should request that the current treating facility demonstrate a causal link between continuing to provide resource intensive care for one or a few patients and the likelihood of disproportionate harm to other patients. But physicians should be aware that this is often difficult, if not impossible, for hospital administrators to show. A patient’s care is likely to be absorbed by the broader operations of the hospital and is unlikely to affect the care provided to other patients in a direct or clearly
identifiable manner. Nonetheless, the case for overriding an individual patient’s safety with the concerns of the hospital must be objective, defensible and ethically compelling.

Despite efforts to fulfill all the responsibilities of a safe discharge practice, in the end, physicians may be unable to make an ethically satisfying decision. Even if a patient is medically ready for discharge and administrators insist that an adequate facility is available, patients and their families may continue to object, thereby creating a stalemate situation. Physicians should then support the patient’s right to seek input from an ethics committee that is independent from the hospital’s administrative functions. Should consensus fail even after such input, a physician should support a patient’s right to seek arbitration before a legal body.[23] Forcing an immigrant to leave the US is a prerogative of the federal government, and should only occur following due process, in which the immigrant’s legal options are exhausted.[23,28] Physicians should not allow hospital administrators to use their significant power and the current lack of regulations on medical repatriations to unilaterally discharge patients abroad.[23] Such patient advocacy is consistent with the physician’s pledge to seek the patient’s safety.

RESPONSIBILITY TO SUPPORT SAFE DISCHARGE ENABLING POLICIES

The challenges associated with discharging uninsured immigrant patients with long-term post-hospital needs are complex. Physicians cannot expect hospitals to provide costly uncompensated care to an indefinite number of patients for indefinite lengths of time. But neither should physicians allow hospitals to arbitrarily determine the fate of an uninsured noncitizen immigrant patient. Resolving this issue will require the collective involvement of various stakeholders in health care, including physicians, health care facilities, insurers, policymakers, and the public.[39] Physicians should participate in the policy development process by supporting proposals that will benefit patients and are consistent with the ethical principles on which the medical profession is established. They should work to ensure that societal decisions about discharge and long-term care safeguard the interests of all patients,[40] including noncitizen immigrant patients who are socially, politically, and economically disadvantaged.

RECOMMENDATION

The Council on Ethical and Judicial Affairs recommends that the following be adopted in lieu of Resolution 4-I-08 and that the remainder of this report be filed:

Physicians’ primary ethical obligation to serve their patients’ needs encompasses an obligation to help ensure a discharge plan that is safe for the patient, including but not limited to medically appropriate care setting and safe transportation. The plan should be developed without regard to socioeconomic status, immigration status, or other clinically irrelevant considerations. However, physicians should also use health care resources responsibly, and therefore it is permissible to consider economic arguments favoring discharge of a medically stable patient whose continued hospitalization is likely to compromise the care of other patients. As advocates for their patients, physicians should resist any discharge requests that are likely to compromise a patient’s safety.

To ensure a patient’s safe discharge from an inpatient unit, including discharge to caregivers outside the US, physicians should:

(a) Determine that the patient is medically stable and ready for discharge from the treating facility;

(b) Collaborate with those health care professionals and others who can facilitate a patient discharge to establish that a plan for medically needed care is in place;

(c) Advise a patient and/or family unwilling to accept a hospital discharge plan to seek an ethics consultation or utilize other available dispute resolution resources; and

(d) Not knowingly compromise the patient’s opportunity to seek protections under US law when the proposed discharge would result in an unwanted repatriation.

REFERENCES


13. 42 C.F.R. § 482.43(d).


3. PHYSICIAN STEWARDSHIP OF HEALTH CARE RESOURCES

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

**HOUSE ACTION:** REFERRED

US health care spending reached 17.6 percent of gross domestic product (GDP) in 2009,[1] almost double that of other industrialized countries.[2] This level of spending presents an enormous burden for federal and state governments, businesses, families, and individuals.[2] The high cost of health care imperils access to care,[3,4] and access is likely to worsen if costs continue to outpace incomes.[5] Since physicians’ recommendations and decisions for patients and organizations greatly affect health care spending, physicians need to be prudent stewards of health care resources. Physician stewardship is the provision of effective medical care through the prudent management of public and private resources. Wise stewardship promotes beneficence by means of carefully reasoned, evidence-based medical decision making.[6]

Physicians’ primary ethical obligation, of course, is to protect and promote the well-being of individual patients (Principle VI, *AMA Principles of Medical Ethics* [AMA Policy Database]). It has long been recognized, however, that physicians also have a responsibility to patients in general, to promote the public health (Principle VII), and promote access to care for all patients (Principle IX). This report by the Council on Ethical and Judicial Affairs (CEJA) briefly examines the role physician treatment decisions play in overall health care costs and analyzes the nature of physicians’ obligation of stewardship. It provides ethical guidance to support physicians in making fair, prudent, cost-conscious decisions for care that meet the needs of individual patients and help to ensure availability of health care for others.

The Council emphasizes that its focus is not on triage decisions, in which multiple patients compete for a clearly defined set of limited resources—e.g., in a pandemic or natural disaster. Decision making under such conditions has been discussed at some length in the literature and is addressed in Opinion E-9.067, “Physician Obligation in Disaster Preparedness and Response.”

Nor does this report focus solely on “high stakes” decisions about interventions that can mean life or death for patients or forestall extremely poor outcomes, such as decisions to initiate mechanical ventilation in emergent circumstances when the patient’s prognosis is uncertain. Arguably, in situations when there is significant risk of harm, cost considerations, if they play a role at all, are better addressed through collectively designed policy than left to individual decisions physicians must grapple with at the bedside. Physicians have unique expertise to judge the potential outcomes of interventions, including in “high stakes” situations. Given physicians’ ethical obligation to benefit and advocate for patients, however, when serious harm might befall a patient if an intervention is withheld, judgments about the cost-worthiness of those interventions should generally be avoided.

In this report, the Council emphasizes the much larger range of less dramatic, everyday situations that are often overlooked, in which physicians’ choice of one among several reasonable alternatives can affect the availability of resources across the community of patients or the aggregate cost of care in the community. For example, a serum pregnancy test costs substantially more than a urine pregnancy test, but for the majority of patients does not provide significant additional benefit. Similarly, some patients with hypertension should be seen frequently, but not every patient with hypertension requires this level of care or is likely to benefit significantly from it. Nor does MRI always offer sufficient incremental benefit over ultrasound imaging so as to be unequivocally appropriate for all patients being evaluated for breast cancer.
TREATMENT DECISIONS, HEALTH CARE SPENDING AND BENEFIT TO PATIENTS

Numerous factors drive the overall cost of health care, many of which are beyond the control of individual physicians. These include high administrative costs,[2,7] population trends (such as aging or obesity[2]); malpractice liability costs; patient expectations and demands; and high prices of drugs, devices, and hospital and professional services.[2,7] Other cost drivers, however, such as extensive use of technologies,[8] and high intensity of services provided at each patient encounter,[2,7] are influenced by physician choices.

Physician orders and recommendations play a significant role in determining which services and how many services patients receive; without a physician’s assent clinical orders or policies generally cannot be implemented.[9] To this extent, physicians have an opportunity to affect health care spending overall. Documented regional variations in Medicare spending are explained in part by variations in physician practice patterns.[10,11] Higher spending regions and institutions have been shown to have higher intensity care, greater use of hospitals and intensive care units, and more utilization of specialists, tests, and minor procedures.[12-14] Practice differences seem to be less for interventions for which there are established guidelines, and more for the “discretionary” interventions that physicians recommend.[11]

More intensive and/or costlier services do not necessarily lead to better health outcomes.[12-17] In fact, lower spending regions appear to have better outcomes on certain measures such as those developed by the Medicare Quality Improvement Organization.[8,10,15,17,18] In many domains, the services that yield the greatest benefits to health are not the factors that drive up costs, and the services that tend to drive up costs are not the ones that yield the greatest benefits to health, at least when measured at the population level.[18]

Stewardship as an Obligation of Professional Ethics

Some argue that physicians should never allow considerations other than the welfare of the patient before them to influence their professional recommendations and treatment.[19,20] This perspective does not mesh with the reality of clinical practice, however. Physicians regularly work with a variety of limits on care: clinical practice guidelines, patient preferences, availability of certain services, the benefits covered by a patient’s insurance plan, and the time physicians and nurses can spend caring for a patient all influence what interventions physicians recommend and what care they provide.

Nor does focusing exclusively on patient interests precisely reflect the ethical expectations of the profession, as physicians’ obligation to benefit the individual patient is not absolute.[21-23] Physicians have obligations to protect public health and safety, even if this might require restricting the liberties of individual patients (Opinion E-2.25, “The Use of Quarantine and Isolation as Public Health Measures”; Opinion E-2.24, “Impaired Drivers and Their Physicians”). Similarly, the Code of Medical Ethics recognizes that without compromising their primary obligation, physicians should be conscious of the costs of care (Opinion E-2.09, “Costs”), that they should consider the needs of broader patient populations (Opinion E-8.054, “Financial Incentives and the Practice of Medicine”), and that they should not provide treatment that is “willfully excessive” (Opinion E-4.04, “Economic Incentives and Levels of Care”).

The ethical obligation of stewardship—i.e., the responsibility to manage wisely the health care resources with which physicians are entrusted[6]—is compatible with physicians’ fundamental ethical commitment to serve the interests of patients, since all patients (and prospective patients) have an interest in keeping health care affordable. Historically, medicine as a learned profession has been understood to have a social responsibility to use knowledge and skills to enhance the common good,[24] and its authority rests on fulfillment of commitments to service and leadership in the public interest.[25]

Medical Liability

The professional responsibility and ethical duty to practice medicine in a manner that is respectful of the finite nature of health care resources does not confer a legal duty to withhold or administer any particular treatment or diagnostic procedure. Rather, responsible stewardship upholds the principle that clinical expertise should be integrated with the best information from scientifically based, systematic research and applied in light of the patient’s values and circumstances.[26]
THE ROLE OF STEWARD

Physicians regularly confront the effects of the uneven or unfair distribution of health care resources in their day-to-day practice. Physicians express moral distress about having to provide different levels of care for those who are uninsured or grossly underinsured than they do for patients with adequate insurance coverage. In addition, physicians witness the adverse consequences for their patients when needed resources (e.g., particular specialists, hospital beds, imaging equipment) are too scarce.[27] As frontline providers, physicians are in a position to identify unacceptably restricted resources in their community, as well as to identify unjust or discriminatory practices, for instance when patients are treated differently based not on medical need but on morally irrelevant characteristics, such as race or ethnicity, type of disease, or financial resources. Physicians' knowledge of what care their patients need (and how urgently they may need it), along with their firsthand experience with the consequences for patients when those needs are not met, means physicians can well appreciate the importance of allocating health care resources responsibly.

As prudent stewards, physicians have a responsibility and an opportunity to seek a fairer distribution of finite health care resources. Patients’ medical need should be the primary basis on which health care services are distributed (E-2.035, “Futile Care”; E-2.19, “Unnecessary Medical Services”; E-4.04, etc.), and physicians’ knowledge and skills therefore must inform the distribution of resources. Even the most evidence-based guidelines cannot take into account the tremendous variety found when caring for patients.[28] A guideline that suggests a particular service is not “needed” may be well justified for most patients, but physicians will inevitably care for patients who qualify as clinically legitimate and ethically justifiable exceptions.

Similarly, for a specific patient, guidelines or standards of care might describe services that are unnecessary because of individual patient details. For example, current quality measures stipulate the frequency of lipid testing and use of lipid-lowering medication for diabetics. However, as is often mentioned in guidelines, co-morbid conditions (e.g., a life-limiting disease not related to diabetes or heart disease) can justify less testing or discontinuation of medication. Conversely, younger diabetics, who have more years in which to develop end-organ damage, might be treated more aggressively in many ways than older ones, sometimes more aggressively than guidelines (or quality measures) describe for the “average” diabetic. Likewise, screening that may be generally recommended for various cancers (especially slowly developing cancers) may have less clinical value for patients of advanced age or who have significant co-morbidities than for younger or healthier patients, for whom earlier detection and intervention may offer greater clinical benefit or may be better able to bear the burdens of treatment.[29]

Making Cost-Conscious Decisions

There is broad consensus that physicians should first take medical need into consideration when making recommendations and providing care. Physicians are expected to refrain from offering or acceding to patients’ requests for interventions or diagnostic tests that are medically unnecessary (E-2.19) or that cannot reasonably be expected to benefit the patient (E-2.035). Physicians are likewise expected to provide—or advocate vigorously for—interventions that will clearly benefit the patient or clearly avert significant harm. However, between these two ends of the spectrum, physicians face decisions about whether to recommend or provide interventions that offer some increment of benefit, but which perhaps pose additional risks or substantial additional financial cost.[29] It is in this grey zone of marginal benefit that principles for wise stewardship should help shape decisions about care.

Taking cost (or limited resources—e.g., hospital beds, nurse time) into consideration as one factor when considering alternatives is ethically appropriate. Making cost-conscious decisions is not far removed from the professional judgments physicians already make. Physicians routinely decide whether interventions with small benefits are worthwhile, whether diagnostic tests need to be STAT or routine, whether a patient needs to be seen urgently or routinely, whether the public health impact of a broad spectrum antibiotic is justified for a certain infection, and whether patient requests for expensive interventions are justified.[30-31]

Well-designed clinical practice guidelines, such as those available through the National Guideline Clearinghouse,[32] or quality measures, such as those developed by the AMA-convened Physician Consortium for Performance Improvement® (“PCPI”),[33] should provide a baseline for treatment recommendations. But guidelines should never simply supplant professional judgment. Physicians have a responsibility to argue for the course of care they judge most appropriate for their individual patients based on patients’ unique clinical circumstances (e.g., E-8.13, “Managed Care”; E-8.135, “Cost Containment Involving Prescription Drugs in Health
Care Plans”; E-4.04), including advocating for services not considered “standard” when a patient’s circumstances warrant the service, and forgoing interventions recommended by guidelines when the patient’s particular circumstances mean the service is not as beneficial.

When guidelines are not available, determining whether a particular intervention is worthwhile for an individual patient necessarily rests heavily on physicians’ professional judgment. Such determinations may differ from patient to patient and for an individual patient as his or her clinical situation changes. To the extent that physicians’ primary task at each patient encounter is to heal, physicians should judge the necessity of an intervention based on its ability to cure, to relieve suffering, or to cultivate health—but always to care.[34]

Reasonable criteria to guide cost-conscious decisions in routine care include the likelihood of benefit for the patient and the anticipated degree and duration of benefit, including change in quality of life (E-2.03, “Allocation of Limited Medical Resources”). Physicians should be aware of the relative strength of the evidence for the anticipated benefit. As noted above, nonclinical considerations, such as the patient’s ethnicity, nationality, gender, or socioeconomic status should not play a role in physician decision making (E-9.12, “Patient-Physician Relationship: Respect for Law and Human Rights”; E-9.121, “Racial and Ethnic Health Care Disparities”). Where age is clinically relevant it can justifiably play a role in judgments about anticipated benefit.

While the default presumption is that physicians should honor patients’ wishes with respect to treatment (E-10.01, “Fundamental Elements of the Patient-Physician Relationship”), patient values and preferences should be balanced against considerations of stewardship. Patients with health care insurance rarely face the entire cost of their care, and in any individual situation they may not recognize or value the need to restrain spending. When patients or their families argue for an intervention the physician deems to offer marginal benefit, physicians should strive to help patients and their families form realistic expectations about whether the intervention is likely to achieve their goals.

For example, a particular patient or family might request off-label use of an expensive chemotherapeutic agent as an adjunct to standard therapy.[35] Physicians should be mindful that patient expectations for particular treatments or procedures can be shaped by many influences, including the advice of family and friends, online information, direct-to-consumer advertising,[36,37] and, of course, a wish to do “something” that might increase their overall survival. Many of these influences are not tailored to the patient’s immediate clinical needs, and naturally most are not sensitive to considerations of cost or fairness.

Physicians should take the time to be transparent and honest in counseling patients about alternatives—including less costly care—instead of deferring to patients’ requests for care that are not consistent with the physician’s considered professional judgment. Honesty and transparency are critical to maintaining patient trust; patients are vulnerable and rely heavily on the physician’s competence and good will.[38] In today’s busy practice environment, it may be expedient for physicians simply to provide what a patient asks for regardless of medical need. Yet such expediency does not serve patient interests well, because it often does not lead to more efficient or higher quality care.

Physicians should make all reasonable efforts to resolve persistent disagreements about whether a particular treatment or procedure is cost worthy in the patient’s situation. Physicians should consider consulting with a colleague or seeking an ethics consultation, for instance. If all efforts to resolve the disagreement fail, the patient may wish to seek care elsewhere. While it may be justifiable to terminate the patient-physician relationship, this should be a last resort and appropriate measures should be taken to ensure continuity of care (Opinions E-8.115, “Termination of the Patient-Physician Relationship”; E-8.11, “Neglect of Patient”; E-10.01, “Fundamental Elements of the Patient-Physician Relationship”).[39-41] Physicians are under no obligation to provide interventions simply because patients request them (E-2.035).

BEYOND INDIVIDUAL PHYSICIANS’ RESPONSIBILITIES

Thus far we have examined physicians’ obligation of stewardship as individual professionals. But physicians cannot and should not be expected to resolve the challenges of wisely managing health care resources and rising health care costs solely “at the bedside.” Medicine as a profession has an equal obligation to engage those challenges at the level of policy, and to help create conditions for practice that make it feasible for physicians to be prudent and trustworthy stewards.
Physicians should become knowledgeable about health care costs and how their individual decisions can affect overall health care spending (H-155,998, “Voluntary Cost Containment”). Education for medical students and practicing physicians alike should include discussion of costs, and health care administrators and organizations should make costs transparent to participating physicians to enable them to make well-informed decisions as stewards.

Many physicians generally recognize an obligation to distribute limited resources responsibly, yet struggle with when and how to take this into account when considering individual treatment decisions.[42] Medicine as a profession along with individual physicians who provide clinical care and health care administrators must strive to re-integrate active commitment to wise, engaged management of health care resources as a fundamental component of ethical professionalism. Medicine must commit itself to nurturing a culture of accountability, in which health care expenditures are directed toward providing high quality care to meet the needs of individual patients in ways that preserve resources to enable physicians to better meet the needs of all.

Physicians collectively must recognize their mutual responsibility to meet the obligation of stewardship. Every physician must be able to trust that the colleagues to whom he or she refers patients will exercise prudent stewardship in making recommendations about a patient’s care. Given the complex structures in which health care is now delivered, responsible stewardship by one will have little overall effect if responsible stewardship is not practiced by all.

**RECOMMENDATION**

The Council recommends that the following be adopted and the remainder of this report be filed:

Physicians have responsibilities to promote public health and access to health care as well as to promote the well-being of their individual patients. These responsibilities require physicians, in conjunction with other healthcare professionals, to be prudent stewards of limited health care resources. This ethical obligation to manage health care resources responsibly is compatible with the professional commitment to serve the interests of individual patients. In routine clinical practice, physicians regularly work within resource constraints. While the patient’s best interests are paramount, physicians must be attentive to the impact of their decisions on shared societal resources.

Physicians should:

(a) Commit to practice responsible stewardship, including addressing patient-related, organizational, and systemic barriers to cost-conscious decision making;

(b) Work with patients to identify their goals of care and help patients and their families form realistic expectations about whether a particular intervention is likely to achieve their goals;

(c) Endorse treatment recommendations that are based on medical need and offer reasonable likelihood of medical benefit;

(d) Use empiric data when available to inform professional treatment decisions;

(e) Seek interventions or services that in the physician’s best professional judgment will substantially benefit the patient without placing undue burdens on health care resources;

(f) Be transparent about alternatives, including disclosing when resource constraints play a role in decision making; and

(g) Participate in efforts to resolve persistent disagreement about whether a costly intervention is worthwhile, which may include second opinions, ethics committee, or other appropriate resources.

Physicians are in a unique position to affect health care spending. But individual physicians cannot and should not be expected to address the systemic challenges of wisely managing health care resources. Medicine as a
profession must create conditions for practice that make it feasible for individual physicians to be prudent stewards by:

(h) Ensuring that physician education enables physicians to be informed about health care costs and how their behavior can affect overall health care spending;

(i) Encouraging health care administrators and organizations to make cost data transparent (including cost accounting methodologies) so that physicians can exercise well-informed stewardship; and

(j) Advocating for policy changes that address systemic barriers that impede physicians in fulfilling their desire to be good stewards.

REFERENCES


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4. SOCIETAL AND ETHICAL CONSEQUENCES OF A FIVE-YEAR BLOOD DONATION DEFERRAL POLICY FOR MEN WHO HAVE HAD SEX WITH MEN

Informational report. No reference committee hearing.

HOUSE ACTION:  FILED (INFORMATIONAL)

Directive D-50.997 (AMA Policy Database) instructs the American Medical Association (AMA) to work with relevant organizations and agencies to “analyze the societal and ethical consequences of a shift to a five-year deferral policy for blood donation from men who have sex with men [MSM].” AMA Policy H-50.974, Revision of the Lifetime Deferral for Blood Donation of the Men Who Have Sex with Men (MSM) Population, recognizes that existing scientific evidence and risk assessment models support a shift to a five-year deferral policy.

After a thorough review of the literature and of current policies regarding deferrals of blood donation, the Council on Ethical and Judicial Affairs (CEJA) has concluded that the request to analyze deferral of blood donation by MSM raises broader ethical questions about policies and practices for ensuring the safety of the blood supply. A strong ethical analysis of this broader scope should examine the following main issues:

- how deferral is used as a strategy to protect the blood supply with respect to bloodborne pathogens and risk behaviors;
- what is or is not an ethically acceptable level of risk in terms of blood safety; and
- what makes a particular level of risk ethically acceptable or unacceptable.

Directive D-50.997 requested that a report be presented to the AMA House of Delegates at its 2011 Annual Meeting. However, to ensure sufficient opportunity to adequately explore these far-reaching issues with other interested parties, CEJA will continue its deliberations and submit its final report at a later time.
5. AMENDMENT TO OPINION E-2.146, “CLONING FOR BIOMEDICAL RESEARCH”

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

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS EDITORIALLY CORRECTED BY CEJA AND REMAINDER OF REPORT FILED

See Policy E-2.146.

Organized Medical Staff Section (OMSS) Resolutions 1, “AMA Opposition to Embryonic Stem Cell Research,” and 15, “Stem Cell Research,” were referred to the OMSS Governing Council (GC) for deliberation at the 2009 Annual Meeting. The OMSS GC believed that these issues would be most appropriately addressed by the Council on Ethical and Judicial Affairs (CEJA).

Both resolutions asked the American Medical Association (AMA) to support specific positions on stem cell research. OMSS Resolution 1 asked that the AMA promote the scientific truth that an embryo is not property but rather is a human being with all the attendant rights; not support embryonic stem cell research as it results in the termination of human life; seek legislative support to restore Executive Order 13455, which was revoked by the current Administration; oppose therapeutic cloning as a way of producing embryonic stem cells with a predetermined genetic patrimony in order to overcome the problem of immune system rejection; and oppose the use of stem cells for selecting the genetic characteristics of offspring.

OMSS Resolution 15 asks that the AMA support President Obama in his consideration of: the ethical issues relating to embryonic cell research; policy to restrict federal funding of research involving human cloning; policy to restrict federal funding of stem cell research that creates human embryos for the sole purpose of research.

The Council reviewed the resolutions along with AMA’s related ethics policy, most relevant being Opinion E-2.146 (AMA Policy Database), “Cloning for Biomedical Research.” CEJA concluded that in order to respond to both resolutions, the Opinion needed clarification and updating to reflect the current state of scientific research.

AMA POLICY

The AMA has House of Delegates policy on stem cell research. Policy H-460.915, “Cloning and Stem Cell Research,” states that the AMA: (1) supports biomedical research on multipotent stem cells (including adult and cord blood stem cells); (2) supports the use of somatic cell nuclear transfer technology in biomedical research (therapeutic cloning); (3) opposes the use of somatic cell nuclear transfer technology for the specific purpose of producing a human child (reproductive cloning); (4) encourages strong public support of federal funding for research involving human pluripotent stem cells; and (5) will continue to monitor developments in stem cell research and the use of somatic cell nuclear transfer technology.[1]

Policy Related to Stem Cell Research

In its 2003 report on cloning for biomedical research, CEJA noted that:

Different types of recommendations have been made to restrict research on stem cells from cloned human embryos. Some have asked that stem cell research be restricted to less controversial sources, such as adult stem cells, which have shown increasing promise. They maintain that these limits would put an end to the unjustified destruction of early forms of human life. For example, a majority on the President’s Council on Bioethics (PCB) recommended a moratorium on research on stem cells derived from cloned human embryos. In the absence of specific criteria that would result in the lifting of the moratorium, this proposed suspension of research has been likened to a recommendation for a ban.

Others maintain that research using stem cells derived from cloned embryos should be undertaken only if no less controversial approach exists that is equally promising. In fact, given the technical difficulties that somatic cell nuclear transfer (SCNT) presents, this restriction already is a reality of laboratory life. The scientific community is using SCNT to produce embryos only for research identified as uniquely promising.

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Several governmental bodies, including the National Bioethics Advisory Commission (NBAC) and the 1994 National Institutes of Health Human Embryo Research Panel (HERP) have proposed restrictions on federal funding of research on stem cells from human embryos deliberately created for research, including those created through SCNT. However, these restrictions would not prohibit the research itself, which could be undertaken in the private sector. In fact, NBAC’s recommendation was to be reconsidered if research in the private sector showed great promise.

It is important to acknowledge that the recommendations of HERP, NBAC, and the PCB were never enacted into law and have been used only for advisory purposes.

In August 2001, President Bush announced a decision to limit federal funding to research on approximately 60 genetically diverse embryonic stem cell lines already in existence in the federal registry, which excludes any lines that were derived with private funds. In fact, currently only nine cell lines currently meet the eligibility criteria for federally funded research and are available to scientists. In addition, all of them were exposed to mouse feeder cells as part of the cultivation process, raising some of the same ethical issues as xenotransplantation. Finally, under the President’s decision, federal funds could not be used to further any of the uniquely promising goals of cloning-for-biomedical-research.[2]

FEDERAL & STATE POLICY

Federal regulations regarding research with embryonic stem cells are currently in flux. On March 9, 2009, President Barack Obama issued Executive Order (EO) 13505, “Removing Barriers to Responsible Scientific Research Involving Human Stem Cells,” which revoked President Bush’s August 2001 policy.[3] EO 13505 and the subsequently released NIH Guidelines for Human Stem Cell Research allowed for federal funding of research on newly created stem cell lines.[4] However, the other three components of the Bush policy remained intact: a cell line may be derived only from an embryo left over from the in vitro fertilization (IVF) process, there must be no financial inducements in obtaining the embryo, and informed consent must be obtained from the embryo donor. Some in the scientific community are concerned that continuing to restrict federal funding to lines created from donated embryos left over from infertility treatment significantly impedes research, given that there are other significant sources of embryos that could be used to establish disease-specific stem cell lines: parthenogenesis, SCNT, and embryos created through IVF specifically for research.[4] On August 22, 2010, the Federal District Court for the District of Columbia issued a temporary injunction halting federal spending for research involving embryonic stem cells in a lawsuit alleging that EO 13505 made it more difficult for researchers using adult stem cells to compete for federal research grants.[5]

State laws vary widely with regard to their stance on research with embryonic stem cells. The primary sources for embryonic stem cells are existing stem cell lines, aborted or miscarried embryos, embryos left over from in vitro fertilization, and cloned embryos. Individual states may permit or restrict research on cells from each of these sources.[3]

Whereas eight states have statutes that promote stem cell research, one state, South Dakota, forbids research on any embryo regardless of the origin. Likewise many states restrict research on aborted fetuses or embryos and half restrict their sale.[3] Louisiana is the only state that banned research on IVF embryos; five states prohibit research on cloned embryos. Several states limit the use of state funds for identified aspects of stem cell research, though more states have specifically authorized funding for such research.[3]

STATE OF THE SCIENCE

The National Institutes of Heath defines stem cells as “cells with the ability to divide for indefinite periods in culture and to give rise to specialized cells.”[6] There are two major categories of stem cells, adult stem cells and embryonic stem cells. Adult stem cells are sometimes referred to as nonembryonic stem cells and are “a relatively rare undifferentiated cell found in many organs and differentiated tissues with a limited capacity for both self renewal (in the laboratory) and differentiation. Such cells vary in their differentiation capacity, but it is usually limited to cell types in the organ of origin. This is an active area of investigation.”[6] Cord blood and some fetal tissues also contain adult stem cells.
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**Adult Stem Cells**

Bone marrow (which contains a type of adult stem cells) has been in clinical use for over 40 years, mostly transplanted to treat blood disorders.[7] Similarly, cord blood stem cells have been used for the past 15–20 years.[7]

Although research with adult stem cells dates back to the 1950s, there continues to be debate in scientific community over the capabilities and limitations of these types of stem cells, particularly if stem cells found in one tissue can give rise to cell types in different tissue. There has been disagreement whether embryonic stem cells may have clinical advantages over adult stem cells; however, in recent years scientists working with adult stem cells have acknowledged that adult stem cells had limitations and could not replace embryonic stem cells in all situations.[8]

Clinical trials have explored using adult stem cells to treat ischemic heart disease, spinal cord lesions, nonunion of fractured bones, Parkinson’s disease, Huntington’s disease, and type 1 diabetes, among other conditions.[7] Although some trials have yielded promising results, it will likely be several years before adult stem cells will be utilized in these clinical settings.

In 2007, scientists identified techniques that would allow some specialized adult human cells to be genetically reprogrammed to assume a stem-cell-like state. Although these “induced pluripotent stem cells” (iPSCs) meet the defining criteria for pluripotent stem cells, the NIH notes that “it is not known [whether] iPSCs and embryonic stem cells differ in clinically significant ways.”[9] While iPSCs have already become important tools in drug development and disease modeling, it will be years before they can be used therapeutically. Current techniques for inducing pluripotency require integration of foreign DNA, and thus transplantation of iPSCs into humans is currently not possible.[10]

**Embryonic Stem Cells**

The second major category of stem cells is that of embryonic stem cells. Whereas research and therapy using adult stem cells has a proven track record, that is not the case with embryonic stem cells, for which bench and clinical science lags by decades. Embryonic stem cells are defined by the NIH as “undifferentiated cells derived from a 5-day preimplantation embryo that are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers.”[6] Embryonic stem cells are thought to have the greatest clinical application due to their ability to differentiate and regenerate.[7,8]

The first embryonic stem cell line was established in 1998 and the first-ever human trial of a medical treatment derived from embryonic stem cells was approved in the United States in 2009 for research into the treatment of spinal cord injuries.[7,11] Potential risks are great and include spontaneous and uncontrolled cellular differentiation, tumorogenesis and the potential for transmission of genetic abnormalities.[8] Other risks include immunological reaction or rejection, unpredictable cell behavior, and unknown long-term health effects.[12] Although clinical trials are underway to examine tolerability of therapy using embryonic stem cells, if these trials are successful it will likely be many more years before therapies are available outside of the research setting.[13]

**ETHICAL ISSUES**

Ethical concern has often focused solely on the source of stem cells. Much of the controversy surrounding biomedical research with stem cells is generated by the use of human embryonic stem cells and the plurality of views in our society regarding the moral status of early embryos. Concern is exacerbated by the fact the current techniques for retrieving stem cells require that the embryo be disaggregated or destroyed. This question of moral status cannot be answered by science and decades of moral debate have not yielded consensus.

Whether it is ethical to create embryos for research purposes by means of IVF or SCNT has also been hotly debated. SCNT, also known as cloning-for-biologic-research, involves introducing nuclear material from a somatic cell into an enucleated oocyte. This process yields an embryo that is genetically nearly identical to the donor of the somatic cell: its nuclear DNA is contributed by the nucleus donor, while its cytoplasmic DNA is contributed by the oocyte donor. Current NIH guidelines restrict research to the use of stem cells derived from donated surplus IVF embryos. Even absent the NIH guidelines, the availability of cloned embryos as sources of stem cells is constrained by the fact that to date human embryos have not been derived through SCNT due to difficulties in initiating human embryo development. Moreover it has been difficult to convince women to undergo the process of oocyte donation, with its...
associated dangers, discomforts, and psychosocial risks, without compensation. At present, the National Academy of Sciences recommends against compensating egg donors and two states have outlawed the practice. One state, however, allows compensation commensurate with what a woman would receive for donating eggs for IVF in treatment of infertility.[3]

The use of adult stem cells and induced pluripotent stem cells derived from somatic cells does not pose questions about the moral status of the embryo. However, stem cell research poses other ethical challenges, regardless of the source of stem cells. As with any research involving human biological materials, stem cell research requires a robust process of informed consent. The emerging consensus about the core components of consent for research with biological specimens requires that donors be informed about the specific procedures involved and their risks; what will be done with the biological specimen—in the case of stem cell research; whether an embryo will be created and then destroyed, the intention to derive immortal cell lines for subsequent use in research and, possibly, therapeutic contexts; and primary and secondary uses (when known) of specimens. Informed consent should also address donors’ rights to restrict use of their biological materials to only specified purposes, what will happen should they withdraw their consent, potential recontact, and donors’ “reach through” rights with respect to commercial products that may be developed through use of their biological materials.[12]

Clinical research involving stem cells poses further ethical challenges. As noted above, questions remain about the safety of therapeutic uses of stem cells or stem cell products, particularly embryonic stem cells. Risks include spontaneous and uncontrolled cell differentiation and tumorigenesis and immunological reactions or tissue rejection, the severity and likelihood of which are uncertain, as well as potential unknown long-term health effects.[12]

RECOMMENDATION

The Council on Ethical and Judicial Affairs recommends that Opinion E-2.146, “Cloning for Biomedical Research” (Appendix) be amended by substitution as follows and that the remainder of this report be filed:

Opinion 2.146 – Research with Stem Cells

Human stem cells are widely seen as offering a source of potential treatment for a range of diseases and are thus the subject of much research. Clinical studies have validated the use of adult stem cells in a limited number of therapies, but have yet to confirm the utility of embryonic stem cells.

Physicians who conduct research using stem cells obtained from any source (established tissue, umbilical cord blood, or embryos) must, at a minimum:

a. adhere to institutional review board (IRB) requirements;

b. ensure that the research is carried out with appropriate oversight and monitoring; and

c. ensure that the research is carried out with appropriate informed consent. In addition to disclosure of research risks and potential benefits, at minimum, the consent disclosure should address:

(i) for a donor of cells to be used in stem cell research:

(a) the process by which stem cells will be obtained;
(b) what specifically will be done with the stem cells;
(c) whether an immortal cell line will result; and
(d) the primary and anticipated secondary uses of donated embryos and/or derived stem cells, including potential commercial uses

(i) for a recipient of stem cells in clinical research:

(a) the types of tissue from which the stem cells derive (e.g., established tissue, umbilical cord blood, or embryos); and
(b) unique risks posed by investigational stem cell products (when applicable), such as tumorigenesis, immunological reactions, unpredictable behavior of cells, and unknown long-term health effects.
The professional community as well as the public remains divided about the use of embryonic stem cells for either research or therapeutic purposes. The conflict regarding research with embryonic stem cells centers on the moral status of embryos, a question that divides ethical opinion and that cannot be resolved by medical science. Regardless whether they are obtained from embryos donated by individuals or couples undergoing in vitro fertilization, or from cloned embryos created by somatic cell nuclear transfer (SCNT), use of embryonic stem cells currently requires the destruction of the human embryo from which the stem cells derive.

The pluralism of moral visions that underlies this debate must be respected. Participation in research involving embryonic stem cells requires respect for embryos, research participants, donors, and recipients. Embryonic stem cell research does not violate the ethical standards of the profession. Every physician remains free to decide whether to participate in stem cell research or to use its products. Physicians should continue to be guided by their commitment to the welfare of patients and the advancement of medical science.

Physicians who conduct research using embryonic stem cells should be able to justify greater risks for subjects, and the greater respect due embryos than stem cells from other sources, based on expectations that the research offers substantial promise of contributing significantly to scientific or therapeutic knowledge.

REFERENCES


APPENDIX – E-2.146 Cloning for Biomedical Research

Stem cells derived from cloned human embryos resulting from somatic cell nuclear transfer technology are promising as a potential source of treatment in a wide range of diseases. However, much controversy arises from the necessity to destroy embryos in order to extract their stem cells for use in biomedical research. The conflict centers on the moral status of embryos, a question that divides ethical opinion and that cannot be resolved by medical science.

(1) While the pluralism of moral visions that underlie this debate must be respected, physicians collectively must continue to be guided by their paramount obligation to the welfare of their patients. In this light, cloning-for-biomedical-research is consistent with medical ethics. Every physician remains free to decide whether to participate in stem cell research or to use its products.

(2) Cloning-for-biomedical-research requires appropriate oversight and monitoring. At a minimum, not only is the oversight of an institutional review board required, but also that of a regulatory body, such as the Office for Human Research Protections, to monitor progress in the field, assist in developing relevant guidelines, and ensure that the technique of cloning-for-biomedical-research is used only if uniquely promising.

(3) Informed consent by subjects participating in cloning-for-biomedical-research is governed by standard principles: voluntary participation and disclosure of all relevant risks and benefits to subjects. Disclosure to the donor of the oocyte and the donor of the somatic cell also must include:

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(a) Description of the procurement procedures specific to the donor

(b) Statement of the intention to create a cloned human embryo through introduction of the somatic cell’s nucleus into the enucleated egg for research purposes (and not for transfer to a woman’s uterus)

(c) Acknowledgment that the extraction of stem cells will require the cloned embryo’s destruction

(d) The intention to derive immortal cell lines from the stem cells to be used in research and possibly in therapeutic contexts; primary and secondary uses should be disclosed and individuals should be free to refuse the use of their biological materials for specified purposes

(e) Potential commercial uses and patent or ownership issues (as described in Opinion E-2.08, “Commercial Use of Human Tissue”)

(4) The informed consent process for potential recipients of stem cells derived from cloned embryos should conform with ethical standards outlined in the Council on Ethical and Judicial Affairs’ Opinion E-2.07, “Clinical Investigation,” and address additional disclosures including provenance of stem cells.

(5) Due to the possibilities of contamination by infectious agents from other species and damage to DNA during growth of new tissues and organs, products of cloning-for-biomedical-research raise ethical concerns similar to those surrounding xenotransplantation. Therefore, the informed consent process for potential recipients of these products also should conform to Opinion E-2.169, “The Ethical Implications of Xenotransplantation.” (V)


6. INFORMED CONSENT IN RESEARCH INVOLVING STORED HUMAN BIOLOGICAL MATERIALS (RESOLUTION 1-A-10)

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

HOUSE ACTION: RECOMMENDATIONS ADOPTED IN LIEU OF RESOLUTION 1-A-10 AND REMAINDER OF REPORT FILED


This report responds to Resolution1-A-10, “Patient Confidentiality in Biobanks” which asked the American Medical Association (AMA) to support the development and use of a universal consent form for research that involves a participant’s stored biological materials. The resolution further asked the AMA to adopt as policy certain specific disclosures as part of the informed consent process for such research.

Based on its review of the data available, relevant federal and international policy, and the ethical analysis that informs current AMA policies, CEJA concludes that a universal consent form would not achieve the purpose intended by the directive—specifically, would not ensure that participants who provide samples of tissue, blood, cells, or DNA (“biospecimens”) fully understand that their biological materials may be pooled and stored for potential future research. Moreover, the Council concludes that the salient ethical issues central to the specific disclosures proposed for a universal consent form are appropriately addressed in existing policy.

RESEARCH WITH STORED HUMAN BIOLOGICAL MATERIALS

More than 300 million human biospecimens are stored in the United States in public and private repositories known as biobanks.1,2 Biospecimens are collected in a variety of settings, including routine clinical and surgical procedures, medical and academic research, pharmaceutical treatment and device trials and judiciary proceedings.2,3 The specimens are stored according to type of sample and the setting from which they were collected, creating biobanks that range from small collections of a single type of sample in academic or hospital settings to large-scale, national repositories of diverse samples. Biobanks vary in terms of the quality of specimens and potential to support further uses.3 They also vary with respect to whether their parent institutions are public or private and for profit or nonprofit, as well as their policies and practices regarding access to specimens and the extent to which specimens can be traced to the donor (i.e., whether they are identified, de-identified, or coded). 5 This wide variation is a result of the many purposes for which biospecimens are collected and maintained.
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Biospecimens contain genetic material that can be analyzed to identify gene variants associated with human diseases. For this reason, they are an increasingly important tool for research into human diseases and their genetic and physiological causes. When linked with demographic and environmental information, biospecimens can support population level research into gene-gene and gene-environment interactions for understanding disease.

Three-fourths of clinical trials submitted to the FDA for approval now include a provision for sampling and storing human tissue for future genetic analysis.

Growing ethical and regulatory interest, especially in regards to large biobanks, has been prompted by ongoing innovation in molecular biology and genomics including advances in techniques and computational capabilities, systematic approaches to genomics, and increasing exchange of specimens and information among researchers.

This has resulted in a large number of guidelines from professional societies, including the AMA, as well as national and international regulatory bodies. Multiple policies and regulations now address privacy and confidentiality, disclosure of research results, intellectual property, benefit sharing, biobank governance, and, most importantly for the present analysis, informed consent.

DISCLOSURE & INFORMED CONSENT IN BIOBANKING

Informed consent is a foundational ethical principle in research that involves human participants, just as it is in clinical medicine. In the research setting, the ultimate goal of the informed consent process is to respect human subjects as persons and protect their autonomy by ensuring that sufficient information is provided to enable prospective research subjects to make voluntary, well-informed decisions whether to participate or not. Participants should “have the opportunity to be informed about, evaluate, and consent to the goals of the intended research.”

The nature and scope of consent has been a key focus of debate with respect to research involving biospecimens, particularly in light of the fact that biobanks are intended to maintain specimens long term and to support multiple research activities over time. Questions have been raised about what kinds of information must be disclosed and, importantly, whether individuals can meaningfully consent to future, as yet undesigned, research with their stored specimens. At the time specimens are collected, researchers may not be able to provide specifics about the potential risks, benefits, or other aspects of future research. Consent that is not specific to the research to be carried out is not ethically sufficient.

A variety of professional societies and agencies in the United States have addressed the need for guidelines for informed consent in the context of biobanking, including the American Society for Human Genetics, the Office for Human Research Protections, the Food and Drug Administration, and the National Cancer Institute (NCI), as has the World Medical Association. Such guidelines are meant to supplement and/or clarify existing regulatory requirements for informed consent (45 CFR 46.116) to address the distinctive issues raised in research with biospecimens.

For example, the NCI’s Best Practices for Biospecimen Research notes that “[r]espect for individuals who have provided data or biospecimens for research is of paramount importance” and that their preferences should be considered in seeking consent, within the provisions of applicable law. NCI further notes that the consent document should clearly address use of biospecimens or data by private or for-profit entities, the possibility that the research will lead to commercial products, whether individual or aggregate results will be released and to whom, how data will be stored and used (including whether and how it will be coded and whether it will be linked to clinical data in the individual’s medical record), whether and with what oversight specimens or data will be shared, and potential risks of genetic sequencing or analysis (if applicable). Guidelines further recommend that, as appropriate for study design and resources of the biobank, participants be allowed to specify types of research for which their specimens may be used and whether they are willing to be contacted regarding research in the future. Finally, the consent guidelines recommend that biobanks develop mechanisms to track the records of participants who withdraw and that the consent process “highlight the human subject’s ability to discontinue participation and describe what will take place should this occur.” (Best Practices also addresses technical and operational issues for biobanks, as well as principles of responsible custodianship, privacy, access to specimens and data, and intellectual property and resource sharing.)

As the introduction to Best Practices acknowledges, the many varying types of research that depend on biobanks, its recommendations “are intended to be adapted, as appropriate, based on the mission and scientific needs of
individual biospecimen resources.”\(^7\)

Entities that conduct research with stored specimens under the auspices of the NCE or other agencies are expected to uphold agency guidelines.

Notably, some countries allow for a blanket or general consent process to be utilized, while in the US a tiered or tailored consent form is usually preferred. A tailored consent form offers specific possible uses (such as research specifically related to the individual’s original disease or other named diseases; any further specified research, requiring a separate consent form; or; commercial uses) and asks the donor to select their preferences.\(^12\)

However, this can become problematic when the biospecimens are intended to be used for a broad range of research, in which case providing a list of potential types of research would be burdensome and uninformative.\(^13\)

Since biobanks have global potential, the dichotomy noted is another impediment to the construction of a universally accepted consent form.

**RELEVANT AMA POLICY**

In addition to providing general guidance about informed consent in Opinion E-8.08, “Informed Consent,” which recognizes that a patient’s “right of self-decision can be effectively exercised only if the patient possesses enough information to enable an informed choice,”\(^14\) AMA ethics policy specifically addresses consent (and other) issues in the research setting. For research intended primarily to gain scientific knowledge (as is most research involving biospecimens), Opinion E-2.07, “Clinical Investigation,” requires that physician-investigators obtain participant’s voluntary, written consent following disclosure of relevant information—in the context of clinical research, that the research involves an investigational drug or procedure and a reasonable explanation of the nature of the drug or procedure.\(^15\)

In the context of genomic research involving biospecimens, this can be interpreted to require discussion of the goals of the study and nature of analyses to be conducted, as well as any unique or unusual risks the study may pose for participants. Opinion E-2.08, “Commercial Use of Human Tissue,” provides that physicians contemplating research use of organs or tissues must disclose possible commercial applications of the research and obtain the consent of the tissue donor prior to any commercial use.\(^16\)

Opinion E-2.079, “Safeguards in the Use of DNA Databanks in Genetic Research,” provides that in addition to standard informed consent requirements (those of applicable regulations and of E-2.07), the physician-investigator must disclose the privacy standards that govern the study, i.e., whether and how data/specimens will be coded and if so under what circumstances the subject can expect to be contacted in the future. Subjects must also be informed that they can refuse to allow the use of their biological material, whether investigators stand to gain financially from the research and when and how stored data and specimens will be discarded.\(^4\) E-2.079 further provides that when research is carried out in an “identifiable community” investigators should consult with the community to address potential harms to the community in addition to obtaining consent from individual participants. Finally, the opinion also recommends that to provide greater protection for confidentiality, genomic research not be conducted with identifiable samples.

Policies of the AMA House of Delegates do not specifically address biobanking but do provide for informed consent and protection of confidentiality in clinical and research settings, including the use of de-identified data (H-315.978, “Privacy and Confidentiality”; H-315.983. “Patient Privacy and Confidentiality”). H-460.931, “Genetics Testing Legislation,” opposes legislation that would “unduly restrict the ability to use stored tissue for medical research.” Where obtaining patient consent for disclosure of personal health information is impracticable, as would be the case for subsequent research with de-identified biospecimens, H-315.983 endorses the oversight and accountability provided by an IRB.

**CONCLUSION**

Given regulatory injunctions to tailor disclosure during the informed consent process to the particulars of the research for which a prospective participant’s consent is sought and existing guidance from CEJA and the House of Delegates, CEJA does not support the creation of a universal consent form to be used in all studies involving stored human biological materials. Certain common elements would likely be necessary in any consent for such research; however, a universal form alone cannot sufficiently provide the study-specific information on which adequately informed consent must be based.

CEJA further holds that existing ethics and House policy already require the types of disclosure called for in Resolution 1-A-10. That is, that individuals asked to provide biological samples should be informed about (a) de-
identification; (b) specimen pooling; (c) sharing of specimens outside of the organization conducting the research study; (d) the selling or exchanging of specimens; (e) future commercial use of specimens, and; (f) access, use or consideration by outside entities.

RECOMMENDATION


REFERENCES

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

Informational report. No reference committee hearing.

HOUSE ACTION: FILED (INFORMATIONAL)

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 http://www.ama-assn.org/ama/pub/category/16848.html.

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.

<table>
<thead>
<tr>
<th>Physicians Reviewed</th>
<th>Summary of CEJA Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Determination of no probable cause</td>
</tr>
<tr>
<td>49</td>
<td>Final determinations following a plenary hearing (including no action taken)</td>
</tr>
<tr>
<td>30</td>
<td>Final determinations without a plenary hearing (hearing affirmatively waived, offer of compromise accepted, non-compliance with probationary/monitoring requirements, or non-response to the offer of a hearing)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Physicians Reviewed</th>
<th>Final Determination (by type of action taken)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>No sanction or other type of action</td>
</tr>
<tr>
<td>8</td>
<td>Monitoring</td>
</tr>
<tr>
<td>16</td>
<td>Probation</td>
</tr>
<tr>
<td>24</td>
<td>Revocation</td>
</tr>
<tr>
<td>4</td>
<td>Suspension</td>
</tr>
<tr>
<td>17</td>
<td>Censure/Admonishment/Reprimand</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Physicians Reviewed</th>
<th>Probation/Monitoring Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>24</td>
<td>Members placed on Probation/Monitoring during reporting interval</td>
</tr>
<tr>
<td>8</td>
<td>Probation/Monitoring concluded satisfactorily during reporting interval</td>
</tr>
<tr>
<td>9</td>
<td>Membership revoked based on non-compliance with the terms of probation/monitoring requirement.</td>
</tr>
<tr>
<td>60</td>
<td>Number of physicians on Probation/Monitoring at any time during reporting interval</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Physicians Reviewed</th>
<th>Reports to AMA Staff of Possible Ethical Violations</th>
</tr>
</thead>
<tbody>
<tr>
<td>30</td>
<td>Physicians under consideration by AMA staff for possible notification at end of reporting interval</td>
</tr>
<tr>
<td>125</td>
<td>Approximate number of physicians reviewed who were not brought to CEJA’s attention.</td>
</tr>
</tbody>
</table>

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8. CEJA’s SUNSET REVIEW OF HOUSE POLICIES

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

HOUSE ACTION: RECOMMENDATIONS ADOPTED AND REMAINDER OF REPORT FILED

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

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

At its 2002 Annual Meeting, the House modified Policy G-600.110 to change the process through which the policy sunset review is conducted. The process now includes the following steps:

- In the spring of each year, the House policies that are subject to review under the policy sunset mechanism are identified.
- Using the areas of expertise of the AMA Councils as a guide, the staffs of the AMA Councils determine which policies should be reviewed by which Councils.
- For the Annual Meeting of the House, each Council develops a separate policy sunset report that recommends how each policy assigned to it should be handled. For each policy it reviews, a Council may recommend one of the following actions: (a) retain the policy; (b) rescind the policy; or (c) retain part of the policy. A justification must be provided for the recommended action on each policy.
- The Speakers assign the policy sunset reports for consideration by the appropriate Reference Committees.

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

2001 POLICIES

In this report, the Council on Ethical and Judicial Affairs presents its recommendations regarding the disposition of 2001 House policies that were assigned to or originated from CEJA.

DUPLICATIVE POLICIES

On the model of the Council on Long Range Planning & Development (CLRPD)/CEJA Joint Report (I-01) and of subsequent reports of CEJA’s sunset review of House policies, this report recommends the rescission of House policies that originate from CEJA Reports and duplicate current opinions issued since June 2005. As noted previously, the intent of this process is the elimination of duplicative ethics policies from PolicyFinder. The process does not diminish the substance of AMA policy in any sense. Indeed, CEJA Opinions are a category of AMA policy.

MECHANISM TO ELIMINATE DUPLICATIVE ETHICS POLICIES

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

For example, at the 2007 Interim Meeting, the HOD adopted the recommendations of CEJA Report 8-I-07, “Pediatric Decision-Making.” It was recorded in PolicyFinder as Policy H-140.865. At the 2008 Annual Meeting, CEJA filed the corresponding Opinion E-2.026, thereby generating a duplicative policy. Under the mechanism to eliminate duplicative ethics policies, CEJA recommended the rescission of Policy H-140.865 as part of the Council’s 2009 sunset report.
The Appendix provides recommended actions and their rationale on House policies from 2000, as well as on duplicate policies.

RECOMMENDATION

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

APPENDIX A – Recommended Actions

<table>
<thead>
<tr>
<th>Policy No.</th>
<th>Title</th>
<th>Recommended Action &amp; Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>H-5.988</td>
<td>Accurate Reporting on AMA Abortion Policy</td>
<td>Retain: Policy remains relevant</td>
</tr>
<tr>
<td>H-65.978</td>
<td>Nondiscrimination in Responding to Terrorism</td>
<td>Rescind: Duplicative of Policies E-9.12, E-9.121, E-10.05</td>
</tr>
<tr>
<td>H-140.964</td>
<td>Enforcement of Code of Ethics</td>
<td>Retain: Policy remains relevant</td>
</tr>
<tr>
<td>H-140.967</td>
<td>Conflicts of Interest</td>
<td>Retain: Policy remains relevant</td>
</tr>
<tr>
<td>H-275.976</td>
<td>Boundaries of Practice for Health Professionals</td>
<td>Retain: Policy remains relevant</td>
</tr>
<tr>
<td>H-440.946</td>
<td>Health Care Workers and HBV - Nonresponders to HBV Vaccine</td>
<td>Retain: Policy remains relevant</td>
</tr>
<tr>
<td>H-440.949</td>
<td>Immunity to Hepatitis B Virus</td>
<td>Retain: Policy remains relevant</td>
</tr>
<tr>
<td>H-460.954</td>
<td>Researchers Lending Their Names as Co-authors of Laboratory Findings in Which They Did Not Participate</td>
<td>Retain: Policy remains relevant</td>
</tr>
<tr>
<td>H-520.987</td>
<td>Condemning the Use of Children as Instruments of War</td>
<td>Retain: Policy remains relevant</td>
</tr>
<tr>
<td>H-520.998</td>
<td>Medical Neutrality</td>
<td>Retain: Policy remains relevant</td>
</tr>
<tr>
<td>H-525.987</td>
<td>Surgical Modification of Female Genitalia</td>
<td>Retain: Policy remains relevant</td>
</tr>
<tr>
<td>D-140.980</td>
<td>Pending Federal Executions</td>
<td>Retain: Policy remains relevant</td>
</tr>
<tr>
<td>D-140.983</td>
<td>Restrictive Drug Policies in Public Programs such as Medicaid</td>
<td>Rescind: Policy no longer relevant (Directive accomplished through 2002 update to Policy E-8.135)</td>
</tr>
<tr>
<td>D-140.988</td>
<td>National Advance Care Planning Day</td>
<td>Retain: Policy remains relevant</td>
</tr>
<tr>
<td>D-140.989</td>
<td>Requesting Consent for Invasive Procedures in the Newly Deceased Patient</td>
<td>Rescind: Policy no longer relevant (Directive accomplished through Policy E-8.181)</td>
</tr>
</tbody>
</table>