

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 4 - A-05

Subject: Patient Privacy and Outside Observers to the Clinical Encounter

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

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

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14 PATIENT-PHYSICIAN RELATIONSHIP AND PRIVACY

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

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

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

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** 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."

1 free to make a full disclosure of information to the physician in order that the physician
2 may most effectively provide needed services. The patient should be able to make this
3 disclosure with the knowledge that the physician will respect the confidential nature of the
4 communication. The physician should not reveal confidential communications or
5 information without the express consent of the patient, unless required to do so by law.
6

7 It can be reasonably assumed that health care professionals know, understand, and observe the
8 tenets of confidentiality. The same cannot be said for individuals who are not health professionals;
9 accordingly, such individuals should not be permitted to observe a clinical encounter until the
10 physician ensures that they understand and are committed to the same medical standards of
11 confidentiality as are health professionals.
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13 Recently, CEJA addressed the notion of privacy in Opinion E-5.059, "Privacy in the Context of
14 Health Care:"
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16 Physicians must seek to protect patient privacy in all of its forms, including physical,
17 informational, decisional and associational. Such respect for patient privacy is a
18 prerequisite to building the trust that is at the core of the patient-physician relationship.
19

20 ... Physicians should be aware of and respect the special concerns of their patients
21 regarding privacy. Patients should be informed of any significant infringement on their
22 privacy of which they may otherwise be unaware.
23

24 With regard to patient's health information, Opinion E-7.025, "Records of Physicians: Access by
25 Non-Treating Medical Staff," cautions that "Only physicians or other health care professionals who
26 are involved in managing the patient... may access the patient's confidential medical information.
27 All others must obtain explicit consent to access the information."
28

29 These policies recognize that, in the provision of health care, neither the claim to privacy nor the
30 expectation of confidentiality can be absolute, but need to be balanced with other requirements. A
31 similar balancing between the protection of patients' legal right to the privacy of their personal
32 health information and the use and transmission of this information has been enacted by the
33 "Privacy Rule" of the Health Insurance Portability and Accountability Act (HIPAA).
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35 OUTSIDE OBSERVERS AND THE THERAPEUTIC ENCOUNTER 36

37 The patient-physician encounter often is not exclusively private: multiple health care professionals
38 participate in the provision of hospital-based care. Others may be observers for educational
39 purposes (see Opinion E-8.087, "Medical Student Involvement in Patient Care").
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41 Patient shadowing and preceptorships introduce into the patient-physician encounter outside
42 observers who are not health professionals and who have goals other than patient care. Some are
43 industry representatives who are engaged, directly or indirectly, in promoting products, and who
44 through their observation of patient-physician interactions, seek to understand and potentially
45 influence the physician's decision-making process.
46

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

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

6 7 CONSENT TO OUTSIDE OBSERVERS

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

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

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

30 31 CONCLUSION

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

40 41 RECOMMENDATION

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

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

1 Physicians are ethically and legally responsible for safeguarding patient privacy and,
2 therefore, must inform outside observers about medical standards of confidentiality and
3 require them to agree to these standards.
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5 Outside observers may be present during the medical encounter only with the patient's explicit
6 agreement. Physicians should avoid situations in which an outside observer's presence may
7 negatively influence the medical interaction and compromise care. The presence of outside
8 observers during encounters between physicians and patients who lack decision-making
9 capacity should not be permitted, except under rare circumstances and with consent of the
10 parent or legal guardian.

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

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