2.1.1 Informed Consent

Informed consent to medical treatment is fundamental in both ethics and law. Patients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care. Successful communication in the patient-physician relationship fosters trust and supports shared decision making.

The process of informed consent occurs when communication between a patient and physician results in the patient's authorization or agreement to undergo a specific medical intervention. In seeking a patient's informed consent (or the consent of the patient's surrogate if the patient lacks decision-making capacity or declines to participate in making decisions), physicians should:

- (a) Assess the patient's ability to understand relevant medical information and the implications of treatment alternatives and to make an independent, voluntary decision.
- (b) Present relevant information accurately and sensitively, in keeping with the patient's preferences for receiving medical information. The physician should include information about:
 - (i) the diagnosis (when known);
 - (ii) the nature and purpose of recommended interventions;
 - (iii) the burdens, risks, and expected benefits of all options, including forgoing treatment.
- (c) Document the informed consent conversation and the patient's (or surrogate's) decision in the medical record in some manner. When the patient/surrogate has provided specific written consent, the consent form should be included in the record.

In emergencies, when a decision must be made urgently, the patient is not able to participate in decision making, and the patient's surrogate is not available, physicians may initiate treatment without prior informed consent. In such situations, the physician should inform the patient/surrogate at the earliest opportunity and obtain consent for ongoing treatment in keeping with these guidelines.

AMA Principles of Medical Ethics: I,II,V,VIII

Opinion 2.1.1 was originally issued in 1981 without an associated background report. Guidance was updated in 2016 and 2006 in the following reports:

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

CEJA Report 6-A-06 Withholding information from patients

CEJA Report 3-A-16 Code of Medical Ethics

2.1.1 Informed Consent

Informed consent to medical treatment is fundamental in both ethics and law. Patients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care. *Successful communication in the patient-physician relationship fosters trust and supports shared decision making. [new content sets out key ethical values and concerns explicitly]*

The process of informed consent occurs when communication between a patient and physician results in the patient's authorization or agreement to undergo a specific medical intervention. In seeking a patient's informed consent (or the consent of the patient's surrogate if the patient lacks decision-making capacity or declines to participate in making decisions), physicians should:

- (a) Assess the patient's ability to understand relevant medical information and the implications of treatment alternatives and to make an independent, voluntary decision. [new content addresses gap in current guidance]
- (b) Present relevant information accurately and sensitively, in keeping with the patient's preferences for receiving medical information. The physician should include information about:
 - (i) the diagnosis (when known);
 - (ii) the nature and purpose of recommended interventions;
 - (iii) the burdens, risks, and expected benefits of all options, including forgoing treatment. [new content sets out key elements of disclosure explicitly to address gap in current guidance]
- (c) Document the informed consent conversation and the patient's (or surrogate's) decision in the medical record in some manner. When the patient/surrogate has provided specific written consent, the consent form should be included in the record. [new content emphasizes the importance of the consent process]

In emergencies, when a decision must be made urgently, the patient is not able to participate in decision making, and the patient's surrogate is not available, physicians may initiate treatment without prior informed consent. In such situations, the physician should inform the patient/surrogate at the earliest opportunity and obtain consent for ongoing treatment in keeping with these guidelines. [new content addresses gap in current guidance]

AMA Principles of Medical Ethics: I,II,V,VIII

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS^{*}

Subject:	Withholding Information from Patients (Therapeutic Privilege)
Presented by:	Priscilla Ray, MD, Chair
Referred to:	Reference Committee on Amendments to Constitution and Bylaws (Joseph H. Reichman, MD, Chair)

INTRODUCTION 1

2

3 Some physicians have withheld medical information from patients when they have believed full 4 disclosure to be medically contraindicated, to avoid potential harm to the patient's physical or 5 psychological well-being. This practice, commonly referred to as "therapeutic privilege," is distinct from circumstances when it is not feasible to disclose information to a patient, such as 6 7 emergency situations or other instances when a patient lacks the capacity of making decisions (see 8 E-8.08, "Informed Consent" and E-8.081, "Surrogate Decision Making"). It also is distinct from 9 disclosure issues that arise from medical errors, which the Council addressed in a previous report 10 (see E-8.121, "Ethical Responsibility to Study and Prevent Error and Harm"). 11 12 Intentionally withholding information may be viewed as presenting a conflict between a physician's ethical imperative to protect patients and a physician's ethical obligation to be truthful 13 and to provide patients with relevant medical information. Moreover, it abrogates the process of 14 shared decision-making and conflicts with contemporary expectations that physicians will respect 15 16 patients' autonomy and enable them to take an active role in making treatment decisions that reflect their interests and preferences. It is in this context that this report re-examines the ethical propriety 17 of withholding medical information from patients. 18 19 20 ETHICAL ANALYSIS 21 22 Non-disclosure of medical information was once uncontroversial when paternalism afforded 23 physicians broad discretion in making treatment decisions on behalf of their patients. Stemming

- 24 from the Hippocratic tradition, physicians were ethically obligated to promote their patients'
- welfare by providing care in accordance with their own judgment regarding the most appropriate 25
- course of treatment.¹ Physicians could opt not to share potentially distressing diagnostic or 26
- prognostic medical information with patients if they believed that disclosure might prove 27
- detrimental to patients' well-being.² Accordingly, the selective withholding of medical information 28

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^{*} Reports of the Council on Ethical and Judicial Affairs are assigned to the reference committee on 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.

could be viewed as fulfilling physicians' obligations both to act beneficently² and to promote 1 2 patients' overall well-being. 3 This practice of non-disclosure was well established in the foundational works of Western medical 4 ethics, such as Percival's *Medical Ethics*, which promoted the beneficent withholding of medical information to minimize patients' distress.⁴ Similarly, the 1847 AMA Code of Medical Ethics 5 stated that physicians had a "sacred duty...to avoid all things which have a tendency to discourage 6 the patient and depress his spirits."⁵ These guidelines helped to establish legal precedents that 7 8 allowed physicians to withhold potentially harmful information from their patients in the event that 9 full disclosure would impede patients' abilities to render rational decisions or harm them in other ways.⁶ 10 11 12 In recent decades, medical paternalism has given way to the contemporary concepts of patient autonomy and shared decision-making.⁷ Today, physicians are called upon to promote patients' 13 well-being by openly discussing the balance between anticipated benefits of a given intervention 14 and its potential harms.⁸ In some instances, a case-specific balance of benefits and harms may 15 appear to some physicians as justification to withhold medical information, with the beneficent 16 17 desire to protect patients from potential harms. However, a physician's concealment of medical 18 information may not prove beneficent if it contravenes a patient's own wishes. 19 Many patients want detailed medical information, even if it means receiving adverse diagnostic or 20 prognostic information.^{9,10} Physicians' communication of detailed medical information has been 21 shown to ease patients' anxiety and improve health outcomes.⁵ Moreover, increased levels of 22 communication and information sharing may also contribute to higher levels of patient 23 satisfaction¹¹ and potentially decrease malpractice liability.¹² Conversely, the lack of adequate 24 information may preclude patients from receiving necessary medical attention or making optimal 25 life decisions on the basis of their individual needs and personal values.^{13,14} 26 27 28 Withholding pertinent medical information from patients without their knowledge or consent may 29 also have negative long-term consequences for the medical profession. The patient-physician relationship is founded upon trust, because patients must rely upon their physicians to provide the 30 information needed to make a properly informed decision.¹⁵ Lack of candid disclosure can 31 32 compromise this relationship if patients suspect (or later discover) that information is being withheld from them.¹⁶ Thus, individual physicians' purportedly benevolent acts of deception risk 33 34 undermining not only individuals, but also public confidence and trust in the medical profession.¹⁷ 35 36 In practice, medical information should never be permanently withheld from the patient because 37 doing so represents a clear violation of patients' trust. However, physicians' obligation of 38 beneficence may allow (or compel) them to postpone the full disclosure of information to patients 39 whose capacity to make competent medical decisions may be compromised, or when disclosure is otherwise medically contraindicated.¹⁸ Delayed disclosure, however, is not justified when 40 physicians merely intend to prevent a patient's refusal of medically necessary treatments,¹⁹ or to 41 instill hope for the future.²⁰ 42 43 Little is known of the extent to which disclosure of alarming medical information may ultimately 44

harm patients.²¹ Physicians are encouraged to consult colleagues or hospital ethics committees

1 when considering the need to temporarily withhold medical information from their patients. Such

2 consultations reflect respect for patients' right of self-determination and can be of real help to

3 physicians in assessing available alternatives to postponement of communicating medical

4 information.

5 When physicians determine that a patient should not receive all relevant medical information at a given time, they need to continue to provide appropriate care for and monitor the patient to identify 6 7 an appropriate time to offer full disclosure. This should be done according to a definite plan, so 8 that disclosure is not permanently withheld. 9 10 PROMOTING PATIENT-PHYSICIAN COMMUNICATION 11 12 Physicians' concerns about disclosure of potentially harmful information should lead them to encourage patients to make choices regarding the receipt of medical information before potentially 13 harmful information becomes available.²² Physicians should tailor their disclosure of medical 14 information in response to the needs, expectations and preferences of individual patients.²³ 15 16 To respect patients' rights of decisional autonomy, physicians must offer all patients the 17 opportunity to receive relevant medical information.²⁴ This may be accomplished by asking 18 19 patients to specify the scope of information they wish to receive and their preferred methods for 20 receiving it. Physicians should then honor these preferences to the extent practicable. 21 Some patients may want certain medical information to be withheld.²⁵ Others may wish to involve 22 23 family members in the decision-making process or, alternatively, to appoint family members or trusted caregivers to act as their proxy.²⁶ Physicians should respect the wishes of competent 24 patients, including accommodation of their cultural and religious beliefs.²⁷ However, physicians 25 should consider patients' decisions sensitively to ensure that their requests are not coerced and 26 genuinely represent the patients' preferences.¹³ Additionally, physicians should educate patients 27 and their proxies about the importance of disclosure and shared decision-making.¹³ 28 29 When communicating medical information, physicians should assess the amount of information 30 that patients want and are capable of receiving at a given time.²⁸ Clinical judgment is required to 31 determine the appropriate means for communicating relevant information, taking patients' 32 personalities and clinical histories into account when possible.² Information should be presented in 33 a way that patients can understand and use in making medical decisions.¹³ Finally, physicians 34 should attempt to confirm that this information has been understood—for example, by asking them 35 to repeat what they have been told—and providing further clarification as necessary.^{29,30} 36 37 Physicians should communicate all requested medical information sensitively and respectfully,³¹ 38 while seeking to minimize any negative effects upon the patient.³² By listening to patients' 39 concerns and responding to their individual needs, physicians can promote the patient-physician 40 relationship³³ and protect against the iatrogenic suffering of patients.³⁴ Physicians can also 41 minimize potential harms by monitoring patients' well-being and by helping them to access 42 appropriate support services, when needed.²¹ 43 44

- 1 CONCLUSION
- 2 3
 - Withholding relevant medical information from patients without their knowledge or consent, in an
- 4 attempt to minimize potential physical or psychological harms, has been called "therapeutic
- 5 privilege." This practice creates a conflict between physicians' concurrent obligations to act
- 6 beneficently and to respect patients' autonomy. Whenever possible, physicians should minimize
- 7 the withholding of medical information by accommodating patients' informational preferences.

1 2	RECOMMENDATIONS
2 3 4	The Council on Ethical and Judicial Affairs recommends:
5 6 7	(1) That the following statement be adopted as new policy, to be subsequently issued as a new ethical opinion:
8	Withholding pertinent medical information from patients under the belief that disclosure is
9	medically contraindicated, a practice known as "therapeutic privilege," creates a conflict
10	between the physician's obligations to promote patients' welfare and respect for their autonomy
11	by communicating truthfully. Therapeutic privilege does not encompass withholding medical
12	information in emergency situations, or reporting medical errors (see E-8.08, "Informed
13	Consent," and E-8.121, "Ethical Responsibility to Study and Prevent Error and Harm").
14 15	Withholding medical information from patients without their knowledge or consent is ethically
16	unacceptable. Physicians should encourage patients to specify their preferences regarding
17	communication of their medical information, preferably before the information becomes
18	available. Moreover, physicians should honor patient requests not to be informed of certain
19	medical information or to convey the information to a designated proxy, provided these
20	requests appear to genuinely represent the patient's own wishes.
21	
22	All information need not be communicated to the patient immediately or all at once; physicians
23	should assess the amount of information a patient is capable of receiving at a given time,
24	delaying the remainder to a later, more suitable time, and should tailor disclosure to meet
25	patients' needs and expectations in light of their preferences.
26 27	Developing may consider deleving disclosure only if early communication is clearly
27	Physicians may consider delaying disclosure only if early communication is clearly contraindicated. Physicians should continue to monitor the patient carefully and offer complete
28 29	disclosure when the patient is able to decide whether or not to receive this information. This
30	should be done according to a definite plan, so that disclosure is not permanently delayed.
31	Consultation with patients' families, colleagues or an ethics committee may help in assessing
32	the balance of benefits and harms associated with delayed disclosure. In all circumstances,
33	physicians should communicate with patients sensitively and respectfully.
34	
35	(New HOD/CEJA Policy)
36	
37	(2) That amendments to Opinion E-8.08, "Informed Consent," proposed below be made at the time
38	the statement above is issued as a new opinion:
39 40	E-8.08, "Informed Consent"
40 41	E-0.00, Informed Consent
42	The patient's right of self-decision can be effectively exercised only if the patient possesses
43	enough information to enable an intelligent informed choice. The patient should make his or
44	her own determination on treatment. The physician's obligation is to present the medical facts
45	accurately to the patient or to the individual responsible for the patient's care and to make

1	recommendations for management in accordance with good medical practice. The physician
2	has an ethical obligation to help the patient make choices from among the therapeutic
3	alternatives consistent with good medical practice. Informed consent is a basic social policy in
4	both ethics and law that physicians must honor, for which exceptions are permitted: (1) where
5	the <u>unless</u> the patient is unconscious or otherwise incapable of consenting and harm from
6	failure to treat is imminent. In special circumstances, it may be appropriate to postpone
7	disclosure of information, (see Opinion E-8.122, "Withholding Information from Patients"). or
8	(2) when risk disclosure poses such an immediate and serious psychological threat of detriment
9	to the patient as to be medically contraindicated Social policy does not accept the paternalistic
10	view that the physician may remain silent because divulgence might prompt the patient to
11	forego needed therapy. Rational, informed patients should not be expected to act uniformly,
12	even under similar circumstances, in agreeing to or refusing treatment.
13	
14	Physicians should sensitively and respectfully disclose all relevant medical information to
15	patients. The quantity and specificity of this information should be tailored to meet the
16	preferences and needs of individual patients. Physicians need not communicate all information
17	at one time, but should assess the amount of information that patients are capable of receiving
18	at a given time and present the remainder when appropriate. (I, II, III, IV, V, VIII)
19	
20	Issued March 1981. Updated June 2006, based on the Report "Withholding Information from
21	Patients (Therapeutic Privilege)."
22	
23	(Modify HOD/CEJA Policy)
24	
25	(3) That the remainder of the report be filed.
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Fiscal Note: Staff cost estimated at less than \$500 to implement.

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