

OPINIONS OF COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

The following opinions, 1-2, were presented by Leonard J. Morse, MD, Chair:

1. THE USE OF ELECTRONIC MAIL

HOUSE ACTION: FILED

At the 2002 Interim Meeting, the American Medical Association House of Delegates adopted the recommendations of Council on Ethical and Judicial Affairs Report 3-I-02, "Ethical Guidelines for the Use of Electronic Mail between Patients and Physicians." The report offers guidelines to physicians who use electronic mail to communicate with patients and online users. The Council issues this Opinion, which is based on CEJA Report 3-I-02. It will appear in the next version of *PolicyFinder* and the next print edition of the *Code of Medical Ethics*.

5.026 The Use of Electronic Mail

Electronic mail (e-mail) can be a useful tool in the practice of medicine and can facilitate communication within a patient-physician relationship. When communicating with patients via e-mail, physicians should take the same precautions used when sending faxes to patients. These precautions are presented in the following considerations:

1. E-mail correspondence should not be used to establish a patient-physician relationship. Rather, e-mail should supplement other, more personal, encounters.
2. When using e-mail communication, physicians hold the same ethical responsibilities to their patients as they do during other encounters. Whenever communicating medical information, physicians must present the information in a manner that meets professional standards. To this end, specialty societies can provide specific guidance as to the appropriateness of offering specialty care or advice through e-mail communication.
3. Physicians should engage in e-mail communication with proper notification of e-mail's inherent limitations. Such notice should include information regarding potential breaches of privacy and confidentiality, difficulties in validating the identity of the parties, and delays in responses. Patients should have the opportunity to accept these limitations prior to the communication of privileged information. Disclaimers alone cannot absolve physicians of the ethical responsibility to protect patients' interests.
4. Proper notification of e-mail's inherent limitations can be communicated during a prior patient encounter or in the initial e-mail communication with a patient. This is similar to checking with a patient about the privacy or security of a particular fax machine prior to faxing sensitive medical information. If a patient initiates e-mail communication, the physician's initial response should include information regarding the limitations of e-mail and ask for the patient's consent to continue the e-mail conversation. Medical advice or information specific to the patient's condition should not be transmitted prior to obtaining the patient's authorization. (I, IV, VI, VIII)

Issued June 2003 based on the report "Ethical Guidelines for the Use of Electronic Mail between Patients and Physicians," adopted December 2002.

2. SURGICAL “PLACEBO” CONTROLS, *AMENDMENT*

HOUSE ACTION: FILED

Since the Council on Ethical and Judicial Affairs developed its report and corresponding Opinion on “Surgical ‘Placebo’ Controls” in 2000, several articles on the topic have been published in the medical literature, including reports of new studies that relied on this sort of “placebo” controls and commentaries that considered the controls’ ethical appropriateness. Based on a careful review of this new literature, CEJA wishes to clarify Opinion 2.076, “Surgical ‘Placebo’ Controls,” by addressing the use of “placebo” operations in efficacy trials of an existing, accepted procedure. The amended Opinion will appear in the next version of *PolicyFinder* and the next print edition of the *Code of Medical Ethics*.

2.076 Surgical “Placebo” Controls

The term surgical “placebo” controls refers to the control arm of a research study where subjects undergo surgical procedures that have the appearance of therapeutic interventions, but during which the essential therapeutic maneuver is omitted.

The appropriateness of a surgical “placebo” control should be evaluated on the basis of guidelines provided in Opinion 2.07, “Clinical Investigation,” as well as the following requirements:

1. Surgical “placebo” controls should be used only when no other trial design will yield the requisite data.
2. Particular attention must be paid to the informed consent process when enrolling subjects in trials that use surgical “placebo” controls. Careful explanation of the risks of the operations must be disclosed, along with a description of the differences between the trial arms emphasizing the essential procedure that will or will not be performed. Additional safeguards around the informed consent process may be appropriate such as using a neutral third party to provide information and get consent, or using consent monitors to oversee the consent process.
3. The use of surgical “placebo” controls may be justified when an existing, accepted surgical procedure is being tested for efficacy. It is not justified when testing the effectiveness of an innovative surgical technique that represents only a minor modification of an existing, accepted surgical procedure.
4. When a new surgical procedure is developed with the prospect of treating a condition for which no known surgical therapy exists, using surgical “placebo” controls may be justified, but must be evaluated in light of whether the current standard of care includes a non-surgical treatment and the benefits, risks and side-effects of that treatment.
 - (a) If foregoing standard treatment would result in significant injury and the standard treatment is efficacious and acceptable to the patient (in terms of side-effects, personal beliefs, etc.), then it must be offered as part of the study design.
 - (b) When the standard treatment is not fully efficacious, or not acceptable to the patient, surgical “placebo” controls may be used and the standard treatment foregone, but additional safeguards must be put in place around the informed consent process. (I, V)

Issued December 2000 based on the report “Surgical Placebo Controls,” adopted June 2000; updated June 2003.

REPORTS OF COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

The following reports, 1-12, were presented by Leonard J. Morse, MD, Chair:

1. CEJA'S SUNSET REVIEW OF HOUSE POLICIES

HOUSE ACTION: RECOMMENDATIONS ADOPTED AND REMAINDER OF REPORT FILED

At its 1984 Interim Meeting, the House of Delegates established a sunset mechanism for House policies (see Policy H-600.110, American Medical Association Policy Database). Under this mechanism, a policy established by the House ceases to be viable after ten 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 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 H-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 leaders of the AMA Councils determine which policies should be reviewed by which Councils.
- 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.

1992 POLICIES

For this report, the Council on Ethical and Judicial Affairs was assigned and has reviewed policy H-245.984, "Treatment Decisions for Seriously Ill Newborns," which originated from CEJA Report I-A-92 of the same title. The Council finds that this policy is in part duplicative of Opinion E-2.215, but that there is a statement that is not reproduced in the opinion. Therefore, it recommends that the policy be retained in part, as outlined in the Appendix.

DUPLICATE POLICIES

Recently, the Council on Ethical and Judicial Affairs and the Council on Long Range Planning and Development collaborated to eliminate duplicative ethics policies. This resulted in the adoption of CLRPD/CEJA Joint Report at the 2001 Interim Meeting, whereby several House policies originating from CEJA reports that duplicated current opinions were rescinded. As noted in the report, this did not diminish the body of AMA policy in any sense because CEJA opinions are a component of AMA policy.

In this report, CEJA continues the effort to make information on AMA policy more accessible and to increase the readability of the *PolicyFinder*. Specifically, since December 2001, the Council has issued a number of opinions that are duplicative of House policies. It is recommended that these House policies, which originate from CEJA reports, be rescinded.

Also, the Council has reviewed other House policies that originated from CEJA reports, which closely match CEJA opinions but are not exactly the same. The Council has found that many of these House policies should be rescinded, as their corresponding opinions differed in very minor ways. Specifically, the Council found that differences in wording in the opinions provided clarification with respect to the language originally presented but that they did not affect the meaning of a guideline.

Finally, the Council also has found that some House policies originating from CEJA reports should be retained in part since they include statements that are not included in the corresponding opinions.

MECHANISM TO ELIMINATE DUPLICATIVE ETHICS POLICIES

The Council will continue to present reports to the HOD and, subsequent to the adoption of these recommendations, they will continue to be recorded in *PolicyFinder* as House policy. After the corresponding CEJA opinion is issued, CEJA will utilize its annual sunset report to rescind the duplicative House policy.

For example at 2001 Interim Meeting, the HOD adopted the recommendations of CEJA Report 2, "Privacy in the Context of Health Care." It was recorded in *PolicyFinder* as Policy H-140.903. At the 2002 Annual Meeting, CEJA filed the corresponding Opinion E-5.059, thereby generating a duplicative policy. Under the proposed mechanism to eliminate duplicative ethics policies, CEJA recommends the rescission of Policy H-140.903 as part of the Council's 2003 sunset report.

RECOMMENDATIONS

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

1. That the House of Delegates rescind the following policies: H-140.897, H-140.902, H-140.903, H-140.904, H-140.905, H-140.906, H-140.907, H-140.908, H-140.928, H-140.930, H-140.931, H-140.944, H-285.982.
2. That the House of Delegates retain-in-part the following policies, as indicated in the appendix to this report: H-210.984, H-245.984, H-275.952, H-515.983

APPENDIX

<i>Policy Number</i>	<i>Title</i>	<i>Recommended Action and Rationale</i>
H-140.897	Cadaveric Organ Donation: Encouraging the Study of Motivation	Rescind: Duplicative of E-2.151
H-140.902	The Use of DNA Databanks in Genomic Research: The Imperative of Informed Consent DNA Databanks	Rescind: Duplicative of E-2.079
H-140.903	Privacy in the Context of Health Care	Rescind: Duplicative of E-5.059
H-140.904	Performing Procedures on the Newly Deceased for Training Purposes	Rescind: Duplicative of E-8.181
H-140.905	Surrogate Decision Making	Rescind: Duplicative of E-8.081
H-140.906	Filming Patients in Health Care Settings	Rescind: Duplicative of E-5.045
H-140.907	Ethical Considerations in International Research	Rescind: Duplicative of E-2.077
H-140.908	The Patient-Physician Relationship	Rescind: Duplicative of E-10.015
H-140.928	Patient-Physician Relationship in the Context of Work-Related and Independent Medical Examinations	Rescind: Duplicative of E-10.03
H-140.930	The Ethics of Human Cloning	Rescind: Duplicative of E-2.147
H-140.931	Sale of Health-Related Products from Physicians' Offices	Rescind: Duplicative of E-8.063
H-140.944	Patenting the Human Genome	Rescind: Duplicative of E-2.105
H-285.982	Ethical Issues in Managed Care	Rescind: Duplicative of E-8.13

<i>Policy Number</i>	<i>Title</i>	<i>Recommended Action and Rationale</i>
H-210.984	Conflicts of Interest	Retain-in-Part: Retain section 3 of the policy; rescind sections 1 and 2 because they are duplicative of E-8.035
H-245.984	Treatment Decisions for Seriously Ill Newborns	Retain-in-Part: That the following statement be retained, as edited: "Physicians should play an active role in advocating for changes in the Child Abuse Prevention Act as well as state laws that require physicians to violate <u>the ethical guidelines stated in E-2.215 'Seriously Ill Newborns.'</u> " That other sections of H-245.984 be rescinded, because they are duplicative of E-2.215
H-275.952	Reporting Impaired, Incompetent or Unethical Colleagues	Retain-in-Part: Retain sections 5, 7, 8 of the policy; rescind sections 1, 2, 3, 4, and 6 because they are duplicative of E-9.031
H-515.983	Physicians and Family Violence	Retain-in-Part: Retain sections 4, 5, 6 of the policy; rescind 1, 2 and 3 because they are duplicative of E-2.02.

H-210.984 Conflicts of Interest

Update on Home Care: The AMA has adopted the following guidelines:

- ~~(1) Physicians who refer patients to home care providers or any other outside facility should avoid possible conflicts of interest by not accepting payment from those providers or facilities for referrals or as compensation for their cognitive services in prescribing, monitoring, or revising a patient's course of treatment. Payment for these cognitive services is acceptable when it comes from patients, who are the beneficiaries of the physician's services, or from the patients' designated third party payors.~~
- ~~(2) In accordance with the AMA's existing guidelines on self-referral, physicians may refer care facilities in which they have an ownership interest if the physician actively participates on-site in the care provided to the patient. Since the appropriate frequency and duration of physician home visits is a medical decision that should be made on a case-by-case basis, there is no specific minimum number of home visits that may be identified as a conclusive test of the physician's involvement in the patient's home care regimen. However, though different patients will have different needs, physicians who directly provide care in the patient's home on at least every fourth visit may presumptively be considered to have made home care a true extension of practice.~~
- (3) The AMA should continue to urge third party payors to allow for remuneration consistent with the services rendered by physicians involved in treating patients at home. (CEJA Rep. I-93-5; Reaffirmation A-02)

E-8.035 Conflicts of Interest in Home Health Care

Physicians who refer patients to home care providers or any other outside facility should avoid possible conflicts of interest by not accepting payment from those providers or facilities for referrals or as compensation for their cognitive services in prescribing, monitoring, or revising a patient's course of treatment. Payment for these cognitive services is acceptable when it comes from patients who are the beneficiaries of the physician's services, or from the patients' designated third-party payers.

In accordance with Opinion 8.032, "Conflicts of Interest: Health Facility Ownership by a Physician," physicians may refer patients to home care facilities in which they have an ownership interest if they actively participate on-site in the care provided to patients. Since the appropriate frequency and duration of home visits is a medical decision that should be made on a case-by-case basis, there is no specific minimum number of home visits that may be identified as a conclusive test of the physician's involvement in the patient's home care regimen. Although different patients will have different needs, physicians who directly provide care in the patient's home on at least every fourth visit may presumptively be considered to have made home care a true extension of practice. (II, III, IV) Issued June 1994 based on the report "Conflicts of Interest: Update on Home Care," adopted December 1993; Updated 1998.

H-245.984 Treatment Decisions for Seriously Ill Newborns

Physicians should play an active role in advocating for changes in the Child Abuse Prevention Act as well as state laws that require physicians to violate the following ethical guidelines stated in E-2.215 Seriously Ill Newborns.:

- ~~(1) The primary consideration for decisions regarding life-sustaining treatment for seriously ill newborns should be what is best for the newborn. Factors that should be weighed are:

 - ~~(a) the chance that therapy will succeed,~~
 - ~~(b) the risks involved with treatment and nontreatment,~~
 - ~~(c) the degree to which the therapy, if successful, will extend life,~~
 - ~~(d) the pain and discomfort associated with the therapy, and~~
 - ~~(e) the anticipated quality of life for the newborn with and without treatment.~~~~
- ~~(2) Care must be taken to evaluate the newborn's expected quality of life from the child's perspective. Life-sustaining treatment may be withheld or withdrawn from a newborn when the pain and suffering expected to be endured by the child will overwhelm any potential for joy during his or her life. When an infant suffers extreme neurological damage and is consequently not capable of experiencing either suffering or joy, a decision may be made to withhold or withdraw life-sustaining treatment. When life-sustaining treatment is withheld or withdrawn, comfort care must not be discontinued.~~
- ~~(3) When an infant's prognosis is largely uncertain, as is often the case with extremely premature newborns, all life-sustaining and life-enhancing treatment should be initiated. Decisions about life-sustaining treatment should be made once the prognosis becomes more certain. It is not necessary to attain absolute or near absolute prognostic certainty before life-sustaining treatment is withdrawn, since this goal is often unattainable and risks unnecessarily prolonging the infant's suffering.~~
- ~~(4) Physicians must provide full information to parents of seriously ill newborns regarding the nature of treatments, therapeutic options, and expected prognosis with and without therapy, so that parents can make informed decisions for their children about life-sustaining treatment. Counseling services and an opportunity to talk with persons who have had to make similar decisions should be available to parents. Ethics committees or infant review committees should also be utilized to facilitate parental decision making for these decisions. These committees should help mediate resolutions of conflicts that may arise among parents, physicians, and others involved in the care of the infant. These committees should also be responsible for referring cases to the appropriate public agencies when it is concluded that the parents' decision is not a decision that could reasonably be judged to be in the best interests of the infant. (CEJA Rep. I, A-92)~~

E-2.215 Treatment Decisions for Seriously Ill Newborns

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conflicts that may arise among parents, physicians, and others involved in the care of the infant. These committees should also be responsible for referring cases to the appropriate public agencies when it is concluded that the parents' decision is not a decision that could reasonably be judged to be in the best interests of the infant. (I, III, IV, V) Issued June 1994 based on the report "Treatment Decisions for Seriously Ill Newborns," adopted June 1992.

H-275.952 Reporting Impaired, Incompetent or Unethical Colleagues

Physicians have an ethical obligation to report impaired, incompetent, and unethical colleagues. Physicians should be familiar with the reporting requirements of their own state and comply accordingly.

~~(1) Impairment.~~

- ~~(a) Impairment should be reported to the hospital's in-house impairment program, if available. If no in-house program is available, or if the type of impairment is not normally addressed by an impairment program, e.g., extreme fatigue and emotional distress, then the chief of an appropriate clinical service, the chief of staff of the hospital, or other appropriate supervisor (e.g., the chief resident) should be alerted.~~
- ~~(b) If a report cannot be made through the usual hospital channels, then a report should be made to an external impaired physician program. Such programs typically would be operated by the local medical societies or state licensing boards.~~
- ~~(c) Physicians in office-based practices who do not have clinical privileges at an area hospital should be reported directly to an impaired physician program.~~
- ~~(d) If reporting to an individual or program which would facilitate the entrance of the impaired physician into an impaired physician program cannot be accomplished, then the impaired physician should be reported directly to the state licensing board.~~

~~(2) Incompetence.~~

- ~~(a) Initial reports of incompetence should be made to the appropriate clinical authority who would be empowered to assess the potential impact on patient welfare and to facilitate remedial action, e.g., the chief resident, the chief of an appropriate clinical service, the chief of the hospital staff, or the medical director of a group medical practice.~~
- ~~(b) The individual who receives a report of incompetence should, in turn, notify the hospital peer review body where appropriate. Physicians who receive reports of incompetence have an ethical duty to critically and objectively evaluate the reported information and to assure that identified deficiencies are either remedied or further reported to the state licensing board.~~
- ~~(c) Instances of incompetence by physicians who have no hospital affiliation should be reported to the local or state medical society.~~
- ~~(d) Continued behavior that is potentially injurious to patients must further be reported to the state licensing board.~~
- ~~(e) If the incompetence is of a sufficiently serious nature as to pose an immediate threat to the health of the physician's patients, then it should be reported directly to the state licensing board.~~

~~(3) Unethical conduct. Unethical behavior (which does not fit into the category of either incompetence or impairment) should be reported in accordance with these guidelines:~~

- ~~(a) Unethical conduct which threatens patient care or welfare should be reported to the appropriate authority for a particular clinical service, i.e., the chief resident, the chief of an appropriate clinical service, or the chief of the hospital staff.~~
- ~~(b) Unethical behavior which violates the provisions of the state licensing board should be reported to the state licensing board.~~
- ~~(c) Unethical conduct which violates criminal statutes should be reported to the appropriate law enforcement authorities.~~
- ~~(d) Examples of unethical conduct which do not fall into the above three categories, or unethical conduct which has not been addressed through other channels should be reported to the local or state medical society.~~

~~(4) Where the impairment, incompetence, or unethical behavior of a physician continues despite the initial report(s), the reporting physician should report to a higher or additional authority. In order to aid physicians who report inappropriate behavior of colleagues in carrying out this obligation, the person or body receiving the initial report should notify the reporting physician when appropriate action has been taken.~~

- (5~~1~~) Physicians should work to assure that state laws provide immunity to those who report impaired, incompetent, or unethical colleagues.
- (6~~) In certain circumstances, an anonymous report may be the only practical method of alerting an authoritative body to a colleague's misconduct. Anonymous reports of misconduct should receive appropriate review and confidential investigation by authorities.~~
- (7~~2~~) Principles of due process must be observed in the conduct of all disciplinary matters involving physician participants at all levels. However, the confidentiality of the reporting physician should be maintained to the greatest extent possible within the constraints of due process, in order to minimize potential professional recriminations.
- (8~~3~~) The medical profession as a whole must correct the misperception that physicians are not adequately protecting the public from incompetent, impaired or unethical physicians by better communicating its efforts and initiatives at maintaining high ethical standards and quality assurance. (CEJA Rep. A, I-91; Reaffirmed: BOT Rep. 17, I-99)

E-9.031 Reporting Impaired, Incompetent or Unethical Colleagues

Physicians have an ethical obligation to report impaired, incompetent, and unethical colleagues in accordance with the legal requirements in each state and assisted by the following guidelines:

Impairment. Impairment should be reported to the hospital's in-house impairment program, if available. Otherwise, either the chief of an appropriate clinical service or the chief of the hospital staff should be alerted. Reports may also be made directly to an external impaired physician program. Practicing physicians who do not have hospital privileges should be reported directly to an impaired physician program, such as those run by medical societies, when appropriate. If none of these steps would facilitate the entrance of the impaired physician into an impairment program, then the impaired physician should be reported directly to the state licensing board.

Incompetence. Initial reports of incompetence should be made to the appropriate clinical authority who would be empowered to assess the potential impact on patient welfare and to facilitate remedial action. The hospital peer review body should be notified where appropriate. Incompetence which poses an immediate threat to the health of patients should be reported directly to the state licensing board. Incompetence by physicians without a hospital affiliation should be reported to the local or state medical society and/or the state licensing or disciplinary board.

Unethical conduct. With the exception of incompetence or impairment, unethical behavior should be reported in accordance with the following guidelines:

Unethical conduct that threatens patient care or welfare should be reported to the appropriate authority for a particular clinical service. Unethical behavior which violates state licensing provisions should be reported to the state licensing board or impaired physician programs, when appropriate. Unethical conduct which violates criminal statutes must be reported to the appropriate law enforcement authorities. All other unethical conduct should be reported to the local or state medical society.

Where the inappropriate behavior of a physician continues despite the initial report(s), the reporting physician should report to a higher or additional authority. The person or body receiving the initial report should notify the reporting physician when appropriate action has been taken. Physicians who receive reports of inappropriate behavior have an ethical duty to critically and objectively evaluate the reported information and to assure that identified deficiencies are either remedied or further reported to a higher or additional authority. Anonymous reports should receive appropriate review and confidential investigation. Physicians who are under scrutiny or charge should be protected by the rules of confidentiality until such charges are proven or until the physician is exonerated. (II) Issued March 1992 based on the report "Reporting Impaired, Incompetent, or Unethical Colleagues," adopted December 1991 (*J Miss St Med Assoc.* 1992; 33: 176-77); Updated June 1994 and June 1996.

H-515.983 Physicians and Family Violence

- ~~(1) Because of its prevalence and medical consequences, abuse must be considered by physicians in the differential diagnosis for a number of medical complaints, particularly when treating women, children, and elderly persons.~~
- ~~(2) Physicians who are likely to have the opportunity to detect abuse in the course of their work have an obligation to familiarize themselves with~~
- ~~(a) protocols for diagnosing and treating family violence,~~
 - ~~(b) their state reporting requirements and protective services, and~~
 - ~~(c) community resources for victims of abuse.~~
- ~~(3) Physicians also have a duty to be aware of societal misconceptions about family violence and to prevent these from affecting the diagnosis and management of abuse. Such misconceptions include the belief that abuse is a rare occurrence; that “normal” individuals are not abusive; that family violence is a private problem best resolved without outside interference; and that victims are responsible for abuse.~~
- (4) The medical profession must demonstrate a greater commitment to ending family violence and helping its victims. Physicians must play an active role in advocating increased services for victims and abusers. Protective services for abused children and elders need to be better funded and staffed, and follow-up services should be expanded. Shelters and safe homes for battered women and their children must be expanded and better funded. Mechanisms to coordinate the range of services, such as legal aid, employment services, welfare assistance, day care, and counseling, should be established in every community. Mandatory arrest of abusers and greater enforcement of protection orders are important law enforcement reforms that should be expanded to more communities. There should be more research into the effectiveness of rehabilitation and prevention programs for abusers.
- (5) Informed consent for interventions should be obtained from competent victims of abuse. For minors who are not deemed mature enough to give informed consent, consent for emergency interventions need not be obtained from their parents. Physicians can obtain authorization for further interventions from a court order or a court-appointed guardian.
- (6) Physicians should inform parents of a child-abuse diagnosis and they should inform an elderly patient’s representative when the patient clearly does not possess the capacity to make health care decisions. The safety of the child or elderly person must be ensured prior to disclosing the diagnosis when the parents or caretakers are potentially responsible for the abuse. For competent adult victims physicians must not disclose an abuse diagnosis to caregivers, spouses, or any other third party without the consent of the patient. (CEJA Rep. B, I-91. Reaffirmed: CSA Rep. 7, I-00)

E-2.02 Abuse of Spouses, Children, Elderly Persons, and Others at Risk

The following are guidelines for detecting and treating family violence:

Due to the prevalence and medical consequences of family violence, physicians should routinely inquire about physical, sexual, and psychological abuse as part of the medical history. Physicians must also consider abuse in the differential diagnosis for a number of medical complaints, particularly when treating women.

Physicians who are likely to have the opportunity to detect abuse in the course of their work have an obligation to familiarize themselves with protocols for diagnosing and treating abuse and with community resources for battered women, children, and elderly persons.

Physicians also have a duty to be aware of societal misconceptions about abuse and prevent these from affecting the diagnosis and management of abuse. Such misconceptions include the belief that abuse is a rare occurrence; that abuse does not occur in “normal” families; that abuse is a private problem best resolved without outside interference; and that victims are responsible for the abuse.

In order to improve physician knowledge of family violence, physicians must be better trained to identify signs of abuse and to work cooperatively with the range of community services currently involved. Hospitals should require additional training for those physicians who are likely to see victims of abuse. Comprehensive training on family violence should be required in medical school curricula and in residency programs for specialties in which family violence is likely to be encountered.

The following are guidelines for the reporting of abuse:

Laws that require the reporting of cases of suspected abuse of children and elderly persons often create a difficult dilemma for the physician. The parties involved, both the suspected offenders and the victims, will often plead with the physician that the matter be kept confidential and not be disclosed or reported for investigation by public authorities.

Children who have been seriously injured, apparently by their parents, may nevertheless try to protect their parents by saying that the injuries were caused by an accident, such as a fall. The reason may stem from the natural parent-child relationship or fear of further punishment. Even institutionalized elderly patients who have been physically maltreated may be concerned that disclosure of what has occurred might lead to further and more drastic maltreatment by those responsible.

The physician should comply with the laws requiring reporting of suspected cases of abuse of spouses, children, elderly persons, and others.

Public officials concerned with the welfare of children and elderly persons have expressed the opinion that the incidence of physical violence to these persons is rapidly increasing and that a very substantial percentage of such cases is unreported by hospital personnel and physicians. A child or elderly person brought to a physician with a suspicious injury is the patient whose interests require the protection of law in a particular situation, even though the physician may also provide services from time to time to parents or other members of the family.

The obligation to comply with statutory requirements is clearly stated in the Principles of Medical Ethics. Absent such legal requirement, for mentally competent, adult victims of abuse, physicians should not report to state authorities without the consent of the patient. Physicians, however, do have an ethical obligation to intervene. Actions should include, but would not be limited to: suggesting the possibility of abuse with the adult patient, discussing the safety mechanisms available to the adult patient (e.g., reporting to the police or appropriate state authority), making available to the adult patient a list of community and legal resources, providing ongoing support, and documenting the situation for future reference. Physicians must discuss possible interventions and the problem of family violence with adult patients in privacy and safety. (I, III) Issued December 1982; Updated June 1994 based on the report "Physicians and Family Violence: Ethical Considerations," adopted December 1991 (*JAMA*. 1992; 267: 3190-93); updated June 1996; and updated June 2000 based on the report "Domestic Violence Intervention," adopted June 1998.

2. ETHICAL RESPONSIBILITY TO STUDY AND PREVENT ERROR AND HARM IN THE PROVISION OF HEALTH CARE

HOUSE ACTION: RECOMMENDATIONS ADOPTED AND REMAINDER OF REPORT FILED

*"Error in judgment must occur in the practice of an art which consists
largely of balancing probabilities" - William Osler*

INTRODUCTION

The Institute of Medicine's report "To Err Is Human" brought patient safety to the forefront of medical news. The report, published in 1999, makes clear that errors are often the consequences of multiple factors that are a byproduct of the increasing complexity of health care. Notwithstanding the complexity of medicine, physicians continue to play a central role in providing medical care to patients. Therefore, two separate but equally important challenges currently face the medical profession: renewing the commitment to improving the safety of patient care, and continuing to foster patient trust. To address these challenges, this report considers physicians' ethical responsibilities to identify, study, and prevent errors and their ethical responsibilities to patients who suffer harm as a result of an error. Both these sets of responsibilities flow from the American Medical Association's *Principles of Medical Ethics*. Indeed, the *Principles* call upon physicians to "provide competent medical service with compassion and respect for human dignity and rights" and to "be honest in all their professional interactions."

DEFINITIONS

Despite great advances, medicine remains an imperfect science, and some procedures carry considerable risks that patients are willing to assume in relation to the expected beneficial outcome. Although the possibility of an untoward outcome due to an error could be viewed as a form of risk, its potentially preventable nature makes it different.

In 1994, one of the leading commentators on the topic of errors, Lucian Leape, defined errors as unintended acts or acts that did not achieve the intended outcome. The Institute of Medicine offered a similar definition, stating that “An error is defined as the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning).”

Independently of whether there are any negative consequences, it is possible to speak of “mistakes,” where decisions or actions with potentially negative consequences would be judged by peers to have deviated from standards. Other investigators have focused on adverse events as “situations in which an inappropriate decision was made when, at the time [when] an appropriate alternative could have been chosen.”

Significantly, these definitions do not depend on the outcome, such that an error in the context of health care need not result in an injury. From the perspective of the Hippocratic tradition, whereby the first duty of physicians is to do no harm, errors that do not result in injury would not automatically imply an ethical lapse. Nevertheless, some errors are preventable. To enhance patient safety, they require careful attention.

In this report, an “error” is defined as an unintended act or omission, or a flawed system or plan, that harms or has the potential to harm patients, whether the harm be direct (physical or psychological) or indirect (such as undermining patient trust). The term should be understood to refer to all errors occurring within a health care environment, and not just errors by physicians.

It is clear that all instances of patient harm are not caused by errors. Nevertheless, physicians’ concern about the welfare of their patients should translate into a compassionate response whenever patients suffer harm. The medical profession’s stewardship of patient well-being is thus the ethical foundation of the profession’s commitment to the prevention of patient harm through error reduction. Additionally, the physician’s duty to deal honestly with patients extends the ethical responsibility beyond error reduction to a duty to relate with openness to patients who may have experienced harm.

HISTORY OF ERROR REDUCTION AND QUALITY IMPROVEMENT EFFORTS

Historically, the medical profession gained much of its knowledge through open reporting of failed interventions, which was viewed as an important educational tool, particularly in the field of surgery. In the words of one commentator, “the open admission of mistakes and the truthful reporting of results among peers, therefore, was important for the development of the profession,” particularly until the introduction of science into medicine, which resulted in upgrading the standard of care, and the institution of ethically based patient protections, such as informed consent.

Various forms of peer review have long been utilized to discuss unsuccessful outcomes. These educational endeavors took the form of morbidity and mortality conferences, case review, and grand rounds. The purpose of these discussions was to facilitate learning and to disseminate knowledge. In more recent times, peer review expanded with the relationship between physicians and hospitals. In this context, peer review has been used as a tool to evaluate the competence of individual doctors by examining the appropriateness of care. Sometimes seen as a disciplinary mechanism, rather than an educational tool, the misuse of peer review has been decried by many physicians. Therefore, there is great concern that peer review be conducted fairly and in good faith, and that appropriate safeguards be in place to protect all parties involved from punishment or unjustified recriminations.

It also is argued that the threat of litigation has become a hindrance to open discussions of errors. Accordingly, many legal and medical commentators have stated that a fundamental reform of medical liability is required, since repetition of errors cannot be prevented if they are not reported and openly discussed.

Overall, the prevention of patient harm through error reduction should be seen as part of a long tradition of mutually beneficial peer review and shared knowledge, and professional dedication to improving the continually expanding provision of medical care.

ERRORS AT THE LEVEL OF THE HEALTH CARE SYSTEM

Some investigators have described medicine as a culture of “perfection,” where committing an error is viewed as a flaw in character, which is then associated with incompetence, and which can lead to some sanction. Many have criticized this approach, noting that to threaten individuals with punishment or shame if they commit an error is a strategy that was abandoned long ago by industries that have achieved much greater levels of safety. Fortunately, there now appears to be a shift away from framing errors as attributable to individual negligence or misconduct. In fact, recognition that many errors are “systems errors” related to the increasing complexity of health care delivery has shifted attention to the need for safer systems and processes. Therefore, the primary goal of a reporting system should be the prevention of future errors rather than the punishment of individual behavior and the system should be built as an educational tool.

Physicians are uniquely positioned to have a thorough view of the medical care in a given setting. Working with all other relevant professionals, they should ensure that appropriate channels are established through which errors can be reported and reviewed, and operational improvements can be implemented as the result of such review. Mechanisms already should exist for early detection of impaired or incompetent colleagues, with the objective of providing rehabilitation, retraining, or restriction of practice before their behavior may result in patient injury.

DISCLOSURE OF ERRORS AT THE LEVEL OF THE PATIENT-PHYSICIAN RELATIONSHIP

Tradition of Honesty and Compassion in Medical Ethics

In addition to error prevention, important ethical considerations arise when an error occurs that results in harm to a patient. Medical ethicists have long held that honesty is fundamental to the practice of medicine. This obligation stems from many important ethical traditions. Most recently, there has been a growing effort to include patients in the decision-making process as an expression of their autonomy. This has led to the expansion of the doctrine of informed consent, whereby physicians provide patients with information concerning treatment options. This approach allows the patient to make choices that are aligned with his or her values and preferences. Accordingly, when asked what should be done when a patient is injured, medical ethicists find the answer to be rather straightforward, regardless of whether the injury was inadvertent or preventable--information regarding the injury should be disclosed to the patient.

The *Code of Medical Ethics* emphasizes this obligation in Opinion 8.12, “Patient Information,” stating that:

Patients have a right to know their past and present medical status and to be free of any mistaken beliefs concerning their conditions. Situations occasionally occur in which a patient suffers significant medical complications that may have resulted from the physician’s mistake or judgment. In these situations, the physician is ethically required to inform the patient of all the facts necessary to ensure understanding of what has occurred....This obligation holds even though the patient’s medical treatment or therapeutic options may not be altered by the new information.

Some contend that the doctrine of “therapeutic privilege” permits a physician to withhold information that, if disclosed, could cause psychological distress or could undermine trust and lead the patient to rash decisions that result in even greater negative effects. In the rare instances where this may be a concern, the physician should involve appropriate members of the patient’s family, or other advocates, and consult a disinterested party, such as a trusted colleague.

More often, candid disclosure of an error that caused harm may help the patient deal better with the situation and enhance the patient’s trust of the physician and the hospital. Physicians, however, should be cautious that premature conclusions may be misleading and inappropriate. If there is uncertainty as to the cause of harm, a physician should explain what is known and what remains to be investigated, and should assure the patient that appropriate information will be shared honestly and openly. If harm is ignored or glossed over, however, patients may feel angry and abandoned; therefore, it is important that their perceptions be validated to the extent that is possible.

Any communication about harm resulting from an error should be made with tact, including an expression of regret. This expression of compassion, acknowledging that an untoward event has occurred, need not represent an admission of responsibility. In addition, to the extent it is possible, there should be an assurance that efforts will be made to prevent subsequent patients from experiencing harm resulting from similar circumstances. Physicians, and hospitals, may also consider whether there should be an offer of restitution for expenses resulting from an error.

These strategies may help reduce the risk of liability in certain circumstances. For example, when the VA Hospital in Lexington, Kentucky, introduced a disclosure policy, which involved a discussion with the patient about the details of the incident, an expression of regret for the outcome, and an offer of restitution when indicated, it was found that the total liability payments at the facility were comparable to those at other facilities without similar disclosure policies. Furthermore, the hospital experienced lower legal costs per claim and lower settlement amounts per claim. These results have since motivated a system-wide disclosure policy for all VA hospitals.

Patient Advocacy: Promoting Patient Interests Through the Investigation of the Causes of Harm

Physicians' unique role as patient advocates also requires them to participate in the investigation regarding the cause of the harm. A physician might feel such a heavy responsibility for a patient's well-being that the physician might accept blame before careful investigation is undertaken. However, investigations often reveal multiple systemic causes that made the harm inevitable despite the physician's intentions and performance. Examples include mislabeling of medications, or the failure to transmit important information. In these instances, the physician may have been the practitioner closest to the patient at the time the harm occurred, but might not have been the causal agent. Uncovering the exact causes of an error and correcting them when possible should be a high priority.

Should the physician be responsible for serious harm to a patient, the physician must acknowledge responsibility to the patient. Many times, this will facilitate preserving trust, and will allow continuity of care with the same health care team, instead of a patient having to build new relationships with other caregivers. This will be most important when decisions need to be made promptly in response to the harm that has occurred. However, if the disclosure injures the patient's trust in the physician or otherwise damages the patient's relationship with the physician so severely that the patient prefers to obtain subsequent care from someone else, the physician has a responsibility to assist the patient in obtaining continuing care. If a physician who is responsible for harm is unwilling or unable to acknowledge his or her responsibility to the patient, a neutral party should communicate the information to the patient.

The obligation to uncover and disclose information regarding an error is related to physicians' responsibility to act as patient advocates and to promote the patient's best interests, irrespective of other interests. This standard has recently been expressed in CEJA Report 1-A-01, "The Patient-Physician Relationship." The report reminded physicians that high ethical responsibilities flow from caring for patients as a consequence of their illness and their dependence on the medical expertise of physicians.

In the context of harm, a physician who has a long-standing relationship with a patient or has been involved in a recent course of treatment often will be in the best position to advocate on behalf of the patient with other health care practitioners, the hospital, or the insurance company, to resolve issues stemming from harm. Disclosure, ultimately, is an expression of fidelity to the patient's interests.

Errors Committed by Others

A somewhat different challenge may present itself when health care professionals witness harm being committed or discover that a patient experienced harm in the past when someone else was caring for the patient. It may be argued that the absence of a relationship with the patient at the time an error occurred absolves the health care professional from ethical responsibilities to report it and to discuss it with the patient. Yet, it is clear that even if a physician is not responsible for the harm, that physician still has the ethical obligation to be honest and forthcoming with information pertaining to the patient. The physician also has an ethical obligation to protect patient welfare in general by reporting the occurrence and promoting operational improvements that enhance patient safety. This latter obligation is recognized under Principle II of the AMA's *Principles of Medical Ethics*, which states in part that: "A physician shall uphold the standards of professionalism...and strive to report physicians deficient...in competence, or engaging in...deception, to appropriate entities." Physicians are provided further guidance under Opinion E-9.031, "Reporting Impaired, Incompetent, or Unethical Colleagues."

ERRORS AND PROFESSIONAL LIABILITY

Physicians concerned with the rise in professional liability claims and awards may find ethical obligations regarding the reporting and disclosing of errors counterintuitive. However, some data suggest that the major determinant of the initiation of professional liability claims may be faulty communication and patient dissatisfaction, rather than the quality of care. On the basis that transparency--as opposed to secrecy--promotes trust, commentators have argued that open disclosure of errors may mitigate patient discontent and maintain patient confidence and, therefore, may be an important tool to reduce the risk of professional liability. Such advice appears consistent with a recent study, which found that 98% of individuals who were presented with various scenarios expected or wished for the physician's active acknowledgement of an error. Indeed, it is considered that some patients may file a lawsuit specifically to uncover information they otherwise have not been able to obtain. Also, for many patients, an offer of money is less likely to make them terminate a legal action against a health care provider than an explanation and an apology, and an assurance that corrective measures would be undertaken to prevent future similar errors. Changes in the current legal system that would facilitate reporting and investigating errors by ensuring confidentiality would enhance the prevention of patient harm.

CONCLUSION

Most patients are confident that the medical care they receive is delivered competently and will produce beneficial outcomes. However, as medicine becomes more complex, and the provision of health care becomes a sophisticated set of interwoven processes, it is inevitable that there will be occurrences that have the potential to cause harm to a patient and may be repeated if they are undetected and uncorrected. These occurrences may arise from unintended actions or omissions or from flawed systems or plans.

Physicians, because of the central role they play in the provision of medical care, and because of the unique ethical responsibilities that flow from caring for patients, must commit to the enhancement of patient safety through identification and correction of medical errors and the prevention of patient harm. This requires that physicians participate in the development of error reporting mechanisms that promote changes in systems rather than punishment. Furthermore, in instances when harm occurs, physicians must reinforce the trust that patients hold in the medical profession by offering an honest disclosure of events.

RECOMMENDATIONS

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

In the context of health care, an error is an unintended act or omission, or a flawed system or plan that harms or has the potential to harm a patient. Patient safety can be enhanced by studying the circumstances surrounding health care errors. This can best be achieved through a legally protected review process, which is essential for reducing health care errors and preventing patient harm.

1. Because they are uniquely positioned to have a comprehensive view of the care patients receive, physicians must strive to ensure patient safety and should play a central role in identifying, reducing and preventing health care errors. This responsibility exists even in the absence of a patient-physician relationship.
2. Physicians should participate in the development of reporting mechanisms that emphasize education and systems change, thereby providing a substantive opportunity for all members of the health care team to learn. Specifically, physicians should work with other relevant health care professionals to:
 - (a) Establish and participate fully in an effective, confidential, and protected error-reporting mechanism;
 - (b) Develop means to review and analyze objectively reports regarding errors, and to conduct appropriate investigations into the causes of harm to a patient;
 - (c) Ensure that the investigation of causes of harm, and the review and study of error reports result in preventive measures that are conveyed to all relevant individuals;
 - (d) Identify and promptly report impaired and/or incompetent colleagues so that rehabilitation, retraining or disciplinary action can occur in order to prevent harm to patients.

3. Physicians must offer professional and compassionate concern toward patients who have been harmed, regardless of whether the harm was caused by a health care error. An expression of concern need not be an admission of responsibility. When patient harm has been caused by an error, physicians should offer a general explanation regarding the nature of the error and the measures being taken to prevent similar occurrences in the future. Such communication is fundamental to the trust that underlies the patient-physician relationship, and may help reduce the risk of liability.
4. Physicians have a responsibility to provide continuity of care to patients who may have been harmed during the course of their health care. If, due to the harm suffered under the care of a physician, a patient loses trust in that physician, the obligation may best be fulfilled by facilitating the transfer of the patient to the care of another physician.
5. Physicians should seek changes to the current legal system to ensure that all errors in health care can be safely and securely reported and studied as a learning experience for all participants in the health care system, without threat of discoverability, legal liability or punitive action.

(References pertaining to Report 2 of the Council on Ethical and Judicial Affairs are available from the Ethics Standards Group.)

3. RETAINER PRACTICES

HOUSE ACTION: RECOMMENDATIONS ADOPTED AND REMAINDER OF REPORT FILED

At the 2001 Interim Meeting, the House of Delegates adopted Resolution 6, which called for the American Medical Association to examine special physician-patient contracts for “non-medical services.” This study was completed by the Council on Medical Service (CMS), which reported its findings at the 2002 Annual Meeting of the House (CMS Report 9). In its report, CMS referred to these special contracts as “retainer practices” and reviewed some of their characteristics, particularly in relation to economic, practical, and legal implications, and discussed relevant AMA policies. The CMS report concluded that retainer practices were consistent with long-standing AMA support of pluralism in the delivery and financing of health care. The CMS report also stated that “To the degree that an exploration of the ethical implications of retainer practices becomes warranted, the Council believes that the Council on Ethical and Judicial Affairs is better suited to undertake such a study.”

Although “executive health programs,” and “cash only” practices are not new, the special contracts whereby physicians offer additional special services and amenities to patients who pay additional fees as retainers has received considerable legislative and public interest. Given that they raise fundamental questions in terms of the nature of the patient-physician relationship, including issues of access and continuity of care, this CEJA report builds on the work of the Council on Medical Service in analyzing the professional and ethical implications of contracting for special services and amenities, such as longer visits, guaranteed availability by phone or pager, counseling for healthy lifestyles, and various other customized services.

ESTABLISHING A PATIENT-PHYSICIAN RELATIONSHIP

The AMA’s *Principles of Medical Ethics* advocate that physicians are free to choose the environment in which to provide medical care and, except in emergencies, whom to serve. This principle is further reiterated in other AMA policies identified in CMS Report 9-A-02 (see Policies H-165.960[5], H-165.916, and H-385.985, AMA Policy Database). There is also AMA policy in support of plurality in the financing and delivery of health care (see Policies H-165.960[7], H-165.913[2]).

Trust, which is essential in a patient-physician relationship, is an important consideration in exercising this freedom. When a physician and a patient are unable to establish a trusting relationship, they should not engage in a relationship (see Opinion E-9.06, “Free Choice”). Retainer practices may be a means to facilitate the establishment of trust-based relationships beyond what is perceived to be possible in the usual context of brief and rushed visits. However, patients who do not pay fees for special services and amenities should continue to expect and receive compassionate and respectful care from their physicians, as required by the *Principles of Medical Ethics* and Opinion E-10.01, “Fundamental Elements of the Patient-Physician Relationship.” The latter specifically states that all patients have the right to “courtesy, respect, dignity, responsiveness, and timely attention to his or her needs.”

Voluntariness

Trust in a relationship can be accomplished when both patient and physician are clear on the terms of the relationship and agree to it. Physicians must present the terms of a retainer contract in an honest manner, being careful not to exert undue pressure on patients to pay additional fees for services they may not want or may not be able to afford. Physicians particularly should recognize that their sickest or most vulnerable patients or those in greatest need of care may feel pressured to pay the fee due to fear of abandonment. Undue pressure may also stem from contractual terms that obligate the patient to pay for future services that might be unwanted if the patient finds another physician before the end of the contract. Confronted with a choice between greater cost and greater inconvenience (such as travelling longer distances to receive medical care), many patients may feel their options are very limited.

Also, if a physician has knowledge that a patient's health care insurance coverage will be compromised by the retainer contract, the information must be discussed with the patient before reaching an agreement on the terms of the retainer contract.

Continuity of Care

Loyalty to the interests of patients is one of the essential characteristics that can be derived from the foundational trust on which the patient-physician relationship is based. It is expressed most clearly through the physician's obligation not to abandon a patient who continues to require medical care. Opinions E-10.01, "Fundamental Elements of the Patient-Physician Relationship," E-8.11, "Neglect of Patients," and E-8.115, "Termination of the Physician-Patient Relationship," all affirm physicians' obligation to promote continuity of care, and to arrange for the transfer of care of a patient in a manner that does not compromise the patient's well-being.

In light of this ethical norm, the conversion of a traditional practice to a retainer practice can place a burden upon patients who must seek another physician and establish a new relationship. Therefore, physicians converting their practices must facilitate the transfer of their patients, particularly those with medical conditions that require ongoing attention. This should include identifying practitioners in the community who are willing to accept patients, and personally communicating the clinical information appropriate to a smooth transition of care. It is inappropriate to charge patients an extra fee for transmission of their medical records.

DIAGNOSTIC AND THERAPEUTIC DECISION MAKING

It is important that a retainer contract for providing special services and amenities not be presented as a promise of more or better diagnostic and therapeutic services. Ethically, the standard of care cannot depend on the patient's ability to pay. It would be particularly condemnable if there were a discrepancy in diagnostic and therapeutic decisions in the context of a mixed practice (a practice consisting of patients with and without retainer contracts). Therefore, it must be clear to patients that retainer practices are not necessary to attain good medical care. However, it remains possible that more personalized attention and greater patient satisfaction may lead to better understanding and compliance with treatment recommendations, and thus improved outcomes for certain aspects of care.

Appropriateness of Care

In all settings, concern for the quality of care the patient receives should be a physician's first consideration (see Opinion E-2.09, "Costs"). However, this concern should be further guided by Opinion E-2.19, "Unnecessary Services," which addresses the appropriateness of services that are offered, stating that "Physicians should not provide, prescribe, or seek compensation for services they know are unnecessary." It is important to note that a determination of necessity under this Opinion applies to diagnostic and therapeutic care and not to special services and amenities of the kind provided under retainer contracts. Nevertheless, physicians proposing retainer contracts to their patients should ensure that no unnecessary medical treatment or procedure is provided. Specifically, medical services should not be provided only to appease a patient who wants them and is willing to pay for them; rather, they should always be based on scientific evidence, sound medical judgment, relevant professional guidelines, and due concern for economic prudence.

COMPENSATION FOR SERVICES

Retainer contracts are a means for physicians to offer special services and amenities with the expectation of appropriate compensation. These contracts fall under a general contractual view of the patient-physician relationship, in which both parties agree on appropriate fees to be charged for pre-defined services.

Also, Opinion 9.132, "Health Care Fraud and Abuse," speaks of the danger of misrepresentation to increase the level of payment or to secure non-covered health benefits. However, physicians are ethically required to be honest when billing for reimbursement. Therefore, after entering into retainer contracts, it remains paramount that physicians continue to observe relevant laws, rules, and contracts regarding reimbursement received from their patients' health care plans. Since no bright line separates special services and amenities from reimbursable medical services, it is desirable that the terms of retainer contracts separate clearly special services and amenities from reimbursable medical services. In the absence of such clarification, identification of reimbursable services will need to be determined carefully on a case-by-case basis.

ACCESS TO CARE IN A COMMUNITY

The principal concern voiced regarding retainer practices relates to access to medical care within a community. It is perceived that if these practices become widespread, the number of physicians not engaging in such contracts would be insufficient to provide medical care to all patients who are unable or unwilling to pay the additional fees. Although there have been no reports of this actually occurring, this possibility threatens medicine's professional ethos to ensure the provision of medical care to all those in need. Principle IX of the AMA's *Principles of Medical Ethics* states, "Physicians shall support access to medical care for all people." This fundamental precept is further elaborated in Opinion E-9.065, "Caring for the Poor."

Recently, the Council examined the need of individual physicians to balance the obligation to facilitate access for all patients in need of medical care with the responsibility to provide for their existing patients. Opinion E-10.05, "Potential Patients," states:

Physicians, as professionals and members of society, should work to assure access to adequate health care. Accordingly, physicians have an obligation to share in providing charity care but not to the degree that would seriously compromise the care provided to existing patients. When deciding whether to take on a new patient, physicians should consider the individual's need for medical service along with the needs of their current patients. Treatments range along a continuum from necessary to sustain life, to necessary to sustain functioning health, to useful to sustain functioning health, to discretionary. Clearly, greater individual need for a service corresponds with a stronger obligation to treat.

Therefore, it should be recognized that when physicians convert their practices to provide care solely to a small panel of patients able and willing to pay for special services and amenities, overall patient care in a community may be compromised. Prior to converting their practices, physicians should attempt to ascertain that other physicians not engaging in such contracts are available to provide medical care to patients who do not enter into retainer contracts. If it is apparent that the conversion of a practice would result in patients losing access to care that had been available to them until that time, the physician's decision to convert a practice could undermine the ethical obligation set forth in the *Principles of Medical Ethics* that a physician shall support access to medical care. If no other physicians are available to care for non-retainer patients in the local community, the physician may be ethically obligated to continue caring for such patients. Physicians who establish retainer practices should remain attentive to their professional obligation to attend to those in urgent need of care, regardless of ability to pay.

CONCLUSION

Individuals are free to select and supplement insurance for their health care on the basis of what appears to them to be an acceptable tradeoff between quality and cost. Retainer fees for special services and amenities, therefore, appear to be consistent with a system based on pluralistic means of financing and delivery of medical care. Whether this trend should be promoted is a question to which there is not yet a definite answer. However, the following observations should help orient this inquiry. First, when a physician significantly reduces a panel of patients, other physicians in a community should be able to absorb those patients now seeking to receive care from someone else.

Beyond concerns at the community level, contracting for special services and amenities must comply with the ethical concept of voluntary action on the part of patients and minimize discontinuity of care. Finally, these practices must respect existing guidelines on the medical appropriateness of treatments or procedures, as well as reimbursement rules.

RECOMMENDATIONS

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

Individuals are free to select and supplement insurance for their health care on the basis of what appears to them to be an acceptable tradeoff between quality and cost. Retainer contracts, whereby physicians offer special services and amenities (such as longer visits, guaranteed availability by phone or pager, counseling for healthy lifestyles, and various other customized services) to patients who pay additional fees distinct from the cost of medical care, are consistent with pluralism in the delivery and financing of health care. However, they also raise ethical concerns that warrant careful attention, particularly if retainer practices become so widespread as to threaten access to care.

1. When entering into a retainer contract, both parties must be clear about the terms of the relationship and must agree to them. Physicians must present the terms of the contract in an honest manner, and must not exert undue pressure on patients to agree to the arrangement. If a physician has knowledge that the patient's health care insurance coverage will be compromised by the retainer contract, the information must be discussed with the patient before reaching an agreement on the terms of the retainer contract. Also, patients must be able to opt out of a retainer contract without undue inconveniences or financial penalties.
2. Concern for quality of care the patient receives should be the physician's first consideration. However, it is important that a retainer contract not be promoted as a promise for more or better diagnostic and therapeutic services. Physicians must always ensure that medical care is provided only on the basis of scientific evidence, sound medical judgment, relevant professional guidelines, and concern for economic prudence. Physicians who engage in mixed practices, in which some patients have contracted for special services and amenities and others have not, must be particularly diligent to offer the same standard of diagnostic and therapeutic services to both categories of patients. All patients are entitled to courtesy, respect, dignity, responsiveness, and timely attention to their needs.
3. In accord with medicine's ethical mandate to provide for continuity of care and the ethical imperative that physicians not abandon their patients, physicians converting their traditional practices into retainer practices must facilitate the transfer of their non-participating patients to other physicians, particularly their sickest and most vulnerable ones. If no other physicians are available to care for non-retainer patients in the local community, the physician may be ethically obligated to continue caring for such patients.
4. Physicians who enter into retainer contracts will usually receive reimbursement from their patients' health care plans for medical services. Physicians are ethically required to be honest in billing for reimbursement, and must observe relevant laws, rules and contracts. It is desirable that retainer contracts separate clearly special services and amenities from reimbursable medical services. In the absence of such clarification, identification of reimbursable services should be determined on a case-by-case basis.
5. Physicians have a professional obligation to provide care to those in need, regardless of ability to pay, particularly to those in need of urgent care. Physicians who engage in retainer practices should seek specific opportunities to fulfill this obligation.

4. GIFTS FROM PATIENTS TO PHYSICIANS

HOUSE ACTION: RECOMMENDATION ADOPTED AND REMAINDER OF REPORT FILED

Gifts from patients may be an important means for some patients or their family caregivers to express gratitude for the care a physician has provided. However, physicians should be aware that gifts may be offered for many different reasons, and that acceptance of certain gifts may compromise the patient-physician relationship. This report addresses some of the issues that can arise from patient gifts to physicians, and points to specific gift-giving issues that physicians should consider when they are offered gifts. The related issue of gift solicitation by physicians, which raises ethical concerns, will be addressed in a future report.

GIFT-GIVING AND THE PATIENT-PHYSICIAN RELATIONSHIP

The literal definition of “giving” is a “voluntary transfer of owned property from one to another without consideration of compensation.” In the context of this report, the patient is the giver and the physician is the recipient. The giver generally exerts primary control over the act of giving by initiating the act and selecting the recipient. Yet the recipient also has control over the act through the decision whether or not to accept the gift. Overall, gift-giving is a complex interaction entrenched in an “unspoken framework of relational rules.”

The manner in which the gift is regarded by the giving patient and the receiving physician may affect the relationship between a patient and physician. Avoiding an adverse effect on the giver or receiver requires mutual understanding of the intent of the gift. A clear statement from the giver as to the gift’s meaning may clarify the intent, although hidden or unconscious meanings may remain.

Acceptance or rejection of a gift could strengthen or weaken a patient-physician relationship. If the gift is a measure of the giver’s gratitude, a refusal could be offensive. If a gift is an attempt to secure preferential treatment, then a refusal may be required to maintain the mutual respect and independent judgment that are essential to the patient-physician relationship. Thus, physicians need to think carefully and exercise judgment when deciding whether to accept or refuse a gift.

MOTIVES FOR GIFT-GIVING

Generally, gifts tend to highlight social relationships and expectations. In the context of the patient-physician relationship, it is important for physicians to recognize that patients may be motivated by various considerations when they offer gifts. Often, the motivation is generosity, as some patients derive pleasure from giving a gift. Gift-giving may also be a demonstration of appreciation, a behavior related to benevolence and which is usually not consciously intended as an attempt to alter the patient-physician relationship. Within many patient-physician relationships, therefore, gifts are a manifestation of goodwill.

Gifts can also be a means for patients to reward extraordinary effort by the physician in dealing with complex or demanding behavioral or medical concerns or with a patient’s difficult personality. There are instances when a patient may offer a gift out of guilt for noncompliance or for being a burden to the physician. In these situations, physicians should remain sensitive to the patient’s emotional state. Accepting this gift may endorse the patient’s guilt or perception of being a burden.

A patient’s family or caregivers may offer a gift to a physician for similar reasons. Not uncommonly, gifts from families and caregivers are offered in memory of a deceased patient. For these families, the gift may be part of their grieving or a way to ensure that the deceased patient remains alive in the memory of the physician. This may present the physician with an opportunity to offer condolences to the family, and to assess whether family members need additional support for their grieving.

Gift-giving can be a manifestation of other psychological needs. For example, a patient may offer gifts to alleviate certain feelings, such as a sense of worthlessness, or to create a personal connection in a seemingly impersonal environment, such as a hospital. Also, some patients may feel intimidated by physicians or threatened by the social stature or knowledge of a physician, and offer gifts that demonstrate their own accomplishments or successes in an

attempt to balance the patient-physician relationship. When physicians perceive that a gift is being offered as an expression of a more deeply rooted psychological need, it may be more appropriate for physicians to address that need in a direct fashion, rather than simply accepting the gift.

Another psychological need of some patients is the desire to be remembered by the physician. This type of motivation can result in a bequest to a physician in a patient's will. If a patient announces his or her plan to make a financial bequest to a physician, the patient should be encouraged to donate to a foundation or charity independent of the physician. This would mitigate inappropriate influence upon the patient-physician relationship and avoid the appearance of impropriety. If the patient's gift is brought to the attention of the physician after the patient's death, of course, it does not influence the therapeutic relationship. Then the physician may choose to solicit the involvement of the family or others who may help assess the sentimental and monetary value of the gift. There may be instances when it is advisable that the physician decline the gift, particularly if it appears extravagant relative to the family's means or appears to cause great conflict within the family.

Gift-giving for some patients may also represent a means to be thought of as more special than the physician's other patients. These gifts are often expensive or very noticeable and designed to be displayed in the physician's office.

For some groups of patients, gift-giving stems primarily from cultural traditions. A cultural tradition common to the United States is the giving of small gifts during the holidays. Rejecting these gifts would more likely disappoint or even upset patients; therefore, many physicians may generally respond with an appropriate expression of gratitude.

In some cultures, gift-giving is an important aspect of the healing process or may be an expected sign of respect toward physicians. However, physicians should recognize that some cultural practices conflict with the ethical practice of medicine in the United States. For example, patients who offer gifts to secure appointments, reduce their wait before receiving a treatment, or expedite referrals or paperwork may be acting according to cultural customs that are contrary to accepted practices in the United States. Physicians should make clear that gifts given to secure preferential treatment compromise their obligation to provide services in a fair manner.

Although it is important to acknowledge the cultural backgrounds of patients, this should not lead physicians to stereotyping. Indeed, physicians should not assume that patients of similar cultural backgrounds hold parallel beliefs or observe the same traditions with respect to gift-giving.

Especially problematic are gifts that patients offer to physicians in an effort to influence the care they receive. When an expectation of favorable treatment is the motivating factor behind a gift, a patient may become resentful if the expected treatment does not materialize. Similarly, these gifts may engender in the physician a sense of obligation for special treatment, especially if the gift was expensive or extravagant. It may also limit the physician's tendency to make treatment-appropriate recommendations, for example to confront the patient's noncompliance. Again, physicians should be able to explain that preferential treatment is contrary to the professional obligation of United States physicians to provide care based on need and in a fair manner. The following section examines more carefully the factors that should be weighed in determining the appropriateness of accepting certain gifts.

ACCEPTING OR DECLINING A GIFT

It may not be inappropriate for physicians to accept some gifts. First, physicians often are viewed as holding a fiduciary duty that requires them to be dedicated to the well-being of their patients, irrespective of any advantage or gain to themselves. Under a strict interpretation of this view, accepting a gift may be an inappropriate gain that undermines the physician's fiduciary duty. Also, some physicians and patients may consider that gift-giving obscures the true value of the medical care, since the provision of life-sustaining treatment is too precious to simply be acknowledged by a gift. Finally, it can be very difficult for physicians to interpret the reason or motive behind gifts and, therefore, some physicians maintain that all gifts should be refused.

Recognizing the possible motives that contribute to gift-giving can aid physicians in determining whether it is appropriate or inappropriate to accept a gift. When the motives for a gift fall within the realm of goodwill or cultural traditions, as discussed above, there may be little concern in accepting a gift. However, if a gift is motivated by expectations of preferential treatment or is intended to influence the physician inappropriately, physicians should use greater caution.

Apart from the motive behind a gift, its monetary value may be another important consideration. For example, nominal gifts that are handmade by the patient, such as baked goods or crafts, are common and probably do not present any concern. In contrast, more extravagant gifts are more likely to represent other motives, such as those discussed above. Of course, the monetary value of a gift is relative. What appears to be a modest gift may represent a considerable expense for a patient with limited financial means, or vice versa. The value also may be misjudged by the physician, who may consider a gift to be more valuable than was intended by the patient and, therefore, more influential. Also, a single gift may be of relatively small value, but several in aggregate may constitute an unacceptably large gift. Overall, regardless of a gift's monetary value, physicians should respond to the gift with due caution.

Physicians also should consider issues related to the timing of gifts. For example, if a gift is offered before or after the patient has made a special request, it is possible that there is expectation that the gift will influence the physician's decision or conduct. Physicians should avoid accepting a gift under such circumstances. However, a small gift during the holidays is unlikely to be problematic.

Finally, gifts can be so personal as to transgress the boundaries of the professional relationship that exists between patient and physician. Ultimately, respect for these boundaries should be the determining factor when considering gifts. The physician's decision whether to accept a gift should be guided by avoiding a disruption or alteration of the patient-physician relationship. Indeed, if it appears that the integrity of the professional relationship might be undermined by the acceptance of a gift, the physician should decline it. In rare instances, this may result in irreparable harm to the patient-physician relationship and may require that the care of the patient be transferred to another physician.

CONCLUSION

Most gifts are expressions of gratitude, although some may be inappropriate because of either the patient's motivation or the gift's monetary value. To avoid any transgression of the patient-physician relationship, physicians should be mindful of their obligation to provide treatment fairly and independent of personal advantage or gain.

RECOMMENDATION

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

Gifts that patients offer to physicians are often an expression of appreciation and gratitude, a reflection of cultural tradition, and can enhance the patient-physician relationship.

Some gifts signal psychological needs that require the physician's attention. Some patients may attempt to influence care or to secure preferential treatment through the offering of gifts or cash. Acceptance of such gifts is likely to damage the integrity of the patient-physician relationship. Physicians should make clear that gifts given to secure preferential treatment compromise their obligation to provide services in a fair manner.

There are no definitive rules to determine when a physician should or should not accept a gift. No fixed value determines the appropriateness or inappropriateness of a gift from a patient, however the gift's value relative to the patient's or the physician's means should not be disproportionately or inappropriately large. One criterion is whether the physician would be comfortable if acceptance of the gift were known to colleagues or the public.

Physicians should be cautious if patients discuss gifts in the context of a will. Such discussions must not influence the patient's medical care. If, after a patient's death, a physician should learn that he or she has been bequeathed a gift, the physician should consider declining the gift if the physician believes that its acceptance would present a significant hardship--financial or emotional--to the family.

The interaction of these various factors is complex and requires the physician to consider them sensitively.

(References pertaining to Report 4 of the Council on Ethical and Judicial Affairs are available from the Ethics Standards Group.)

5. PROFESSIONAL SELF-REGULATION AND THE JUDICIAL FUNCTION OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

HOUSE ACTION: FILED

The Council on Ethical and Judicial Affairs has recently undertaken a careful review of its judicial function. This review was motivated in part by the considerable attention the concept of professionalism has received in many areas of medicine. When professionalism is defined, three key elements are generally identified: the expertise that is acquired by a professional through specialized training; the societal value of the activity the professional performs; and the public trust that the profession will regulate itself, which often leads to the establishment of a code of conduct. These characteristics clearly pertain to the medical profession and have been embodied in many of the activities of the American Medical Association since it was established in 1847. Since then, the Council on Ethical and Judicial Affairs, or its predecessors, has been instrumental in defining the elements of medical professional integrity by establishing standards of ethical conduct and by encouraging AMA members to uphold these standards.

The Council's work pertaining to the review of physician misconduct (on the basis of our AMA's *Principles of Medical Ethics*) and possible action against membership in the Association needs to be emphasized. Based on anecdotal information, CEJA believes that many AMA members are not fully aware of how CEJA exercises its judicial functions. This report is intended to clarify certain aspects of CEJA's procedures, particularly as they concern: the categories of physicians whose ethical conduct may be investigated; the evidence CEJA considers when it makes a determination; the types of disciplinary sanctions CEJA can impose and the criteria used for imposing sanctions; and certain other procedural aspects of the disciplinary peer review process.

BACKGROUND AND RELEVANT AMA BYLAWS

The following sections of the AMA Bylaws are most relevant to this report:

- 1.111 Admission.** A person eligible for active constituent membership in the American Medical Association becomes a member of the AMA upon certification by the secretary of the constituent association to the Executive Vice President of the AMA, provided there is no disapproval by the Council on Ethical and Judicial Affairs. The Council may consider information pertaining to the character, ethics, professional status and professional activities of the applicant. The Council shall provide by rule for an appropriate hearing procedure to be provided to the applicant.
- 1.121 Admission.** Active direct members are admitted to membership upon application to the Executive Vice President of the American Medical Association, provided that there is no disapproval by the Council on Ethical and Judicial Affairs. The Council may consider information pertaining to the character, ethics, professional status and professional activities of the applicant. The Council shall provide by rule for an appropriate hearing procedure to be provided to the applicant.
 - 1.1212 Objections.** Objections to applicants for active direct membership must be received by the Executive Vice President of the American Medical Association within forty-five (45) days of receipt by the constituent association of the notice of the application for such membership. All objections will immediately be referred to the Council on Ethical and Judicial Affairs for prompt disposition pursuant to the rules of the Council on Ethical and Judicial Affairs.
- 1.20 Maintenance of Membership.** A member may hold only one type of membership in the American Medical Association at any one time. Membership may be retained only as long as the member complies with the provisions of the Constitution and Bylaws and Principles of Medical Ethics of the AMA.
- 1.611** The Council on Ethical and Judicial Affairs, after due notice and hearing may censure, suspend or expel an active constituent member from the American Medical Association for an infraction of the Constitution or these Bylaws, for a violation of the Principles of Medical Ethics, or for unethical or illegal conduct.

1.621 The Council on Ethical and Judicial Affairs, after due notice and hearing, may censure, suspend or expel any active direct, affiliate, honorary or international member of the AMA for an infraction of the Constitution or these Bylaws, for a violation of the Principles of Medical Ethics, or for unethical or illegal conduct.

6.403 Original Jurisdiction. The Council on Ethical and Judicial Affairs shall have original jurisdiction in:

6.4031 All questions involving membership.

DESCRIPTION OF CEJA DISCIPLINARY ACTIVITIES

Categories of Physicians Whose Ethical Conduct May Be Investigated: AMA Members and Applicants for Membership

The Council's disciplinary function primarily pertains to current AMA members and to membership applicants. The Bylaws specifically require that CEJA ascertain the ethical fitness of AMA members. The Bylaws do not grant CEJA the explicit authority to investigate nonmember physicians, although Bylaw 6.4023 allows CEJA to investigate matters of general interest to the medical community and Bylaw 6.4025 allows the President to appoint investigating juries in special situations.

If CEJA were to investigate the conduct of a nonmember and determine that he or she had violated the *Principles of Medical Ethics* or other ethical standard, action would be limited to censure of the physician or reporting of the conduct to an appropriate entity. Also, such extension of the Council's role could require time and resources beyond the current capabilities of the Council. Finally, although both the common law and the Federal Health Care Quality Improvement Act, 42 U.S.C. §11111, may shield CEJA from defamation actions when it has reviewed the ethical conduct of AMA members, these legal defenses are less likely to apply if CEJA should extend its scope of review beyond AMA membership. Therefore, the Council has not adjudicated complaints against AMA nonmember physicians.

Evidence Considered in Making Disciplinary Determinations

The Council generally considers disciplinary cases in which the person under investigation has previously been found liable by, or pleaded guilty before, a governmental tribunal, such as a state licensing board, a criminal court, or a court martial, or before a governmental agency, such as the Federal Drug Enforcement Agency or the United States Department of Health and Human Services. It may also consider a case in which another medical society or a hospital medical staff has taken disciplinary action against a physician.

Except in the rarest of circumstances, CEJA does not reexamine the determination of liability or of guilt. It confines its inquiry to evidence bearing on whether to impose sanctions against the existing member or to reject an application for membership. It also weighs evidence relevant to the type of disciplinary sanction to be imposed. These restrictions are based, in part, on the fact that the time and other resources available to CEJA for its disciplinary function are limited.

Evidence Regarding Potential Misconduct of Medical Experts

Over time, much attention has been paid to the conduct of physicians who participate in litigation as expert witnesses. The Council regularly receives complaints from physicians who have been defendants in medical malpractice suits, asking for a review of the conduct of expert witnesses who have testified against them and the imposition of sanctions on the basis that such testimony violates Opinion E-9.07, "Medical Testimony." This opinion generally encourages physicians, when called upon, to assist in the administration of justice. It also requires that medical experts testify "honestly and truthfully, to the best of their medical knowledge."

It is worth noting that the decision in *Austin v. American Association of Neurological Surgeons*, 253 F.3d 967 (7th Cir. 2001), cert. denied, 534 U.S. 1078 (2002), supports a professional association's right to discipline members for false testimony. In light of this decision, various other medical societies and our AMA House of Delegates itself have expressed interest in such procedures.

With regard to misconduct by an expert witness, CEJA reviews a violation of Opinion E-9.07 in the same manner as other violations of the Code of Medical Ethics. The Council would, as a routine matter, review such a violation if a court were to find a member or applicant guilty of perjury for false testimony or a licensing board were to make its own determination and impose licensure sanctions for this reason. However, such a situation has not yet occurred.* Absent such finding by a court or licensing board, CEJA would be unlikely to investigate or impose sanctions for this type of alleged violation.

Types of Disciplinary Sanctions

Bylaw 1.111 explicitly authorizes CEJA to disapprove a membership application, and Bylaws 1.611 and 1.6121 explicitly authorized CEJA to censure, suspend, or expel current members. Implicit in their grants of authority is the right to impose lesser or substantially similar sanctions. Disciplinary sanctions that CEJA may impose against an existing AMA member or a membership applicant are:

- rejection of an application;
- acceptance of an application, but conditioned on terms of probation;
- expulsion of an existing member;
- probation of an existing member;
- suspension of an existing member; or
- admonishment, reprimand, or censure.

Rejection or expulsion is imposed only when CEJA determines that the conduct of the physician under review has seriously violated the *Principles of Medical Ethics* and that it would discredit our AMA to have that physician as a member.

Probation stems from a determination that a physician may obtain or retain AMA membership, but only so long as the physician behaves ethically and submits periodic written reports to CEJA attesting to that conduct. Probation is imposed on applicants or members who have committed serious professional offenses but for whom rejection or expulsion would be inappropriate, because, for example, the physician has participated in a remediation or rehabilitation program. The right to impose probation arises from CEJA's authority to reject applicants or expel them outright.

The Council will frequently consider probation in situations involving substance abuse, provided that the physician participates in an appropriate treatment program. The physician periodically reports on his or her progress throughout the treatment program. Optimally, after the successful completion of the program, full membership will be reinstated.

Suspension is a conditional or temporary revocation of membership rights, which CEJA rarely invokes.

Admonishment, reprimand, or censure are also disciplinary options, which arise from the provisions in the Bylaws that allow CEJA to censure existing members. Admonishment is less severe and censure is more severe than a reprimand. All of these terms refer to a declaration that a member has violated the *Principles of Medical Ethics*. With such decisions, the physician nevertheless would retain his or her AMA membership.

Criteria for Imposing Sanctions

Background

The AMA Bylaws require CEJA to determine membership fitness based on "character, ethics, professional status and professional activities" (Bylaws 1.111 and 1.121), and on violations of the *Principles of Medical Ethics* or unethical or illegal conduct (Bylaws 1.611 and 1.621). At its 1987 Annual Meeting, the House of Delegates adopted Board of Trustees Report II, which states:

* The North Carolina Medical Board recently found that a physician had testified falsely against another physician in a professional liability suit and revoked his license (*In re Gary James Lustgarten, MD*). The matter is being appealed. This physician, however, is not an AMA member.

The AMA has developed the following criteria for identifying physicians who should be immediately expelled from the Association, subject to the notice and hearing procedures set forth in the Rules of the Council on Ethical and Judicial Affairs:

- Physicians with convictions for fraud or a felony involving professional misconduct or moral turpitude by a court of law or other tribunal with acknowledged jurisdiction;
- Physicians who have had a license revoked or have been forced to surrender a license for reasons relating to incompetence or unprofessional conduct;
- Physicians who have been discharged from the armed forces or government employ for reasons related to and based on a finding of incompetence or unprofessional conduct.

The report also notes that even physicians who have committed offenses within these criteria might be suitable for AMA membership if they have “demonstrated rehabilitation” and their past difficulties have been “fully resolved.” Furthermore, it acknowledges that physicians may fall into an “intermediate” category, in which case individual consideration would be required.

Criteria for Determining when To Impose Sanctions

When it engages in its disciplinary function, CEJA gives careful consideration to the criteria set forth in Board of Trustees Report II (A-87). However, the report itself states that even those physicians who fall within the categories of preemptory exclusion nevertheless might be suitable for membership if they have been rehabilitated. Therefore, while CEJA generally will terminate the membership of physicians who fall under the report’s “immediate expulsion” categories, it will not invariably do so. The Council determines a physician’s suitability for AMA membership by deliberating the circumstances of each case individually.

The Council also carefully considers the findings and decisions of courts or of governmental agencies, which may have previously adjudicated an action against an AMA member or membership applicant. For example, if a medical licensing board has revoked an AMA member’s medical license because of criminal or immoral behavior, CEJA will generally exercise a parallel action and expel the member. Likewise, if a medical licensing board has imposed probationary terms on an AMA member, CEJA will generally also impose a co-terminus probation. However, CEJA does exercise individual discretion in each case it reviews.

In light of this framework, CEJA has considered whether it should publish written guidelines to determine membership eligibility status. After careful deliberation, CEJA believes that it should not codify such criteria at this time. The Bylaws and Board of Trustees Report II (A-87) establish general standards, which CEJA considers to be appropriate and sufficient.

Of necessity, new membership applicants with questionable backgrounds must be placed in a pending status, without full membership rights, until CEJA has had an opportunity to examine the applicants’ credentials. Current members, however, retain full membership status and have access to all benefits until final adjudication by CEJA.

Other Procedural Aspects of the Disciplinary Process

The disciplinary process begins when a possible violation, by a present member or by a membership applicant, of the Principles of Medical Ethics or of illegal or other unethical conduct is reported to the AMA. Such information generally arises from statements made in the membership application form or from a report of disciplinary action taken by a state licensing board, state medical association, or specialty society. On occasion, CEJA may learn of a member’s improper conduct through media reports.

Bylaw 1.1212 defines a procedure wherein objections to an applicant for active direct membership can be made by an external source. This situation has never, within CEJA’s knowledge, occurred.

If it appears that an ethical or legal violation could merit CEJA’s attention, the member or applicant is contacted to ascertain whether he or she wishes to present any additional information for CEJA’s consideration. Based on all information that is presented to it, CEJA determines whether the physician’s conduct may be excused or whether it warrants a plenary hearing. A plenary hearing affords the member or applicant the right to present further

arguments or other information to CEJA either personally or through an attorney. Although the physician could participate in such hearings in person, invariably hearings have been conducted by teleconference. An attorney from the AMA Office of General Counsel, along with Council members and the Secretary to the Council, participate in the hearing.

The Council never imposes a sanction without offering a hearing to the physician. If CEJA does take a disciplinary action, the decision is, to the extent required under the procedures of the Health Care Quality Improvement Act, reported to the National Practitioner Data Bank and to the respective state medical or specialty societies.

The rules that guide CEJA's disciplinary function are published as an appendix to the *Code of Medical Ethics*.

CONCLUSION

This report provides information on the scope of the Council's disciplinary activities and the process that is followed. The Council also believes this report can serve as a reminder of the responsibility a profession holds in preserving professional integrity by establishing as well as enforcing standards of conduct. The *Code of Medical Ethics* of our American Medical Association serves as a guide for physician behavior, and the Council's judicial function serves as a model for professional self-regulation. Moreover, by conferring membership only upon those physicians who uphold the values of medical ethics and professionalism, the AMA assumes a leading role in demonstrating that the medical profession considers self-regulation a paramount responsibility. These efforts, along with those of state societies and specialty associations, are critical to protecting the public's trust in medicine.

APPENDIX - CEJA JUDICIAL FUNCTION: FEBRUARY 3, 2002 - APRIL 13, 2003

<i>Physician Members and/or Applicants</i>	<i>Reports of Possible Violations</i>
25	Initial letters informing physician of CEJA's review
40+	Physicians currently under consideration for possible notification
	Approximately 200 physicians were reviewed and their cases were found not to necessitate CEJA's attention
	<i>Summary of CEJA Activities</i>
3	Determination of no probable cause
2	Reviewed and deferred
17	Reviewed/found probable cause/offered the right to plenary hearing
17	Plenary hearings
10	Final determinations without a plenary hearing (hearing waived or non-response to the offer)
10	Members currently on probation and reviewed semi-annually
	<i>Final Actions</i>
5	No discipline imposed
4	Denial (applicants)
5	Revocation (existing AMA members)
2	Suspension
2	Censure
1	Admonishment
8	Probation

6. USE OF HEALTH-RELATED ONLINE SITES

HOUSE ACTION: RECOMMENDATIONS ADOPTED AND REMAINDER OF REPORT FILED

The Internet is “an interconnected system of networks that connects computers around the world via the TCP/IP protocol” and which provides information and visual content to users. Online sites and online software providers (e.g., America Online) can vary in their sophistication, some allowing for audio-visual transmission, others allowing only for text communication through means such as electronic mail (e-mail), private chat rooms, online discussion groups (also known as Usenet groups), and instant messaging.

It has been estimated that more than 10,000 online sites contain health information on the Internet. Individuals turn to the Internet to find information quickly and efficiently. However, many ethical concerns have been raised regarding medical information and services on the Internet. This report will address those ethical concerns.

HEALTH-RELATED ONLINE SITES

Health-related online sites, including those developed by physicians, exist in many formats that broadly fall under two categories: informational sites and interactive sites. Informational online sites often provide a wide range of information including information related to physicians’ practices, or information regarding certain medical conditions or specific treatment options. These informational sites are not intended to offer individualized diagnostic or therapeutic advice to online visitors. In contrast, interactive sites may provide a forum for individuals to request specific health information. These sites may specify that questions are reviewed by health care professionals, including physicians, or may provide the e-mail addresses of participating physicians whom individuals can contact for additional information. Other interactive online sites facilitate only the exchange of administrative information, such as appointments, rather than medical information.

Consumer Use and Expectations

Increasingly, individuals seek online consultations through health-related online sites. In 2001, approximately 3 million people used the Internet for online consultations with a medical expert. By using the Internet, online visitors can eliminate geographic or logistical obstacles in obtaining medical information. For example, a recent survey revealed that 41% of patients participating in the study were reluctant to spend time in physicians’ offices to ask questions that could be answered through other means of communication, such as e-mail. The survey also concluded that 81% of the online population would like to receive e-mail reminders for preventive care and 83% would like follow-up e-mails after a visit to their physicians.

Patients may obtain second opinions through online sites. For example, the Cleveland Clinic established e-Cleveland Clinic, an Internet site through which expert review of medical records and diagnostic tests can be sought to obtain a second opinion. Individuals enter a secure online site and fill out an online questionnaire that documents their medical condition. They also are asked to submit necessary information, such as medical records or test results, through the site. Within a few days, individuals receive an e-mail message instructing them to access the secure online site to read the second opinion.

The second opinion provided by e-Cleveland Clinic is accompanied by a disclaimer, which explicitly states that it is offered without the benefit of information usually obtained during a face-to-face encounter or through a physical examination and, therefore, that important information may have been missing on which the second opinion was based. In light of this limitation, the e-Cleveland Clinic strongly encourages second opinions to be shared with the requestor’s treating physician. When mandated by law or requested by the patient, the second opinion is directly sent to the treating physician. In such circumstances, the second opinion is rendered within an established patient-physician relationship. However, in the absence of communication with the treating physician, providing a second opinion via a health-related online site can be problematic. Specifically, there may be an increased risk of misdiagnosis or an inappropriate treatment recommendation due to the absence of more complete information, which usually is obtained when there is an established patient-physician relationship.

Interestingly, there are important differences between consumer and physician expectations regarding the function of health-related online sites. A study of patient use of health-related online sites found that although the number of health information consumers was climbing, the satisfaction of the users was declining. The survey revealed that more patients wanted to use the Internet to communicate with their physician. More specifically, patients wanted advice and services from their physicians while online and were disappointed when their physicians resisted e-mail communication. A 2002 survey found that only 26% of online physicians used the Internet to contact patients. These results illustrate a challenge for patients and physicians: how to use the Internet as a supplement to the patient-physician relationships.

Physician Online Sites

While 89% of physician respondents to a 2002 survey use the Internet for some clinical purpose, approximately 30% of physicians have their own online site. Many physicians develop interactive online sites for administrative purposes in response to patient preferences. Online sites that allow patients to schedule or cancel appointments, or to obtain prescription renewals or a referral appear to reduce the number of requests that account for 80% of physicians' daily phone calls.

Besides addressing administrative functions, some physicians establish or participate in interactive online sites that provide medical information. For example, some online sites facilitate general dialogues related to a medical condition. These online sites enable patients to ask specific medical questions. This may occur in the form of real-time dialogues with therapists, primary care physicians, or other medical specialists. In some instances, however, a computer response is generated that may contain a diagnosis and treatment recommendations, without any direct physician involvement.

Also, there are interactive online sites that offer prescription drugs to patients. For example, one online site uses board-certified primary care physicians from Illinois and Indiana to diagnose and prescribe medication to individuals in those two states. The online site uses a triage system to separate minor illnesses from serious conditions and only offers online assistance for acute, minor illnesses. Individuals with serious or life-threatening conditions are advised to seek immediate medical attention. Patients are charged for the services and consultation they received.

Most people pay out-of-pocket for online services. However, to encourage cost-effective physician contacts, several health insurance companies are considering reimbursements for health care services rendered over the Internet.

QUALITY STANDARDS AND GUIDELINES

The quality of health-related online sites and the reliability of the information that is provided vary considerably. Individuals can find many highly sophisticated Internet resources that are sponsored by well-known entities such as reputable medical institutions, which will generally offer reliable information or services. Other sites may appear very similar but offer incomplete or outdated information, propagate false information, or dispense services that are unregulated. Some sites may be sponsored by entities with a financial interest in the information or services provided. Yet, they may not appear as commercial sites to some users.

Although only 2% of online users know someone who has been seriously harmed by online site-based medical advice or health information, the quality of health-related online sites is a concern for many online visitors and physicians. In a 2001 study, it was found that a majority of health-related online sites that had been reviewed lacked completeness in information and accuracy. Furthermore, a recent inspection of online sites worldwide uncovered more than a thousand sites that make false claims or provide misleading information.

Guidelines exist to protect online visitors and physicians when using interactive online sites. The Federation of State Medical Boards created guidelines for physicians who offer health-related online sites, emphasizing five ethical standards: candor, privacy, integrity, informed consent, and accountability. Overall, information contained on physician online sites should be truthful and not misleading or deceptive. Also, physicians have an obligation to disclose information that could influence patients' understanding or use of the information, including financial, professional or personal conflicts of interest.

In December 2002, a consortium of medical societies and medical liability carriers concluded that physicians should engage in online consultations with previously established patients only and existing standards from the eRisk Working Group for Healthcare were updated to discourage the online treatment, diagnosis, or prescription of medications to unknown individuals. These new standards were based on disciplinary actions that had been taken by some licensing boards against physicians who had offered medical treatment to unknown, online patients, and were intended to provide uniform standards for all state licensing boards.

Other forms of protection for users of health-related online sites include the work of the American Accreditation HealthCare Commission (also known as URAC), which accredits health-care sites. This accreditation process is based on the ethical standards set by Health Internet Ethics (Hi-Ethics), which address privacy, security, quality of information, fairness of transactions, and professional conduct. Thus far, 16 health-related online sites have received accreditation by URAC. Unfortunately, only 19% of Internet users find accreditation “very important” and only one-quarter of online users follow guidelines for checking the sources and timeliness of an online site’s information. Many consumers tend to focus on the style or the “look” of an online site rather than the accuracy or reliability of its content.

To address security and privacy concerns, the AMA Internet ID provides a reliable authentication technique and also protects patient and physician information when it is sent or received over the Internet. This feature alleviates many worries that have been voiced by both patients and physicians. Also, the AMA has issued guidelines for all AMA-affiliated online sites to address content definitions, privacy and confidentiality concerns, funding and sponsorship, and content quality.

Finally, many health-related online sites include disclaimers. These disclaimers often make clear the physician’s scope of responsibility and the intent of the provided health information. However, disclaimers do not absolve physicians from their responsibility to patients or their responsibility to provide reliable and factual information.

ETHICAL CONSIDERATIONS

Interactive as well as informational online sites may raise ethical concerns, including accuracy, the credentials or qualifications of web-based physicians, conflicts of interest, and advertising. Moreover, the security, privacy, and confidentiality of information transmitted to and from interactive online sites, including those limited to administrative functions, must be considered.

Accuracy, Qualifications, and Standard of Care

With regard to online sites that provide health-related information, both online visitors and physicians are leery of the accuracy of the information. To alleviate these concerns, information presented on online sites should identify the source of their information and be updated frequently since outdated information can be misleading and harmful. When physicians develop their own sites, they should strive to make information easily accessible to the patient population they generally serve, particularly in relation to patients’ levels of health literacy and proficiency in English.

It is also important that information regarding credentials or qualifications of web-based physicians be accurate. To the extent that interactive online sites could constitute the practice of medicine, participating health care professionals should bear in mind that the practice of medicine by an unlicensed person is unethical, as well as illegal.

Health-related online sites that provide medical advice or care outside an existing patient-physician relationship and without information from a physical exam, or that rely on computer generated responses, are also ethically problematic because of the increased risk of misdiagnosis or inappropriate treatment recommendations. Therefore, physicians should refer to general and specialty-specific standards regarding the appropriate use of interactive online sites, including their possible use in the absence of a pre-existing patient-physician relationship, as well as the use of algorithms that may generate diagnoses or prognoses that are directly transmitted to users.

Conflicts of Interest and Advertising

When establishing or participating in an online site, physicians should consider any potential conflicts of interest that could emerge, particularly when the site is commercially sponsored or offers commercial services. To this end, the AMA's *Guidelines for Medical Information Online sites* maintains that all sponsorship or funding of online sites should be clearly indicated and any advertising should be easily distinguished from and should not be clinically related to the content of a web page.

Existing guidelines from the AMA's *Code of Medical Ethics* concerning conflicts of interest or commercial biases also apply to health-related online sites, including the prohibition against the provision of unnecessary service or the limitations on self-referral and the sale of products. Also, when making promotional claims on their online sites, as with other forms of advertising, physicians must be mindful of Opinion E-5.02, "Advertising and Publicity."

Security, Privacy, and Confidentiality

When establishing or participating in interactive online sites, physicians must consider security and privacy concerns. This also applies to the use of interactive online sites that are limited to administrative functions, since they are likely to include personal information such as the patients' name or address, or even a diagnosis or other sensitive information. Physicians who establish or participate in online sites through which they answer e-mails from individuals should follow the ethical guidelines provided in CEJA Report 3-I-02, "Ethical Guidelines for the Use of Electronic Mail between Patients and Physicians."

CONCLUSION

Health-related online sites offer a wide range of information and services and are used by health professionals, patients, and the public with increasing frequency. While there is great hope that the Internet can become a reliable resource for health-related matters, it is necessary to remember that currently it is largely unregulated. Therefore, it is important that physicians who establish health-related online sites or are involved in the provision of information or services through them must adhere to guidelines issued by professional groups. These standards will ensure that online sites are used in a manner that is beneficial to patients rather than fraught with potential harm. In time, with assistance from their physicians and information provided by health online site accreditation agencies, patients may learn to optimize their use of health-related online sites to find reliable information. It also may be possible for patients to receive services in a manner that is efficient, does not compromise their health, and enhances the personal encounters and ongoing personal relationships upon which the therapeutic alliance has traditionally been founded.

RECOMMENDATIONS

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

As Internet prevalence and access rapidly increases, individuals turn to the Internet to find health-related information quickly and efficiently. Online users can access innumerable informational or interactive online sites, many of which are maintained by physicians or rely on their services. Physician involvement should be guided by the following considerations:

1. Physicians responsible for the health-related content of an online site should ensure that the information is accurate, timely, reliable, and scientifically sound, and includes appropriate scientific references.
2. The provision of diagnostic or therapeutic services through interactive online sites, including advice to online users with whom the physician does not have a pre-existing relationship or the use of decision-support programs that generate personalized information directly transmitted to users, should be consistent with general and specialty-specific standards. General standards include truthfulness, protection of privacy, principles of informed consent, and disclosures such as limitations inherent in the technology.
3. When participating in interactive online sites that offer email communication, physicians should follow guidelines established in Opinion 5.026, "Use of Electronic Mail."

4. Physicians who establish or are involved in health-related online sites must minimize conflicts of interest and commercial biases. This can be achieved through the development of safeguards regarding funding and advertising that require disclosure and honesty. It also requires that physicians not place commercial interests ahead of patient health; therefore, physicians must not use health-related online sites to promote unnecessary services, refer patients to entities in which they have ownership interests, or sell products outside of established ethical guidelines (see Opinions 2.19, "Unnecessary Services," 8.032, "Conflicts of Interest: Health Facility Ownership by a Physician," 8.062, "Sale of Non-Health-Related Goods from Physicians' Offices," and 8.063, "Sale of Health-Related Products from Physicians' Offices"). Promotional claims on online sites must conform to Opinion 5.02, "Advertising and Publicity."
5. Physicians who establish or are involved in health-related online sites that use patient specific information must provide high-level security protections, as well as privacy and confidentiality safeguards.

(References pertaining to Report 6 of the Council on Ethical and Judicial Affairs are available from the Ethics Standards Group.)

7. CLONING-FOR-BIOMEDICAL-RESEARCH

HOUSE ACTION: RECOMMENDATIONS ADOPTED AND REMAINDER OF REPORT FILED

In July 2002, the President's Council on Bioethics (PCB), created by executive order of George W. Bush, issued its first report: "Human Cloning and Human Dignity: An Ethical Inquiry." The topic of human cloning had been and continues to be featured regularly in the professional and lay press for the scientific promise and moral quandaries it presents. It also has captured the attention of legislators. At this time, it is important that organized medicine offer guidance to physicians as to how they should proceed from the viewpoint of professional ethics because various interventions made possible by human cloning are likely to rely on physicians' expertise and could have an impact on their clinical activities.

TERMINOLOGY AND SCOPE

Cloning is a term used to describe the asexual production of a new organism through somatic cell nuclear transfer (SCNT), which involves the introduction of the nuclear material of a somatic cell into an enucleated oocyte. This process yields an embryo that is genetically virtually identical to the donor of the somatic cell; that is, its nuclear DNA is contributed by the nucleus donor, while its cytoplasmic DNA is contributed by the oocyte donor.

If the cell resulting from the transfer of a human somatic nucleus to an enucleated oocyte by SCNT technology were to divide and develop successfully, the product would lead to a cloned human embryo. In theory, if such an embryo were implanted in a woman's uterus and the ensuing pregnancy carried to term, the resulting child would be genetically virtually identical to the donor of the somatic cell. The President's Council on Bioethics has referred to this activity as "cloning-to-produce-children." In contrast, the process of producing cloned human embryos from SCNT with the intent to extract their stem cells for use in medical research has been termed "cloning-for-biomedical-research."

Stem cell research has received increasing attention because of the potential benefit it holds for patients (see Council on Scientific Affairs Report 5). This report of the Council on Ethical and Judicial Affairs specifically considers the ethical appropriateness of using embryonic stem cells in biomedical research, particularly where stem cells are derived from human embryos created through SCNT technology.

This report does not expand on broad ethical considerations raised by possible long-term consequences of all stem cell research, such as the evolution of our concepts of aging and mortality, or of personal identity and bodily integrity if we acquired the ability to replace and regenerate bodily tissues and organs.

STATUS OF THE HUMAN EMBRYO

Much of the controversy surrounding biomedical research on embryonic stem cells in general arises from the plurality of views within our society regarding the moral worth of early embryos, particularly because the retrieval of stem cells necessitates the embryo's disaggregation or destruction. The various moral perspectives give rise to incompatible notions of how much respect is owed to and what rights are possessed by preimplantation human embryos at the blastocyst stage.

Those who believe that an embryo at any stage possesses the same moral status and rights as a mature person will be opposed to destruction of an embryo for any reason. For others, though respect for the blastocyst may symbolize a commitment to life, it does not have full moral status in the absence of a nervous system and differentiated organs. Therefore, some adhering to this view believe that biomedical research on embryonic stem cells should be permitted out of respect and concern for living persons, because of the research's potential to yield medical advances that will help treat disease, improve the quality of life of patients, and save lives. Others would require a compelling argument for using embryonic stem cells instead of other types of stem cells.

Cast in these terms, the debate over embryonic stem cell research seems to focus on the moral worth of an embryo at the blastocyst stage rather than on the method through which the embryo is created. From a professional perspective that relies on the *Principles of Medical Ethics*, a strong argument can be made that physicians' professional obligation to living individuals overrides their obligation to the earliest forms of life. As noted by the American College of Obstetricians and Gynecologists, in its Committee Opinion on "Preembryo Research," the preimplantation embryo, at less than 14 days, does not possess the biologic individuality necessary for a concrete potentiality to become a human person. With its individuality not yet determined (an embryo at this stage could divide naturally to form twins, for example), the blastocyst should not be attributed the same worth as a human person.

In connection with the general debate on the moral status of the embryo, some draw moral distinctions based on the intended use of the embryos--embryos created in the context of IVF to assist couples in conceiving and those created solely for the purpose of research. It is also important to note that some embryos created for uterine implantation are not used for this purpose because they are no longer needed (supernumerary embryos), and therefore are often discarded or are used for research.

Only embryos intentionally created for biomedical research are, from their inception, lacking in the potentiality to become a human being and therefore not due the corresponding respect. Some maintain that such embryos are "instrumentalized" or treated as though they were objects, in a way that disrespects human life. Others look at the same facts and conclude that because no future life was intended from the outset, there are no future interests of a human life to be harmed, so the process is morally less problematic. Finally, some have argued that it is no worse to destroy a blastocyst intended from the start for biomedical research by extracting the stem cells from its inner mass than to discard a frozen embryo.

Cloned Embryos

Similar to the concerns discussed above, it appears that some of the resistance toward the use of stem cells from embryos created through SCNT technology arises from confusion between cloning-to-produce children and cloning-for-biomedical-research. Technically, both these activities would rely on the same baseline technology, SCNT; however, it would be used toward fundamentally different goals. Other reasons for which cloning-for-biomedical-research has been opposed include fear that the research might lead to new forms of the "instrumentalization" of life, or using embryos as mere means to an end. If cloned embryos are regarded as disposable commodities, then scientists might mass-produce them.

Another objection is that cloning-for-biomedical-research may open the door to cloning-to-produce children. Even though scientists involved in stem cell research may have no intention of exploring the possibility of transferring a cloned embryo into a woman's uterus with the goal of a resulting pregnancy, it is argued that they are helping to improve the technique of SCNT, so that it may become possible for a cloned embryo to develop to the stage where it could be implanted successfully. However, given the low success rates and high safety concerns associated with the cloning of mammals, and repeated failed attempts to create a primate through SCNT technology, there is little reason to expect that human beings would succeed in producing cloned children using this technology. At this time,

cloning-to-produce-children appears impossible. Therefore, it is inaccurate to claim that cloned human embryos have the potentiality for human life. Fears related to cloning-to-produce children may offer a compelling argument for effective protections against certain uses of cloned embryos, but they do not justify the prohibition of all cloning.

POLICY RELATED TO CLONING-FOR-BIOMEDICAL-RESEARCH

Restricting Embryonic Stem Cell Research

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 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 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.

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.

Justifications for Research on Stem Cells Derived from Cloned Human Embryos

Proponents of embryonic stem cell research base their arguments on its potentially powerful contributions to treating human disease and disability. Many scientists, for example, take the view that benefits from this form of research are likely to be so great that it must be allowed to proceed. This is reflected in the respective reports on stem cell research of the American Association for the Advancement and Institute for Civil Liberties, as well as the Committee on the Biological and Biomedical Application of Stem of Science, Board on Life Sciences, National Research Council, Board on Neuroscience and Behavioral Health, Institute of Medicine, all of which are supportive of continued research on embryonic stem cells. Some argue that prohibiting this research would be more disrespectful of human life than the destruction of embryos it entails. At least, they argue that embryonic stem cell research should be pursued along with other stem cell research, until it becomes known whether one is more promising or whether perhaps the different types of research offer distinct possibilities.

If the promise of stem cell research is realized with regard to renewable sources of cells replacement, gene therapy or tissue and organ transplantation, cloning-for-biomedical-research could prove uniquely promising. It could lead to the growth of tissues or organs that are immunologically compatible with the individual in need, removing the most important barrier to successful transplantation. This is addressed in CSA Report 5, as is the unique opportunity that research on stem cells derived from cloned human embryos provides to understand molecular and cellular events underlying human diseases.

EMBRYONIC STEM CELL RESEARCH: A VIEW FROM ORGANIZED MEDICINE

By examining the ethical considerations this research raises, organized medicine can advocate responsible conduct of research to the medical community. As an issue that is based on moral values and matters of personal conscience rather than scientific discourse, the moral status of the embryo cannot be settled by organized medicine. This is not to say that investigators should proceed with cloning-for-biomedical-research with no regard for ethics, but rather that professional standards of ethics should guide the process.

Relevant AMA Policies

Research on stem cells derived from cloned embryos offers possibilities for medical advancement that could save lives, improve quality of life, and alleviate suffering. It is consistent with principles of medical ethics, particularly physicians' paramount obligation to the welfare of their patients (Principle VIII) and their responsibility to advance scientific knowledge (Principle V). Therefore from the standpoint of medical professionalism, physicians may participate in and support cloning for biomedical research, so long as they proceed in accordance with adequate research ethics standards and with the law. Individual physicians remain free to decide whether to participate in stem cell research or to use its products.

An important methodological approach in bioethics is to compare and contrast the new ethical dilemmas technological advances create to established standards, in an effort to begin to resolve them. A similar exercise, relying on existing policies in the *Code of Medical Ethics*, may help clarify physicians' ethical responsibilities in relation to SCNT.

Opinion E-2.14, "In Vitro Fertilization," is unambiguous in its support of IVF to assist couples reproduce. Specifically, the *Code* is clear that producing embryos to assist child bearing is ethically acceptable. The opinion also allows fertilized ova no longer intended for implantation to be used in research, if certain ethical safeguards are respected. Overall, the opinion acknowledges the usefulness of IVF in contributing to medicine's understanding of how genetic defects are transmitted and how they might be prevented or treated. Similarly, Opinion E-2.141, "Frozen Pre-embryos," states that "research on pre-embryos should be permitted as long as the pre-embryos are not destined for transfer to a woman for implantation and as long as the research is conducted [ethically]."

While the *Code* in its current form supports research on supernumerary embryos, it has not offered a systematic ethical analysis of embryos created expressly for the purpose of conducting biomedical research or of cloned human embryos produced for biomedical research.

THE NEED FOR APPROPRIATE SAFEGUARDS IN CLONING-FOR-BIOMEDICAL-RESEARCH

Medical science cannot settle all the ethical quandaries that surround cloning-for-biomedical-research and divide our society. However, organized medicine can join those who recommend special safeguards to protect research subjects. In addition to such safeguards, continuing oversight and monitoring of findings will be needed.

Informed Consent

Prior to producing an embryo through SCNT technology for research purposes, specific consent must be obtained from at least two categories of subjects, the egg donor and the somatic cell donor. Beyond customary information regarding relevant risks and benefits to subjects, disclosure to each donor must include:

- description of the procurement procedures specific to the donor;
- 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);
- acknowledgment that the extraction of stem cells will require the cloned embryo's destruction;
- 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; and
- potential commercial uses and patent or ownership issues (as described in Opinion E-2.08, "Commercial Use of Human Tissue").

The informed consent process for potential recipients of stem cells derived from cloned embryos should conform with ethical standards outlined in CEJA's Opinion E-2.07, "Clinical Investigation," and address additional disclosures regarding provenance of stem cells and ethical considerations associated with xenotransplantation, as outlined in Opinion E-2.169, "The Ethical Implications of Xenotransplantation."

Research Oversight

Currently, federal funds cannot be used to create embryos solely intended for research purposes or to conduct research that entails the destruction or discarding of human embryo. However, this does not mean that there exists no federal oversight mechanism to regulate and monitor cloning-for-biomedical research. Indeed, when tissue transplantation is the endpoint, every step of cloned human embryo stem cell research is subject to regulation of cell-based therapies by the Food and Drug Administration (FDA). However, if SCNT research has objectives other than transplantation, researchers in the private sector are left without a clear set of regulatory guidelines. As described in Opinion E-2.07, "Clinical Investigation," the scientific validity and the ethical considerations raised by any research should be carefully assessed and given due weight by qualified bodies such as institutional review boards. Because research on stem cells extracted from cloned human embryos raises unique social concerns that are not addressed in general guidelines that govern the conduct of research, the Office for Human Research Protection or other similar entity should help monitor progress in the field and assist in developing relevant guidelines.

RECOMMENDATIONS

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

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. An individual 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:
 - (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; and
 - (e) potential commercial uses and patent or ownership issues (as described in Opinion 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."

(References pertaining to Report 7 of the Council on Ethical and Judicial Affairs are available from the Ethics Standards Group. The Council also gratefully acknowledges R. Alta Charo, JD, Associate Dean for Research and Faculty Development, University of Wisconsin Law School, Professor of Law and Bioethics, University of Wisconsin Law and Medical Schools; and Robert Lanza, MD, Vice President, Medical and Scientific Development, Advanced Cell Technology, for their comments on this report.)

8. DISRESPECT AND DEROGATORY CONDUCT IN THE PATIENT-PHYSICIAN RELATIONSHIP

HOUSE ACTION: RECOMMENDATIONS ADOPTED AND REMAINDER OF REPORT FILED

At the 2001 Interim Meeting, Resolution 1, "Non-Discrimination in Responding to Terrorism," was adopted in response to the events of September 11, 2001, which affected health care workers and patients across the country. In part, the resolution asked that the American Medical Association declare its opposition to discrimination against patients, physicians, or other health care workers on the basis of religion, culture, nationality, or country of medical education and/or training. The resolution urged the AMA's support of the idea that the nation's response to terrorism must not involve such discrimination or acts of violence against any person on the basis of religion, culture, or nationality.

In light of Resolution 1, the Council reviewed Opinion 9.12, "Patient-Physician Relationship: Respect for Law and Human Rights," and found that it adequately addresses issues of discrimination and the patient-physician relationship. However, media reports and other evidence following September 11, 2001, revealed cases of refused treatment and verbal abuse of patients based on their ethnic background. These cases displayed unbecoming behavior from health care professionals responsible for treating all those in need without prejudice. The Council concluded that guidance related to derogatory conduct would complement current guidelines included in the *Code of Medical Ethics*.

RECOMMENDATIONS

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

The relationship between patients and physicians is based on trust and should serve to promote patients' well-being while respecting their dignity and rights. Trust can be established and maintained only when there is mutual respect.

Derogatory language or actions on the part of physicians can cause psychological harm to those they target. Also, such language or actions can cause reluctance in members of targeted groups to seek or to trust medical care and thus create an environment that strains relationships among patients, physicians, and the health care team. Therefore, any such conduct is profoundly antithetical to the *Principles of Medical Ethics*.

Patients who use derogatory language or otherwise act in a prejudicial manner toward physicians, other health care professionals, or others in the health care setting, seriously undermine the integrity of the patient-physician relationship. Such behavior, if unmodified, may constitute sufficient justification for the physician to arrange for the transfer of care.

9. DISCLOSURE OF FAMILIAL RISK IN GENETIC TESTING

HOUSE ACTION: RECOMMENDATIONS ADOPTED AND REMAINDER OF REPORT FILED

At the 2002 Annual Meeting, the American Medical Association House of Delegates adopted the recommendations of Council on Ethical and Judicial Affairs Report 2, "Disclosure of Familial Risk in Genetic Testing" (see Policy H-140.899, AMA Policy Database). The recommendations provided guidance for physicians to discuss with their patients, prior to genetic testing, circumstances under which the familial quality of genetic information could compromise the duty of confidentiality.

At the 2002 Interim Meeting, CEJA opted to withdraw Opinion 2, which corresponded to the recommendations of CEJA Report 2-A-02, in response to concerns that were brought to its attention by the American Society of Clinical Oncology, as well as several other genetics interest groups. The Council carefully reconsidered the standard of disclosure that should apply to familial risk in genetic testing. In light of this review, the Council proposes amendment to Policy H-140.899, "Disclosure of Familial Risk in Genetic Testing," which was derived from CEJA Report 2-A-02.

RECOMMENDATIONS

The Council on Ethical and Judicial Affairs recommends that Policy H-140.899, "Disclosure of Familial Risk in Genetic Testing" be amended as follows, and that the remainder of this report be filed:

H-140.899 Disclosure of Familial Risk in Genetic Testing

- (1) Physicians have a professional duty to protect the confidentiality of their patients' information, including genetic information.
- ~~(2) Physicians who order genetic tests should have adequate knowledge to impart accurate information to patients. In the absence of adequate expertise in pre-test and post-test counseling, the primary physician should refer the patient to an appropriate specialist.~~
- ~~(3) Pre- and post-test counseling should consider must include implications of genetic information for patients' biological relatives. At the time when patients are considering undergoing genetic testing, physicians should discuss with them whether to invite family members to participate in the testing process. (4) Before testing, physicians should inform patients of Physicians also should identify circumstances under which the physician they would expect the patients to notify biological relatives of the availability of information related to risk of disease. In this regard, physicians should make themselves available to assist patients in communicating with relatives to discuss opportunities for counseling and testing, as appropriate, disclose relevant results of the genetic tests to biological relatives, or would feel compelled to breach a patient's confidentiality to notify affected biological relatives of relevant findings. If the patient still wants to be tested and an agreement cannot be reached regarding conditions for disclosure, the physician should refer the patient to another health professional. In the event physician and patient find themselves in conflict after testing has occurred, despite a satisfactory informed consent, the burden falls to the physician to demonstrate why an explicit breach of confidentiality would be justified.~~
- (3) Physicians who order genetic tests should have adequate knowledge to interpret information for patients. In the absence of adequate expertise in pre-test and post-test counseling, a physician should refer the patient to an appropriate specialist.
- ~~(4) Physicians should encourage genetic education at all stages of throughout a medical career. (CEJA Rep. 2, A-02)~~

10. MAINTENANCE OF CERTIFICATION - ETHICAL DIMENSIONS

HOUSE ACTION: FILED

At the 2002 Annual Meeting, the House of Delegates adopted Council on Medical Education Report 7, "Internal Medicine Board Certification Report - Interim Report." This report responded to several resolutions addressing recertification. Among its recommendations, the report called for a study of the ethical implications of the Maintenance of Certification (MOC) program including the patient assessment component vis-à-vis the doctor-patient relationship and the ethical implications of the peer review component vis-à-vis the practice environment. This directive to take action has been referred to the Council on Ethical and Judicial Affairs.

BACKGROUND

As the CME report describes, the "Maintenance of Certification" concept is supported by the American Board of Medical Specialties (ABMS) through its commitment to the assessment of continuing competencies of physicians. It includes four basic components: evidence of professional standing; evidence of a commitment to lifelong learning and involvement in a periodic self-assessment process; evidence of cognitive expertise; and evidence of evaluation of performance in practice.

However, the CME report focused on the American Board of Internal Medicine (ABIM), which had taken a lead in developing comprehensive approaches to the evaluation of physician performance, as part of Continuous Professional Development (CPD). It is within this framework that patient and peer assessment was identified as an important modality to obtain feedback on non-technical aspects of competence, such as communication skills and humanistic or professional aptitudes. However, among reactions to the ABIM efforts to implement CPD, the CME report noted that concerns had been raised that patient and peer feedback could be perceived as intrusive and potentially inappropriate.

ETHICAL CONSIDERATIONS

Relevant Ethical Policies

In exploring the professional and ethical concerns that may arise from the innovative evaluation tools being developed in the context of MOC, it is worth turning to the *Principles of Medical Ethics* for guidance. Three principles, in particular, should be considered:

- I. A physician shall be dedicated to providing competent medical care....
- II. A physician shall uphold the standards of professionalism....
- V. A physician shall continue to study, apply, and advance scientific knowledge, maintain a commitment to medical education....

Together, these statements are a clear expression of physicians' commitment to competency and education (Principles I and V), but also recognize that these responsibilities are embodied through the medical profession as a whole (Principle II), and not solely through individual physicians.

Other than these broad statements, the *Code of Medical Ethics* considers education and professional development through several opinions. For example, Opinion E-9.011, "Continuing Medical Education," emphasizes the value of furthering one's education throughout one's career. Specifically, it states: "...for only by participating in continuing medical education (CME) can [physicians] continue to serve patients to the best of their abilities and live up to professional standards of excellence." The *Code*, however, does acknowledge that matters related to education can be distorted or undermined. In this regard, Opinion E-9.01, "Accreditation," warns that "Physicians who...certify the attainment of specialized professional competence have the ethical responsibility to apply standards that are relevant, fair, reasonable, and non-discriminatory."

Some form of peer assessment is also addressed in Opinion E-9.10, "Peer Review." This opinion recognizes that the oversight of professional conduct compromises professional freedom but that it serves to "balance a physician's right to exercise medical judgement freely with the obligation to do so wisely and temperately."

It also is worth noting that the role of patients in education was recently included in the *Code* in explicit terms. Opinion E-10.02, "Patient Responsibilities," was amended in December 2000 to include the following guideline: "Participation in medical education is to the mutual benefit of patients and the health care system. Patients are encouraged to participate in medical education by accepting care, under appropriate supervision, from medical students, residents, and other trainees."

Potential ethical concerns arising from peer and patient assessment

Peer assessment

Throughout medical education and training, students and trainees are most often evaluated by teachers and supervisors, rather than peers, although such evaluation methods do exist in some educational settings. Once a physician has fulfilled all the formal requirements of training, however, his or her practice may come under the review of peers more frequently. There are various established traditions of peer review, which the Council recently acknowledged constituted the basis of endeavors to improve care and the dissemination of knowledge. The Council also noted that peer review has been used as a tool to evaluate the competence of individual doctors by examining the appropriateness of care. In this context, concerns have been raised that peer review can be misused. This has led to the establishment of explicit expectation that peer review be conducted fairly and in good faith, and that appropriate safeguards be in place to protect all parties involved from punishment or unjustified recriminations.

Interestingly, there is a long-standing informal practice of implicitly evaluating colleagues' performance by either referring patients to them or not. In the words of one sociologist: "If a practitioner is dissatisfied with another's work, and talking to him does not lead to desired changes in his behavior...the tendency is not to try to change [the practitioner's] performance so much as to avoid choosing him to work with, and keeping one's own patients away from him."

Because peer assessment in the context of CPD is part of a structured approach to evaluate performance, it is appropriate to consider it in relation to concerns that generally have been raised regarding formal peer review. Foremost, peer assessment should be fair. Yet, because many components of the questionnaire do not lend themselves to an objective evaluation (e.g., respect, integrity, compassion, etc), it is difficult to ensure the fairness of an evaluation that uses a point scale. As peer assessment evolves, it would be important to identify the characteristics of optimal performance for each components of an evaluation.

For the time being, when the assessment of a physician's conduct varies considerably among the assessors, reliability of the results may be problematic. Indeed, it will be difficult to determine whether assessors are reporting a physician whose performance varies in quality, or whether the variation represents differing perceptions. In the absence of objective measures, uniform assessments also could be problematic. For example, low or poor assessments could reflect an environment that is highly competitive or plagued by rivalry, whereas high assessments could reflect an environment that is collegial, supportive, and where criticism is limited.

Aside from the objectiveness and reliability of the assessment, it can be expected that physicians will be concerned about its confidentiality. Any entity that institutes a form of peer review must be able to anticipate which other parties may be interested in the results, which of them have the authority to demand the results, or with which it is appropriate to share results. Next, such information must be shared with the physicians who undergo the review or assessment prior to it taking place.

Finally, it must be recognized that through the assessment of physicians' competencies, poor performances will be identified. Therefore, before a program of assessment is undertaken, it must be clear how such results will be addressed. Assessments intended to be formative, whereby feedback is provided to a physician but no remedial action is required, differ significantly from assessments that are summative, whereby a physician's low performance would require remedial action or result in sanction (i.e., de-certification). Boards should recognize that if poor assessments do not lead to any intervention, it could be argued that they are failing to ensure the competencies of specialists, which in turn could undermine public trust.

Also, it will be important for boards to make clear that peer assessment, as part of CPD, is not a substitute for other mechanisms that exist to report physicians who are incompetent (see Opinion E-9.031, "Reporting Impaired, Incompetent, or Unethical Colleagues"). Therefore, in anticipation that assessors may become aware of conduct that

jeopardizes the health and welfare of patients at the time they conduct assessments, they should be informed of mechanisms that exist to bring such matters to appropriate authorities responsible for the protection of patients notified.

Patient assessment

Innovative evaluation methods that involve patients, such as evaluation of students' or trainees' professionalism, are being introduced in some educational settings. Specialty boards should rely on knowledge that arises from this sphere to inform their efforts. However, until more research is completed to assess the impact of these innovations, boards should remain mindful that, whenever the patient-physician relationship is expanded beyond the therapeutic alliance, prudence must prevail. Also, patient assessment should not be a determining factor in the re-certification process until the reliability, reproducibility and validity of such information has been established.

Above all, there must be a clear understanding on the part of the patient that the request has no bearing on the therapeutic alliance. This entails that the patient must be capable of appreciating the nature of the request. However, the CME report and many other sources that describe the current health care environment point to a significant proportion of patients with limited literacy skills. Along the same vein, many patients have limited English skills, and may not understand the exact nature of the survey, or may not understand the specific questions. A similar concern related to the impact on the therapeutic relationship arises in the context of patients who are very ill, frail, or distraught.

Beyond concerns related to the potential impact on the therapeutic relationship, it is important to recognize that patients with limited access to health care may have only sporadic interaction with physicians and may not be asked to participate in assessments. Altogether, the sample of patient assessors is likely to represent a segment of the physician's patient population that is literate, fluent in English, insured, and relatively healthy. Other potential biases may surface, for example on the basis of cultural or ethnic differences, and should be the object of comprehensive study.

Having identified a patient who is capable to participate, it remains very important not to unduly influence a patient to participate. Ensuring voluntariness, however, may not be as simple as making a request. Indeed, without some additional explanation, patients may misunderstand the nature of the survey. It is possible that some patients may fear that a refusal to participate could have future repercussions on their care. Patients who would accept to participate under such circumstances would most likely rate their physicians more favorably than if they understood the true purpose of the assessment. To limit the possibility that a patient may feel "pressured" to participate, it would be preferable that the request to complete a survey not be made directly by the physician, but rather by a nurse, other office staff, or an independent third party. The requester should emphasize that participation is voluntary, and should clearly present the assessment as a tool intended to assist physicians to better understand how they are perceived by their patients, and possibly improve their performance.

As with peer assessment, the confidentiality of the patient assessment process must be protected. However, it too may not be absolute, and patients should be informed of possible disclosures, even though this may affect their evaluations.

Finally, if patients do not understand the educational nature of the assessment, but rather believe it may be used by disciplinary bodies, they may expect an intervention to take place if they rate a physician very poorly. Trust could be severely undermined if a returning patient who had expected an intervention finds the physician's manners unchanged. This risk adds to the importance of clearly explaining the nature of the assessment and differentiating it from other mechanisms that exist to report misconduct or perceived negligence.

CONCLUSION

Professionalism demands that physicians remain competent. In this context, the American Board of Internal Medicine's Continuous Professional Development initiative presents itself as an innovative attempt to evaluate all dimensions of a physician's practice. Moreover, the use of patient and physician assessment represents an evaluation method that may provide physicians with valuable information, although its impact has only begun to be studied. Therefore, it is important that specialty boards develop such tools carefully, in light of the potential ethical concerns they could raise.

In particular, it will be important to strive for objectivity and fairness. Before peer and patient assessments are used as determining factors for purposes of re-certification, their reliability, reproducibility and validity should be established. In particular, it will be important to identify specific characteristics that describe the expected or optimal performance for each component of an evaluation. Moreover, in the context of patient assessment, it will be important to study whether biases toward certain groups of patients (literate, proficient in English, insured, relatively healthy) affect the results.

With regards to results, specialty boards will need to specify explicitly and in advance how they will be used (e.g., whether remedial actions or sanctions may be imposed), and be prepared to address instances where an assessment reveals conduct that places patients at risk of harm. Although such outcomes should be rare, they are likely to raise the greatest ethical challenges, and underscore the importance of protecting the confidentiality of the assessment.

Finally, specialty boards should recognize that the role of patient as assessor could impact the therapeutic alliance. Research should be conducted early to evaluate whether patients understand the nature of the assessment and whether their participation is truly voluntary.

(References pertaining to Report 10 of the Council on Ethical and Judicial Affairs are available from the Ethics Standards Group.)

11. AMA'S *PRINCIPLES OF MEDICAL ETHICS* (RESOLUTION 11, A-02)

HOUSE ACTION: RECOMMENDATION ADOPTED AND REMAINDER OF REPORT FILED

At the 2002 Annual Meeting, the Utah Delegation introduced Resolution 11, "AMA's *Principles of Medical Ethics*," which called for Principle VI to be amended as follows:

- VI. A physician shall, in the provision of appropriate patient care, except in emergencies, be free to choose whom to serve, with whom to contract, with whom to associate, and the environment in which to provide medical care.

The resolution was referred to the Board of Trustees, and the Board referred it to the Council on Ethical and Judicial Affairs for report back. The Council has the authority to interpret the *Principles of Medical Ethics* (Bylaw 6.4022); however, ownership of the *Principles* resides with the House of Delegates. Referral of Resolution 11 (A-02) permits a careful review of the proposal so that the House can better evaluate whether the American Medical Association's *Principles* should be amended at this time.

FREEDOM OF CONTRACT IN THE *CODE OF MEDICAL ETHICS*

The resolution noted that Opinion E-9.06, "Free Choice," and Opinion E-8.05, "Contractual Relations," both address freedom to contract. Specifically, Opinion E-8.05 explains that:

The contractual relationships that physicians assume when they join or affiliate with group practices or agree to provide services to the patients of an insurance plan are varied....In the operation of such plans, physicians should not be subjected to lay interference in professional medical matters and their primary responsibility should be to the patients they serve.

In addition, it is worth noting that Opinion E-6.11, "Competition," also favors that medical practice occur under free market conditions, and that patients be able to choose among competing physicians and health plans.

Altogether, these Opinions are elaboration upon the current Principle VI, and make clear that physicians should be able to exercise their freedom to choose the conditions within which they practice. It is also implicit that these conditions can be established through contracts, and that physicians can exercise their freedom to choose contracts to enter into with health care institutions as well as contracts to engage in relationships with patients.

Also, CEJA Report 3, “Retainer Practices,” being presented to the 2003 Annual Meeting includes language in the recommendations that reinforces the notion of freedom to contract. Specifically, it states:

Retainer contracts, whereby physicians offer special services and amenities...to patients who pay additional fees distinct from the cost of medical care, are consistent with pluralism in the delivery and financing of health care.

AMENDING THE AMA’S *PRINCIPLES OF MEDICAL ETHICS*

The *Principles of Medical Ethics* are intended to be broad statements that are elaborated upon or clarified through Opinions. The process to amend the *Principles* is described in Bylaw 13.20, which states:

The *Principles of Medical Ethics* of the American Medical Association may be amended at any meeting on the approval of two-thirds of the members of the House of Delegates present and voting, provided that the proposed amendment shall have been introduced at the preceding meeting.

The *Principles* were last amended in June 2001, representing the culmination of CEJA’s work over several years (CEJA Report 1-I-00), which had been undertaken in response to several resolutions referred to CEJA (Resolutions 8 [I-97], 2 [A-98], 2 [A-99], and 2 [I-99]). The Council conducted a comprehensive review of other medical codes of conduct and solicited broad input from the Federation through written communication and testimony at CEJA’s Open Forum in June 1998 and June 1999. The Council then presented a proposal to the House for amendments to the *Principles* in December 2000, which laid over until the June 2001 meeting, where the report “Action on the Proposed Revision of the *Principles of Medical Ethics*,” received the required proportion of votes.

The Council considers that amending the *Principles* should be undertaken only on rare occasions to address significant issues that are either completely absent from the *Principles* or, due to changes in the environment, require modifications. In effect, the *Principles* first appeared in the form of short statements in 1957, and were amended only once--in 1980--before the 2001 amendments.

CONCLUSION

The Council carefully weighed whether the proposed amendment is directed at an issue that is inappropriately addressed in the *Principles* or is absent from them. It found that the current language, by referring to free choice of association, implies free choice of contract, and that this theme is interpreted in greater details in CEJA Opinions. Therefore, the Council concludes that the proposed amendment does not need to be made at this time. The Council will continue to address ethical issues that arise from various contractual relationships physicians may enter through reports and opinions, as necessary.

RECOMMENDATION

The Council on Ethical and Judicial Affairs recommends that Resolution 11 (A-02) not be adopted, and the remainder of this report be filed.

12. FILMING PATIENTS FOR EDUCATIONAL PURPOSES

HOUSE ACTION: RECOMMENDATIONS ADOPTED AND REMAINDER OF REPORT FILED

Respect for the patient should be central in every interaction within the health care system. This should extend to respect for patient privacy, and to confidentiality. Indeed, whenever patient privacy or confidentiality is compromised, trust in the patient-physician relationship may be weakened.

Moreover, the *Principles of Medical Ethics* require physicians to be committed to providing competent medical care for the individual patient; to remain committed to medical education; and to participate in activities that will better public health. Although filming for medical education can be used as a tool to facilitate these goals, it can create a conflict between the physician’s ethical obligation to protect the privacy and confidentiality of patient, and a professional obligation to further the education of current and future health care providers. This report examines the

balance between patient autonomy and patient privacy, and the educational value of films. Similar ethical concerns exist when filming patients for commercial use. These concerns were examined in CEJA Report 3-A-01, "Filming Patients in Health Care Settings."

FILMING FOR MEDICAL EDUCATION

It is important to recognize that filming patients for educational purposes has direct implications to privacy, which itself has become the object of detailed laws including recent federal regulations. Nevertheless, issues arising from filming require analysis from the perspective of the ethics of the patient-physician relationship.

Filming is an important tool both in teaching and evaluating medical students and physicians-in-training. For example, videotaped patient encounters can be used to demonstrate interviewing skills, physical exam skills, or other specific medical techniques. Films may also be used to review and evaluate the skills of medical trainees.

Filming offers unique advantages over other forms of observation. Films can be stopped at pertinent points for instruction, something that is not possible during real-time patient encounters; they can be shown to large groups; and they can illustrate rare cases that trainees otherwise may not be exposed to during their training.

ETHICAL CONSIDERATIONS WHEN FILMING

Ethical questions that were previously examined in the CEJA Report on commercial filming are re-examined here in light of the unique educational opportunities filming offers.

Privacy

Privacy limits the access others may have over a person. In law, it is linked to freedom from intrusion by the state or other persons. In the health care context, it generally designates a domain of personal decision about important matters related to bodily integrity. In its report devoted to privacy, the Council referred to four types of privacy relevant to patients: (1) physical, which focuses on individuals and their personal spaces; (2) informational, which addresses personal data; (3) decisional, which focuses on personal choices; and (4) associational, which refers to family or other intimate relations. In the context of filming for educational purposes, several aspects of a patient's privacy may be affected, since the patient's image and related information will cease to be within the patient's absolute control.

Confidentiality

In relation to confidentiality, filming for educational purposes raises fewer concerns than when it is intended for commercial broadcast, since the intended viewers are ethically bound to respect confidentiality. Indeed, educational filming may be compared to sharing patient information with medical professionals directly involved in the care of a patient, a common and acceptable practice. For example, Opinion E-7.025, "Records of Physicians: Access by Non-Treating Medical Staff," permits disclosure of personal information without specific authorization when it is (1) relevant to patient care, and (2) made to persons who are bound to uphold confidentiality. Arguably, these guidelines may be of limited value if the filming has limited direct impact on the care of the filmed patient. Alternatively, filming may resemble more closely informal case consultations, where all patient identifiers are removed, another generally accepted practice.

Patient Consent

When privacy or confidentiality may be compromised, it is important that patients be given an opportunity to assess the consequences. In the context of filming, this can be achieved by obtaining the patient's consent. The Joint Commission on Accreditation of Healthcare Organizations maintains that filming patients for medical education is appropriate as long as consent is obtained prior to filming or as soon as possible thereafter and the film is not used until consent is obtained. The Society for Academic Emergency Medicine also states that educational filming is appropriate provided that informed consent is obtained and patient confidentiality is respected.

A recent study revealed that current methods of requesting consent from patients for video observation may fail to include the standard components of informed consent, namely: (1) that the patient understands that participation is voluntary, (2) that the procedure is described such that a "reasonable person" can understand, (3) that risks are

clearly identified, (4) that a viable alternative is provided (such that the patient knows that his or her care will not be affected if consent is not given), and (5) that the patient is clear about implied benefit (e.g., educational benefits to health care professionals viewing the film). Failure to inform the patient of these five criteria seriously undermines the patient's ability to make an informed decision.

A discussion regarding the potential benefits of filming for educational purposes requires careful attention, because patients may be unclear of the exact purpose of the film. Also, physicians should be mindful that patients may assess benefits very differently. To prevent misunderstanding, potential direct benefits (filming itself may be therapeutic or filming provides information that is subsequently pertinent to the patient's care), should be distinguished from indirect benefits (patients are helping future patients by helping to educate physicians).

Using films for educational purposes is not intended and is unlikely to benefit a patient medically, so consent should be sought from the patient. Surrogate decision-makers may substitute for the patient only when the patient temporarily lacks capacity to consent to the filming. When the patient regains decision-making capacity, his or her consent should be obtained before the film is used. As in the case of commercial filming, it is permissible to obtain consent for filming from the parent or guardian of a minor child or the guardian of a permanently incompetent patient (see Opinion 5.045, "Filming Patients in Health Care Settings").

When to Obtain Consent

Respecting patient autonomy and protecting patient privacy requires that every effort be made to obtain consent before filming for educational purposes. If it is not possible to obtain consent from the patient before filming, then consent must be obtained before using the film for educational purposes. If consent cannot be obtained from the patient or the surrogate, as discussed above, educational use of the film is not justifiable.

The discussion about the possibility of filming should be afforded all the privacy of any other consent process. Patients should be encouraged to speak candidly about any apprehension they have toward filming. If a patient is inclined to refuse participation, the medical team may offer the patient an opportunity to make a final decision as to the use of the film after reviewing it.

One study has shown that consenting patients had varied responses to the presence of a video camera. Physicians should recognize that, at the end of a filmed encounter, patients may regret their decision to allow filming, particularly if they feel it has negatively impacted the clinical encounter. Therefore, a patient's expression of unwillingness for filming to continue, or for a film to be used for educational purposes, should be respected.

Filming and Medical Records

Some uncertainty persists as to whether audiovisual records of patient-physician encounters are part of a patient's medical record. The American Health Information Management Association states that the recording should be treated as part of the patient's medical record. It is worth noting that the Privacy Rule under the Health Insurance Portability and Accountability Act offers protections to the designated record set, which is composed of the official medical record and billing record, along with any other information related to the health of an individual or the provision of care and payment for it.

In determining whether to include a film as part of the medical record, it may be appropriate to distinguish between films that may contain relevant information, e.g., films made of a patient interview or made during surgery, and films with little information relevant to the individual patients, such as films used to improve trainees' communication skills.

Error Prevention and Disclosure

Educational filming can serve as an important tool to prevent errors. By reviewing films, it may be possible to analyze and discuss complicating factors and help improve the overall competency of physicians. However, because films will allow physicians to scrutinize medical interventions, errors may be more readily detected. In such circumstances, physicians should act in accordance with existing policies on the reporting of errors and follow available ethical guidance on disclosure to patients.

CONCLUSION

Filming patient encounters and medical procedures offers an important means to enhance medical education, particularly as audiovisual technology becomes more widely accessible in health care institutions. Educational films can facilitate the demonstration of skills and can also permit detailed evaluation of medical trainees. Physicians should use these educational tools, but should be mindful that filming may compromise patient privacy and confidentiality. With proper safeguards in place, patients should be encouraged to participate in the education of medical students and other physicians in training, including through the use of films in which patients are featured. To ensure that the use of films for education purposes in which patients are featured respects their autonomy and privacy, patients generally should consent prior to the filming. If consent cannot be obtained at that time, nor before use of the film for educational purposes, the film should not be used.

RECOMMENDATIONS

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

It is important to recognize that filming patients for educational purposes has direct implications in relation to privacy, which itself has become the object of recent detailed federal regulations. Therefore, filming for educational purposes in the health care setting should comply with relevant laws and regulations. In addition, filming for educational purposes should be analyzed from the perspective of the ethics of the patient-physician relationship. In this regard, an important distinction can be drawn between filming for commercial purposes (see Opinion 5.045, "Filming Patients in Health Care Settings") and filming for educational purposes, since the latter is performed and viewed by members of the health care team, who are bound by ethical responsibilities regarding patient autonomy, privacy, and confidentiality. Specifically:

1. Informed consent should be obtained before filming whenever possible. If it is not possible to obtain consent from the patient before filming, then consent must be obtained before the film is used for educational purposes. A surrogate decision-maker may give consent for filming only if the patient temporarily lacks capacity to give consent before the filming. When the patient regains decision-making capacity, his or her consent should be obtained before the film is used. In the case of minor children or permanently incompetent adults, consent may be obtained from the patient's parent or guardian (see Opinion E-5.045, "Filming Patients in Health Care Settings").
2. When obtaining consent, physicians should disclose information similar to that provided for other medical interventions, including an explanation of the educational purpose of film, potential benefits and harms (such as breaches of privacy and confidentiality), as well as a clear statement that participation in filming is voluntary and that the decision will not affect the medical care the patient receives. Moreover, physicians should be aware that filming may affect patient behavior during a clinical encounter. The patient should be given ample opportunity to discuss concerns about the film, before and after filming, and a decision to withdraw consent must be respected.
3. Information contained in educational films must be held to the same standards of confidentiality as other patient information. If filming requires the presence of non-clinical persons, these persons must agree to protect the patient's privacy and confidentiality. Viewing must be limited to health professionals, professionals-in-training, and students in the health professions, unless it has been disclosed to the patient that non-health professionals would view the film and the patient has consented to such viewing. If the film is to be distributed outside the institution in which it was produced, disclosure of the distribution must be made and explicit consent obtained.
4. Films contain a record of personal patient information. Depending on its content, a film may or may not be considered part of the patient's medical record, and may be protected under privacy law. Irrespective of these legal standards, films should be securely stored and final disposal should ensure that they are properly destroyed.

(References pertaining to Report 12 of the Council on Ethical and Judicial Affairs are available from the Ethics Standards Group.)