

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE FOR CIVIL RIGHTS**

**Modifications to the HIPAA Privacy, Security, and Enforcement Rules under the
Health Information Technology for Economic and Clinical Health Act**

COMMENTS OF THE HEALTH RECORD BANKING ALLIANCE

The Health Record Banking Alliance (HRBA or the Alliance) submits these comments in response to the captioned notice of proposed rulemaking (NPRM), 75 Fed. Reg. 40868 (July 14, 2010).

Interest of the HRBA in this Rulemaking

The Alliance is a membership organization whose goals are to promote health record banks – national, regional, state, or community repositories in which consumer can compile, store, and control their health records as obtained from the variety of doctors, hospitals, and other care providers. The compiled copies of patients' health records are owned and controlled by each patient (or by an agent acting for the patient).

Health record banks are an affordable, technically feasible, efficient, and sustainable technology that patients can use to compile their medical records securely. A health record bank account is similar to a checking or savings account in a financial institution, except that the account contains medical information rather than money.

Consumers (patients or their authorized agents) can compile copies of the health records in electronic form using standards-based software. Patients can then use their compiled records to better manage their health and their interactions with physicians, hospitals, pharmacies, drug plans, insurance companies, and other providers of healthcare or related services. Patients can determine who has access to the medical records under their control. They may make access available to healthcare providers, family, friends, or other advisors, and to insurance companies and government agencies. In all these ways, health record banks promote consumer engagement in their own health and healthcare. The result will be better outcomes, healthier citizens, and – because engaged and informed patients can make better, more efficient decisions about their care – lower healthcare costs for the nation overall.

HRBA furnishes information and other assistance to governments, communities, and other entities considering building health record banks, and promotes and comments on government policies, legislation, regulation consistent with national, state, regional, and community health record banks (see <http://www.healthbanking.org>). HRBA members include state and community health information exchange organizations, health information providers, physicians, and vendors interested in health information technology, health information exchange, and related services.

Patients' Access to their Records under HIPAA and HITECH

For consumers to compile their medical records affordably and efficiently, it is crucial that they be able to obtain copies of their records rapidly and efficiently from doctors' offices, hospitals, pharmacies, drug plans, and other healthcare providers and related entities such as health insurance companies and government agencies, including HHS itself. The difficulty, delay, and expense that patients (or their agents) face in obtaining copies of their records have remained a barrier to the use and adoption by patients of health record bank accounts. HRBA's goal in preparing these comments is to urge the Department to reduce these barriers to the maximum practicable extent.

For that reason, HRBA's comments are directed solely to the proposed changes to 45 C.F.R. §164.524(c), 75 Fed. Reg. 40923-24, and related NPRM text, *Id.* at 40901-03. The purpose of our comments is to make the patients' tasks easier and less expensive when obtaining copies of their medical records.

Generally, HRBA favors the proposed rule changes because they promote more efficient, faster access by patients to their records. The proposed changes recognize that, once providers maintain clinical, administrative, and billing records in electronic form, furnishing a copy of all those records upon a patient's request can be done at essentially no additional cost, quickly, and easily. HRBA therefore supports the NPRM's proposals regarding permissible charges that covered entities and their business associates may make in furnishing patients, on their request, with copies of their medical records.

1. Patient requests that copies of the medical record be sent via unencrypted E-mail should be protected explicitly by rule.

The rules as currently proposed allow a covered entity to furnish a requested copy to a patient via electronic mail, or e-mail. HRBA believes that the final rules should specifically address the very common situation where a patient (or the patient's designated agent) requests that a copy of the patient record be sent to the patient or a designated third party by e-mail and requests that the e-mail not be encrypted or that other security requirements not be imposed.

In this situation, and once the identity of the requesting patient (or patient's agent) is verified as required under the privacy and security rules, HRBA believes that the patient should be allowed to make the choice to have the covered entity (or business associate) send the copy of the record by unencrypted e-mail. This is a choice that many patients will make. They will do so because they believe the security risk of using e-mail without encryption is acceptable, and because they do not want the inconvenience of having to establish encrypted e-mail connections.

While some commentators may suggest that patients (or their agents) not be permitted to elect use of unencrypted e-mail for purposes of receiving a requested copy, that attitude is unduly paternalistic. It also fails to recognize that patients themselves ought to be given the choice of whether the information in their records is so sensitive that it should not be sent via e-mail that is unencrypted.

Patients – consumers – have sufficient experience to select the convenience of unencrypted e-mail, with its attendant speed and, more important, without the special technical features, additional cost, and additional operational complications that accompany the requirement to encrypt e-mail. For most consumers in most situations, this is a tradeoff they understand. They should have the right via regulation to choose the convenience of unencrypted e-mail for this purpose.

HRBA recommends that covered entities and their business associates inform patients of the choice that patients may elect between encrypted and unencrypted channels for receiving copies of medical records that the patients request. Thus, patients should receive notice of the availability of easily accessible encrypted channels (including the system requirements patients must meet in order to use those channels), and the opportunity patients have to opt in to use those channels. We note that use of encrypted email, with its attendant system requirements, should be an opt-in choice. It should not be structured as opt-out. This preserves the principle, and the fact, of maximum consumer choice.

This explicit choice is needed so that covered entities and business associates are able to honor consumers' requests free from worries that granting the request will subject them to liability under HIPAA/HITECH for failing to be sufficiently diligent. It is essential to remove this cloud so that consumers who so elect can receive copies of their records via unencrypted e-mail – the fastest, least costly, most convenient means for many consumers.

HRBA recognizes that the text explaining proposed changes to 45 C.F.R. § 164.524(c) states, in passing, and somewhat elliptically, that a covered entity may accede to a patient's request that a copy of a record be furnished via unencrypted e-mail. 75 Fed. Reg. 40902 (third column, bottom). However, HRBA is concerned that a covered entity or business associate might nevertheless believe that they are compelled to require additional assurances from the patient before using unencrypted e-mail to transmit the record. The covered entity or business associated might even conclude that its obligations to be diligent – and the potential liability for not being sufficiently diligent – should override a patient's decision that unencrypted e-mail was sufficiently secure and private under the circumstances. Thus, HRBA believes that a patient's right to make the election to have a copy delivered via unencrypted email deserves specific attention, and explicit protection, in the final rule.

2. Covered entities should respond to most requests within two business days.

The NPRM seeks comment on how quickly a covered entity should respond to a request for a copy of a patient's record. HRBA believes that the current standard of 30 days, with an additional extension of 30 days, is hopelessly obsolete. Moreover, HRBA believes that the NPRM's detailed approach to possible options – offering a confusing matrix of time periods in which covered entities would be allowed to respond to requests for copies – is far too complicated. It would be too confusing for consumers, too complex for covered entities to administer consistently, and too cumbersome and expensive for HHS to enforce.

HRBA emphasizes that patients are often under great stress and time pressure when they seek copies of their records. Moreover, when records are maintained in electronic form by a covered entity, a copy can be delivered very rapidly in the great majority of situations.

Thus, HRBA suggests that the Department adopt the following default rule: When records are maintained electronically, a covered entity should furnish a requested copy with two business days, or 48 business hours, of receiving the patient's request. There should be exceptions for unusual or emergency conditions, including computer system failures.

The rule for exceptions should, at least initially, be set forth in terms of a rule of reason (possibly with illustrative examples), rather than as a detailed set of specific exceptions. The only items that HRBA suggests be listed as explicit exceptions are (1) emergencies such as power or system failures and (2) situations where the electronic records are stored offsite and must be retrieved from that site (for example, remotely stored tapes) before the request can be processed electronically. In that event, HHS might consider that the time for response be extended by five business days (or some other number of business days that HHS deems reasonable).

This rule will serve patients and, once phased in, is very likely to be compatible with the systems capabilities of most covered entities that maintain medical records in electronic form.

This default rule must be supplemented to account for situations where patients make requests for copies before medical record data, and particularly notes and other narrative, are entered in the patients actual electronic record. In situations where the patient makes the request, the covered entity honors the request, and the copy is produced within 48 business hours but before all entries relevant to a particular encounter are entered, a patient should be entitled to make an additional request in order to obtain a copy of all the encounter data once it is entered in the institutional record. In this kind of situation, the covered entity and the patient should be permitted to agree on the timing of additional patient requests in order to serve the patient's needs while obviating the need on the part of the hospital to respond to duplicative requests and do not result in the patient's receiving additional record data.

The default rule must also be supplemented to deal with situations where clinicians or other professionals must review a record before a copy can be released in whole or part to a patient. This situation is discussed in the following section.

3. Covered entity should in most instances send records requested by patients without additional, unnecessary review.

The process of responding to a request for a copy of a patient's record can bog down unnecessarily at the step where a covered entity (usually a physician's office or a hospital or clinic) must review the record prior to its being copied and released to the patient.

HRBA urges the Department to allow physicians, at the time of entering data in patients' records, specifically to annotate any record that requires review before a copy can be furnished to the patient upon request. This annotation could take the form of an electronic check box,

accompanied when appropriate by a short statement of why the record requires pre-copy-release review and what specific portions of the record must be so reviewed. The accompanying short statement could be made by checklist, drop-down box, or similar feature, with a narrative supplement as appropriate.

The benefit of this rule is to eliminate delay in the covered entity's response when a request is made for a copy of a record that will not require the covered entity to review it before a copy can be furnished to a requesting patient. It reduces the records that need review, and thus produces efficiencies for the covered entity and speeds receipt of the copy to the patient in the situations where review will not be necessary.

Where review is noted and therefore appropriate, the default rule of 48 hours should be extended. HRBA believes that the additional time for review should not exceed three days or 72 business hours, absent exigent circumstances. This framework should also be included in the final rule, with exigent circumstances generally defined.

Conclusion

HRBA believes that health record bank accounts will prove to be a highly significant benefit to patients. Ownership and control of a compiled copy of health records will engage patients, and greatly enhance their ability to manage their health and make efficient, effective choices in dealing with healthcare providers. Patients' access to their health records will thus lead to better outcomes, a more healthy population, and lower healthcare costs nationwide.

For all these reasons, it is essential that the Department facilitate patient's rapid and easy access to copies of their health records. Our comments, and the suggestions in them for enhancing the final rules in 45 C.F.R §164.524(c), are designed to serve those ends.

Respectfully submitted,

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