3.1.2 Patient Privacy & Outside Observers to the Clinical Encounter

Individuals legitimately present during patient-physician encounters include those directly involved in the patient's care, and can include other members of the health care team or employees of pharmaceutical or medical device companies when they are present to provide technical assistance, in keeping with ethics guidance.

When individuals who are not involved in providing care seek to observe patient-physician encounters, e.g., for educational purposes, physicians should safeguard patient privacy by permitting such observers to be present during a clinical encounter only when:

(a) The patient has explicitly agreed to the presence of the observer(s). Outside observers should not be permitted when the patient lacks decision-making capacity, except in rare circumstances and with the consent of the parent, legal guardian, or authorized decision maker.

(b) The presence of the observer will not compromise care.

(c) The observer understands and has agreed to adhere to standards of medical privacy and confidentiality.

Under no circumstances should physicians accept payment from outside observers to allow those observers to be present during a clinical encounter.

AMA Principles of Medical Ethics: I,IV,VIII

Background report(s):

CEJA Report 3-A-16 Modernized *Code of Medical Ethics*

CEJA Report 4-A-05 Patient privacy and outside observers to the clinical encounter

3.1.2 Patient Privacy & Outside Observers to the Clinical Encounter

Individuals legitimately present during patient-physician encounters include those directly involved in the patient's care, and can include other members of the health care team or employees of pharmaceutical or medical device companies when they are present to provide technical assistance, in keeping with ethics guidance. [new content identifies explicitly who may ethically be present during patient care]

When individuals who are not involved in providing care seek to observe patient-physician encounters, e.g., for educational purposes, physicians should safeguard patient privacy by permitting such observers to be present during a clinical encounter only when: [new content sets out key ethical values and concerns explicitly]

(a) The patient has explicitly agreed to the presence of the observer(s). Outside observers should not be permitted when the patient lacks decision-making capacity, except in rare circumstances and with the consent of the parent, legal guardian, or authorized decision maker.

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AMA Principles of Medical Ethics: I,IV,VIII

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 4 - A-05

Subject: Patient Privacy and Outside Observers to the Clinical Encounter

Presented by: Michael S. Goldrich, MD, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws (Art L. Klawitter, MD, Chair)

Adoption of Resolution 8 (A-03), "Patient Privacy and Sales Representatives," established new AMA policy that "oppose[s] the presence, inclusion or involvement of pharmaceutical sales representatives in clinical situations without the full knowledge and informed consent of patients" (Policy H-100.967, AMA Policy Database).** The resolution also directed the American Medical Association to promulgate appropriate guidelines to protect patient privacy and confidentiality and to prevent inappropriate intrusion into the doctor/patient relationship, in collaboration with the pharmaceutical industry.

In addition to the privacy and confidentiality concerns raised by the practice known as "shadowing," concerns may stem from arrangements termed "preceptorships," which entail payments to physicians who agree to allow an industry representative to observe interactions with patients. This Council on Ethical and Judicial Affairs (CEJA) Report examines these practices.

PATIENT-PHYSICIAN RELATIONSHIP AND PRIVACY

The AMA's Code of Medical Ethics includes several opinions that make clear the importance of protecting patient privacy and the confidentiality of their health information. This key dimension of the therapeutic alliance is first noted in the *Principles of Medical Ethics*, which states that a physician "shall safeguard patient confidences and privacy within the constraints of the law."

This Principle is elaborated in Opinion E-10.01, "Fundamental Elements of the Patient-Physician Relationship," which states: "The patient has the right to confidentiality. The physician should not reveal confidential communications or information without the consent of the patient, unless provided for by law or by the need to protect the welfare of the individual or the public interest." The notion of confidentiality is further elaborated in Opinion E-5.05, "Confidentiality," which explains:

> The information disclosed to a physician during the course of the relationship between physician and patient is confidential to the greatest possible degree. The patient should feel

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* Reports of the Council on Ethical and Judicial Affairs are assigned to the reference committee on Amendments to Constitution and Bylaws. They may be adopted, not adopted, or referred. A report may not be amended, except to clarify the meaning of the report and only with the concurrence of the Council.

** Resolution 8 (A-03) was adopted in lieu of Resolution 15 (A-03), "Patient Shadowing," which directed "our American Medical Association [to] request that its members evaluate the ethical and confidentiality problems of pharmaceutical representatives shadowing physicians in order to follow their practice patterns;" and that "our AMA refer this issue of 'shadowing' to the AMA Council on Ethical and Judicial Affairs."

> free to make a full disclosure of information to the physician in order that the physician may most effectively provide needed services. The patient should be able to make this disclosure with the knowledge that the physician will respect the confidential nature of the communication. The physician should not reveal confidential communications or information without the express consent of the patient, unless required to do so by law.

It can be reasonably assumed that health care professionals know, understand, and observe the tenets of confidentiality. The same cannot be said for individuals who are not health professionals; accordingly, such individuals should not be permitted to observe a clinical encounter until the physician ensures that they understand and are committed to the same medical standards of confidentiality as are health professionals.

Recently, CEJA addressed the notion of privacy in Opinion E-5.059, "Privacy in the Context of Health Care:"

> Physicians must seek to protect patient privacy in all of its forms, including physical, informational, decisional and associational. Such respect for patient privacy is a prerequisite to building the trust that is at the core of the patient-physician relationship.
>
> ... Physicians should be aware of and respect the special concerns of their patients regarding privacy. Patients should be informed of any significant infringement on their privacy of which they may otherwise be unaware.

With regard to patient's health information, Opinion E-7.025, "Records of Physicians: Access by Non-Treating Medical Staff," cautions that "Only physicians or other health care professionals who are involved in managing the patient… may access the patient's confidential medical information. All others must obtain explicit consent to access the information."

These policies recognize that, in the provision of health care, neither the claim to privacy nor the expectation of confidentiality can be absolute, but need to be balanced with other requirements. A similar balancing between the protection of patients' legal right to the privacy of their personal health information and the use and transmission of this information has been enacted by the "Privacy Rule" of the Health Insurance Portability and Accountability Act (HIPAA).

OUTSIDE OBSERVERS AND THE THERAPEUTIC ENCOUNTER

The patient-physician encounter often is not exclusively private: multiple health care professionals participate in the provision of hospital-based care. Others may be observers for educational purposes (see Opinion E-8.087, "Medical Student Involvement in Patient Care").

Patient shadowing and preceptorships introduce into the patient-physician encounter outside observers who are not health professionals and who have goals other than patient care. Some are industry representatives who are engaged, directly or indirectly, in promoting products, and who through their observation of patient-physician interactions, seek to understand and potentially influence the physician's decision-making process.

It is important to distinguish personnel who facilitate or contribute to patient care from those wishing to observe patient-physician encounters for purposes other than the patient's benefit. For example, some industry representatives may contribute to patient care by training and supporting physicians in the use of new medical devices. Others simply wish to observe for their own purposes.

An outside observer's willingness to offer payment to access clinical encounters clearly indicates that these encounters advance the observer's goals, rather than the patient's. This undermines the patient-physician relationship. Consequently, physicians should not accept payment from outside observers wishing to access clinical encounters.

CONSENT TO OUTSIDE OBSERVERS

Patient autonomy is expressed through the power to make choices. Although the right to self-determination relates most importantly to choosing among diagnostic and treatment options, it extends to other aspects of health care, such as controlling disclosure of health information. Therefore, whenever an outside observer is to be privy to a patient-physician encounter, the patient must be told the party's role, and must be afforded the opportunity to exclude from the encounter an observer who is not required for the provision of safe and efficient care. This not only pertains to industry personnel, but to other third parties such as legislators or community leaders who may wish to observe patient-physician encounters for the purpose of better understanding various aspects of medical practice and health care.

It is important for physicians to recognize that some patients may want to exclude outside observers, but feel uncomfortable refusing their presence. Physicians, therefore, must be alert to the possibility that an observer's presence negatively affects the interaction and compromises care. On such occasions, the observer should be excluded. Also, it should be made clear to patients that they retain the right to refuse the observer's presence at any time during the encounter.

Finally, when patients lack decision-making capacity, physicians should discuss the inclusion of outside observers in the medical encounter with the surrogate decision-makers. Observation by persons who are not health professionals of encounters between physicians and patients lacking decision-making capacity, however, represents a substantial invasion of privacy and generally should not be permitted, except under rare circumstances and with consent of the legal guardian.

CONCLUSION

Absolute privacy of the patient-physician encounter is often not possible due to needed assistance by other professionals or patient caregivers. Nevertheless, physicians are ethically and legally bound to protect their patients' privacy, so the presence of outside observers should be limited. Moreover, observers should join a patient-physician encounter only after patients have been informed of the parties' roles and have given consent to their inclusion in the encounter. It is inappropriate for physicians to accept payment from third parties who are observers of patient-physician encounters.

RECOMMENDATION

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

> Outside observers are individuals who are present during patient-physician encounters and are neither members of a health care team nor enrolled in an educational program for health professionals such as medical students.

Physicians are ethically and legally responsible for safeguarding patient privacy and, therefore, must inform outside observers about medical standards of confidentiality and require them to agree to these standards.

Outside observers may be present during the medical encounter only with the patient's explicit agreement. Physicians should avoid situations in which an outside observer's presence may negatively influence the medical interaction and compromise care. The presence of outside observers during encounters between physicians and patients who lack decision-making capacity should not be permitted, except under rare circumstances and with consent of the parent or legal guardian.

Physicians should not accept payment from outside observers because accepting such payment may undermine the patient-physician relationship. (New HOD/CEJA Policy)

Fiscal Note: Staff cost estimated at less than $500 to implement.