3.3.3 Breach of Security in Electronic Medical Records

When used with appropriate attention to security, electronic medical records (EMRs) promise numerous benefits for quality clinical care and health-related research. However, when a security breach occurs, patients may face physical, emotional, and dignitary harms.

Dedication to upholding trust in the patient-physician relationship, to preventing harms to patients, and to respecting patients' privacy and autonomy create responsibilities for individual physicians, medical practices, and health care institutions when patient information is inappropriately disclosed.

The degree to which an individual physician has an ethical responsibility to address inappropriate disclosure depends in part on his or her awareness of the breach, relationship to the patient(s) affected, administrative authority with respect to the records, and authority to act on behalf of the practice or institution.

When there is reason to believe that patients' confidentiality has been compromised by a breach of the electronic medical record, physicians should:

- (a) Ensure that patients are promptly informed about the breach and potential for harm, either by disclosing directly (when the physician has administrative responsibility for the EMR), participating in efforts by the practice or health care institution to disclose, or ensuring that the practice or institution takes appropriate action to disclose.
- (b) Follow all applicable state and federal laws regarding disclosure.

Physicians have a responsibility to follow ethically appropriate procedures for disclosure, which should at minimum include:

- (c) Carrying out the disclosure confidentially and within a time frame that provides patients ample opportunity to take steps to minimize potential adverse consequences.
- (d) Describing what information was breached; how the breach happened; what the consequences may be; what corrective actions have been taken by the physician, practice, or institution; and what steps patients themselves might take to minimize adverse consequences.
- (e) Supporting responses to security breaches that place the interests of patients above those of the physician, medical practice, or institution.
- (f) Providing information to patients to enable them to mitigate potential adverse consequences of inappropriate disclosure of their personal health information to the extent possible.

AMA Principles of Medical Ethics: IV,VIII

Background report(s):

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

CEJA Report 3-A -09 A physician's role following a breach of electronic health information

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

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AMA Principles of Medical Ethics: IV,VIII

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

CEJA Report 3-A-09

	Subject:	A Physician's Role Following a Breach of Electronic Health Information
	Presented by:	Regina M. Benjamin, MD, Chair
	Referred to:	Reference Committee on Amendments to Constitution and Bylaws (Daniel W. Van Heeckeren, MD, Chair)
1 2 3 4 5 6 7 8 9 10	Adopted Resolution 9 (A-08) asked our American Medical Association (AMA) to study the physician's role in informing a patient when the physician has reason to believe the individual's protected health information has been inappropriately disclosed. A physician's obligation to respect confidentiality and guard a patient's privacy is a well-established principle of professional ethics that dates back to the Hippocratic Oath. ¹ The AMA's Code of Medical Ethics, in Opinion E-5.07, "Confidentiality: Computers," (AMA Policy Database) sets out precautionary steps to protect the confidentiality of electronically stored health information. ² However, current policy does not address physicians' ethical responsibilities in the event the security of electronic records is breached and patient data are inappropriately accessed. This report examines physicians' professional ethical responsibility in this area.	
11 12	ELECTRONIC	MEDICAL RECORDS (EMR)
13 14 15 16 17 18 19 20 21 22 23 24	capacity of elec EHRs) to store, physicians and enhance patient patient care, EM record systems, and decision su administrative of improvement, p	tion is "central to the practice of medicine and the quality of health care." ³ The tronic medical records (EMRs, also referred to as "electronic health records," access, and transmit detailed patient information accurately and rapidly among other health care professionals, health care administrators, and payers can greatly care and the efficiency of the health care system overall. At the level of individual IRs can support functions that are impossible or cumbersome to implement in paper including clinical reminders, drug interaction alerts, physician order entry systems, pport tools. ^{4, 5} At the level of the health care system, EMRs can facilitate operations as well as enable access to population-level data for quality public health, and research purposes. ^{6, 7}
25 26 27 28 29 30 31 32 33	survey, 38.4% of including billing increase from 2 practices. ^{9, 10} Ho carried out by n from patient to limited regulation	the U.S. have been adopting EMRs in greater numbers in recent years. In a 2008 of physicians reported using fully or partially functional EMR systems, not g records, in their office-based practices. ⁸ These numbers represent a significant 001, when 18.2% of physicians reported using EMRs in their office-based owever, the collection, storage, and management of health information in the U.S. is umerous, diverse public and private institutions. The flow of medical information health care provider to health insurance industry and beyond is conducted with on and oversight. Existing data security laws and agencies have been characterized , sometimes conflicting, patchwork" of policies. ⁴ The combination of these factors

^{*} 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.

1 may be contributing to breaches of EMRs. Physicians need guidance about their responsibilities

2 when the confidentiality of patients' electronic personal health information has been

- 3 compromised.¹¹
- 4 5

SECURITY BREACHES AND HARM TO PATIENTS

- Recent developments have significantly increased the potential harms that can result when EMR
 systems are breached. For one, there has been a trend in recent years to gather and record more
 detailed information in medical records.¹² For another, the range of uses to which EMR systems are
 put have expanded. The aggregated nature of EMRs facilitates secondary use indirectly related to
 patient care, such as clinical research; quality measurement, reporting, and improvement; public
 health; marketing; and managed care decision-making.^{7, 13}
- 12

14 The potential for harm from a security breach may depend on several factors, including the intent 15 of the perpetrators of the breach, nature of the information that was breached, and to whom the 16 information was disseminated. Still, the detailed and complex patterns of collecting and using 17 patient information in today's health care environment mean that the risk of harm to patients from security breaches is higher than ever before. One profound harm may be medical identity theft, the 18 fastest growing form of identity theft.^{14, 15} Medical identity theft can result not only in 19 20 inconvenience, discrimination, or negative effects on a victim's credit rating, but can pose harms 21 specifically related to health care in the form of improper exhaustion of insurance benefits. 22 wrongful billing for the costs of the thief's health care, and the burden of proving that the victim 23 isn't responsible for such charges and can adversely affect insurability. Of particular concern are 24 the potential adverse effects of such theft on a victim's subsequent health care, notably inappropriate care based on erroneous entries in his or her record.^{3, 15} 25 26 27 Beyond this sort of material harm that may follow from inappropriate disclosure of a patient's

personal health information are the dignitary harms that result. The commitment to benefit the 28 patient is a basic tenet of a physician's professional ethic.¹⁶⁻¹⁸ Effective healing cannot take place 29 30 without a patient-physician relationship that rests on the physician's competence, skills, and good 31 will.¹⁹ The healing encounter is one in which the physician claims the necessary expertise and dedication to help and (implicitly) invites the vulnerable patient's trust.²⁰ The physician is 32 accountable to his or her patients in this relationship of fidelity in trust.²¹ Trust is fragile in today's 33 34 health care system as patients increasingly question physicians' loyalty in the face of physicians' competing commitments to the interests of managed care plans, jobs, or incomes.¹⁹ 35

36

The commitment to benefit patients also entails respecting a patient's freedom to act in accord with his or her values and sense of self.¹ Inappropriate disclosure of a patient's personal information violates his or her right to (informational) privacy, a fundamental expression of autonomy.

40

41 LEGAL ENVIRONMENT

42

Currently, 44 states require companies doing business in their state to advise residents when the residents' information may have been compromised.¹⁵ These laws were intended to make victims of a data breach aware of the increased danger of identity theft so that they could take action to protect themselves. Many medical records, e.g., those that contain a patient's name and social security number, could fall under such state statutes. California recently broadened its notification law to explicitly apply to medical or health insurance-related information.²²

49

50 Until recently, federal law unfortunately provided little specific guidance for how privacy interests 51 in identifiable health information are protected in the event of a breach. While the Health Insurance 1 Portability and Accountability Act (HIPAA) established national standards for privacy and security

2 designed to protect the confidentiality and integrity of electronic personal health information, it

does not advise physicians or administrators how to respond in the event of an actual security
 breach.²³

5

6 However, disclosure is now required by the newly enacted American Recovery and Reinvestment 7 Act of 2009 (ARRA). The portion of the act devoted to health information technology, known as 8 the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH Act), 9 strengthens existing federal privacy and security provisions and mandates that a health care 10 provider notify data subjects when the provider knows or has reason to believe the individuals' information has been inappropriately disclosed.²⁴ The law provides detailed guidance on what is 11 considered a "breach," outlines appropriate methods of notification, and specifies the content 12 which must be included in the notice to the extent possible.²⁴ Wherever ARRA contains stricter 13 health-related privacy and security measures than state law, this federal law takes precedence. 14 15 ARRA also requires HHS to issue regulations on breach notification requirements by August 16. 16 2009.

17

18 IMPLICATIONS FOR ETHICAL PRACTICE

19

20 Helping to restore a sense of control over health records to the patient is of great moral import. Indeed, studies consistently show that patients prefer to be informed of breaches of their health 21 records or other medical errors.²⁵ Voluntarily disclosing to a patient that his or her information has 22 (or may have) been inappropriately disclosed when the patient may otherwise be unaware of the 23 24 breach respects the patient's dignity and supports his or her right to take appropriate steps to avert or minimize potential harms. Beyond fulfilling the physician's obligation to be candid with 25 patients, disclosing the incident and taking time to discuss possible harms and potential means of 26 27 averting them may enhance trust. Conversely, the lack of disclosure may erode trust, especially if it 28 leads to harm.

29

30 The patient safety movement has made it clear how difficult it can be for health care professionals

to take responsibility for an event that has created a significant risk of harm or has caused harm.

Like being candid with a patient about a medical error, being candid with a patient when his or her information has been inappropriately disclosed may be difficult or uncomfortable. However, this

34 does not change the fact that it is the ethically appropriate response.

35

The material cost of adequately responding to a breach of security can be significant in terms of actual costs associated with the loss of patients, recruitment of new patients, and damage to the reputation of the physician, practice or institution. However, evidence has shown that litigation rates and related costs decrease when errors are promptly disclosed to patients and families.²⁶⁻²⁸ It is also important to keep in mind that security measures and breach notice requirements should be practical and affordable so as to not hinder the ability of physicians to operate their practices and care for their patients.

43

44 The emotional toll on physicians relaying bad news can be burdensome, particularly given the

45 value the profession places on confidence, authority, and "perfection." Unfortunately, in some

46 institutions a culture of silence impedes admitting error or implicating colleagues. Yet evidence

47 suggests that disclosure may alleviate some of the burdens associated with knowing about a

48 situation that might cause harm to patients.²⁹ Institutional efforts to support candor and

49 transparency may not only help alleviate emotional discomfort, but also help prevent similar errors

50 in the future by raising awareness and increasing caution. More importantly, the commitment to

1 uphold trust in the patient-physician relationship, to prevent harms to patients, and to respect

2 patient autonomy form a compelling basis for a physician's involvement in efforts to promptly

3 disclose security breaches that pose a risk of harm. This commitment also supports an obligation to

4 assist patients to minimize potential adverse consequences of disclosure of personal health

5 information—for example, sharing information on steps individuals should take to protect

6 themselves from potential harm resulting from the breach such as using credit monitoring services,

7 an identity theft hotline or other services.

8

9 A physician's responsibility to notify patients of an inappropriate disclosure and to take steps to 10 help mitigate potential adverse consequences is not without limit.³⁰ A physician's ability to act may be limited by several factors, including what relationship the physician has with the affected patient 11 12 or what his or her administrative authority is. A physician who is not in a position to have personal 13 knowledge that a breach has occurred or take effective action to prevent breaches—for example, 14 who works in a large health care institution whose EMR system is managed by others-has 15 relatively limited responsibilities. In such circumstances, physicians might join others in the 16 institution to make sure that the institution takes appropriate action. Physicians in solo or small 17 group practices or those who are institutionally responsible for ensuring the security and integrity of electronic health information have a more immediate responsibility, both to ensure the security 18 19 of their EMRs and to notify patients when information has been inappropriately disclosed.

20

Whatever the nature of the physician's involvement, in dealing with inappropriate disclosure of patient information the physician should place the interests of affected patients above the interests of their practices or institutions. The commitment to affected patients should be tempered only by potential harms of equal magnitude to other patients. Such patient advocacy may take courage, but courage is implicit within a physicians' dedication to the well-being of their patients and their commitment to being trustworthy.²¹

27

Disclosure of a breach should occur as soon as practicable and in accordance with statutory timelines after the breach is known and should be carried out in a way that minimizes patients' distress and respectfully restores their control over their own privacy. Like relaying other "bad news," disclosing a breach in health records should generally occur in a setting conducive to discussion. A private place and adequate time may need to be set aside for this purpose.²⁹

33

At minimum, the discussions should include a thorough explanation of what information was or might have been disclosed and how the breach happened, its potential negative consequences, the corrective actions that have been and will be taken by the institution or practice, and the steps that patients themselves could take to mitigate potential harm. The physician making the disclosure should communicate regret and avoid behaving defensively.

39

40 These suggestions are not intended to be comprehensive. They define a starting point from which 41 to develop appropriate responses in light of the particular circumstances of a given breach and 42 medicine's fundamental ethical obligations to patients whose personal health information is 43 inappropriately disclosed.

- 44
- 45 RECOMMENDATION
- 46

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

1	When used with appropriate attention to security, electronic medical records (EMRs) promise	
2	numerous benefits for quality clinical care and health-related research. However, when a	
3	security breach occurs, patients may face physical, emotional, and dignitary harms.	
4		
5	Dedication to upholding trust in the patient-physician relationship, to preventing harms to	
6	patients, and to respecting patients' privacy and autonomy create responsibilities for individual	
7	physicians, medical practices, and health care institutions when patient information is	
8 9	inappropriately disclosed. The degree to which an individual physician has an ethical responsibility to address inappropriate disclosure depends in part on his or her awareness of the	
10	breach, relationship to the patient(s) affected, administrative authority with respect to the	
10	records, and authority to act on behalf of the practice or institution.	
11	records, and authority to act on behalf of the practice of institution.	
12	When there is reason to believe that patients' confidentiality has been compromised by a	
14	breach of the electronic medical record, physicians should:	
15	oreach of the creations medical record, physicians should.	
16	(1) Ensure that patients are promptly informed about the breach and potential for harm,	
17	either by disclosing directly (when the physician has administrative responsibility for	
18	the EMR), participating in efforts by the practice or health care institution to disclose,	
19	or ensuring that the practice or institution takes appropriate action to disclose.	
20	of ensuring that the practice of institution takes appropriate action to disclose.	
20	(2) Follow ethically appropriate procedures for disclosure, which should at minimum	
22	include:	
23	menude.	
24	(a) carrying out the disclosure confidentially and within a time frame that provides	
25	patients ample opportunity to take steps to minimize potential adverse	
26	consequences; and	
20	consequences, and	
28	(b) describing what information was breached; how the breach happened; what the	
29	consequences may be; what corrective actions have been taken by the physician,	
30	practice, or institution; and what steps patients themselves might take to minimize	
31	adverse consequences.	
32		
33	(3) Support responses to security breaches that place the interests of patients above those	
34	of the physician, medical practice, or institution.	
35		
36	(4) To the extent possible, provide information to patients to enable them to mitigate	
37	potential adverse consequences of inappropriate disclosure of their personal health	
38	information, such as credit monitoring services or identity theft hotline.	
39	mornation, such as creat monitoring services of facility more notifie.	
40	(New HOD/CEJA Policy)	

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

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