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## **IMPROVING THE HIPAA ACCOUNTING FOR DISCLOSURES REQUIREMENT**

Hospitals certainly support efforts to enable patients to learn more about the information that hospitals must report to America's trusted public health officials. The regulatory requirements for "accounting of disclosures of protected health information," found in §164.528 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) medical privacy regulations, create a number of serious negative unintended consequences on patient care and essential hospital operations. HHS must develop an approach to the accounting requirement that meets the information needs of patients yet remains workable for the hospitals that provide them with care.

### **The Problem with the Accounting Requirement**

While the accounting for disclosures requirement in the HIPAA medical privacy rule is intended to provide patients with meaningful information about what hospitals share with public health agencies, the method imposed upon hospitals by the current HIPAA regulations to ensure that such a laudable objective is achieved is unnecessarily burdensome. Hospitals are currently required to report information for dozens of critically important and widely accepted health-related purposes, such as tracking births and deaths, cancer patterns, child abuse, and defects in medical devices. As currently drafted and interpreted, the HIPAA requirements for accounting for disclosures will require hospitals to create a burdensome paperwork system to account for these numerous and frequent disclosures of information reported to public health authorities.

The HIPAA accounting for disclosures requirements only add to hospitals' enormous existing regulatory paperwork burdens that already consume 30 minutes to one hour for every hour of patient care and would divert unnecessarily millions of dollars from patient care. Moreover, according to state public health officials, the requirements could discourage hospital participation in important public health initiatives, including new reporting initiatives to detect potential bioterrorism related outbreaks and measure and improve patient safety.

### **Solutions to Address the Significant Paperwork Burden Imposed by the Accounting Requirement**

To respond directly to the specific challenge from Department of Health and Human Services (HHS) Secretary Tommy Thompson that hospitals should propose solutions to address any negative unintended consequences on patient care and essential operations created by the HIPAA medical privacy standards, the AHA offers the following approaches as concrete solutions to address the significant burdens imposed by the regulatory requirements for accounting of disclosures.

*Regulatory Change.* It would be preferable for HHS to modify the regulatory language of the HIPAA medical privacy rule to explicitly exclude the disclosures that hospitals must report to

America's trusted public health officials from the accounting for disclosures requirement and thereby eliminate the unjustifiable paperwork burden on hospitals that the requirement imposes. Since HHS is limited to making only annual modifications to the HIPAA medical privacy regulations, the AHA urges HHS to issue *without delay* such a rule change proposal in order to ensure that the necessary modifications to the rule are completed and applicable to hospitals' compliance efforts as soon as allowable.

*Interpretative Guidance on the Regulatory Requirement.* Following are brief descriptions of the distinct categories of disclosures that arguably should be excluded entirely from the accounting requirements or for which an alternative simplified form of accounting should be allowed as well as those limited few that would remain subject to the full accounting of disclosures requirements:

Disclosures that are not required to be included in an accounting of disclosures to a specific individual

- Disclosures for covered functions that support a covered entity's ability lawfully to provide treatment to individuals or to be eligible to pay or be paid for health care are health care operations. (Q&A #1)
- Public health disclosures that do not include direct identifiers do not pertain to a specific individual or action to be taken with respect to an individual and do not provide a reasonable basis to believe that the recipient could use the information to identify the individual. (Q&A #2)
- In disclosures for reviews preparatory to research, the disclosure is incidental to the research preparation and the reviewer is prohibited from removing any information from the premises of the covered entity and is prohibited from taking any action with respect to the individual. (Q&A #4)
- Disclosures for research pursuant to an Institutional Review Board or Privacy Board waiver of authorization under which direct identifiers must be removed or destroyed by the researcher before use of the data for research do not provide any reasonable basis to believe that the information can be used to identify the individual and the researcher is prohibited from taking any action with respect to the individual. (Q&A #5)

Disclosures for which an alternative, generalized method of accounting to a specific individual is most appropriate

- An alternative, generalized accounting provides the most appropriate method for informing an individual of public health reporting that involves direct identifiers where the reporting is triggered by a disease or condition that is itself noted in the protected health information maintained by the covered entity. (Q&A #3)

### Disclosures that remain subject to the detailed individualized accounting requirement

- Disclosures that relate to an individual personally or that could affect public or private actions taken with respect to an individual must be included in an individualized accounting to the individual. (*Q&A #6*)

The attached Q&A sets forth in greater detail our proposed interpretations for each of these categories of disclosures. The attachment resulted from the AHA's effort to find an effective but less burdensome compromise solution that achieves the specific policy objectives that the Office of Civil Rights (OCR) has informed us underlie the HIPAA accounting for disclosures requirements. Namely, the proposed interpretations would ensure that a patient receives a detailed accounting of any disclosures of the patient's records made by the hospital that could affect directly the individual public or private legal interests or other obligations of that patient while limiting the paperwork associated with other disclosures made for more general public health or oversight purposes.

The AHA urges OCR to adopt these specific interpretations and to issue promptly the attached Q&A as guidance for hospitals and other covered entities to follow in implementing appropriately the HIPAA medical privacy rule's requirements for accounting for disclosures. By doing so, OCR will ensure that patients continue to get exactly the information they need to understand what information about them hospitals are required to disclose to public agencies while offering immediate relief to hospitals already overburdened with unnecessary regulatory paperwork burdens so they can keep their focus on providing quality care to their patients.

Attachment

**PROPOSALS TO IMPROVE THE HIPAA  
ACCOUNTING OF DISCLOSURES REQUIREMENT**

**Frequently Asked Questions**

**Q1: Are disclosures of protected health information to auditors, licensing authorities, inspectors and investigators that are necessary for a covered entity to continue operating and to be eligible to receive payment for health care services considered health care operations?**

**A1:** Yes. Disclosures of protected health information that a covered entity makes to a government entity, an entity acting under a grant of authority from a government entity, or third party payors are considered health care operations, as they are necessary for the covered entity to retain its license, continue its operation or receive payments for health care from a payor, including Medicare or Medicaid. Health care operations are defined as those that relate to covered functions. The disclosures described above relate to covered functions because they enable the covered entity to continue to be a health care provider, health plan or health care clearinghouse and support a covered entity's ability lawfully to provide treatment to individuals or to be eligible to pay or be paid for health care. These health care operations disclosures do not relate to a specific individual or affect public or private actions taken with respect to an individual, and based on the Notice of privacy practices, may be expected to occur as appropriate. As such, they are not required to be included in an accounting of disclosures to a specific individual.

**Q2: Are public health reports that do not include direct identifiers relating to an individual (as defined in 45 C.F.R. 164.514(e)(2)) subject to the individual accounting requirements?**

**A2:** No. Public health disclosures that do not include direct identifiers do not pertain to a specific individual or action to be taken with respect to such individual. Where such disclosures are made to an entity in accordance with 45 C.F.R. 164.512(b), there is no "reasonable basis to believe that the information can be used to identify the individual" as is required for the reported information to be considered "individually identifiable health information" as defined in 45 C.F.R. 160.103. As such, public health disclosures that do not include the direct identifiers are not considered disclosures of protected health information; they do not relate to a specific individual or affect public or private actions taken with respect to an individual, and based on the Notice of privacy practices, may be expected by all to occur as appropriate. As such, they are not required to be included in an accounting of disclosures to a specific individual.

**Q3: What is the form required for an accounting of disclosures of protected health information made for public health purposes?**

**A3:** Public health reporting pursuant to § 164.512(b) that involves direct identifiers (e.g., births, deaths, communicable diseases) relates to a specific individual or may affect public or private actions taken with respect to an individual and thus is subject to the

individual accounting of disclosures requirements. Where the public health reporting requirement is triggered by a disease or condition that is itself noted in protected health information maintained by the covered entity, the requirement of an accounting can be satisfied by the covered entity by one of two methods: (1) an individualized report of all disclosures of a specific individual's protected health information, or (2) a generalized report. To use the generalized reporting method, the covered entity must make available a Public Health Accounting Report that includes the following information for every type of public health disclosure the covered entity makes: (1) the name of the entity or person who receives the protected health information and, if known, the address of such entity or person (e.g., State Health Department); (2) a brief description of the protected health information disclosed (e.g., birth; PKU result; specific disease diagnosis); (3) a brief statement of the purpose of the disclosure that reasonably informs the individual of the basis for the disclosure (e.g., to report births for State tracking); and (4) the general time frame within which such disclosures typically occur (e.g., births are reported within 24 hours of the birth). When using the generalized method for public health disclosures, each individual accounting should state that to the extent the individual had a condition or event included in the Public Health Accounting Report of reportable public health conditions or events, the law and institutional policy require the individual's protected health information to be disclosed as provided in the generalized report of public health disclosures. Covered entities are not required to review the individual's record to determine whether the individual had a birth, communicable disease, cancer or some other reportable condition or event. Providing the generalized report and explanation regarding reportable conditions or events meets the requirements for an accounting and strikes the right balance between an individual's right to be informed and the administrative burden on covered entities.

**Q4: Are uses and disclosures of information for reviews preparatory to research (45 C.F.R. 164.512(i)(1)(ii) subject to the individual accounting requirements?**

**A4:** No. In order to provide access to protected health information for reviews preparatory to research, the covered entity must prohibit the reviewer from removing any information from the premises of the covered entity, and require the reviewer to represent that access to the information is being sought solely to prepare for research. The reviewer's exposure to identifying information is incidental to the research preparation, the reviewer is bound to protect the confidentiality of the reviewed information, and the reviewer is prohibited from taking any action with respect to the individual. As such, reviews preparatory to research are not required to be included in an accounting of disclosures to a specific individual.

**Q5: Are disclosures for research pursuant to a waiver of authorization by an Institutional Review Board or Privacy Board in accord with 45 C.F.R. 164.512(i)(1)(i) subject to the individual accounting requirements?**

**A5:** Yes, if the IRB or Privacy Board has allowed the researcher to obtain and maintain direct identifiers for research purposes. This is a disclosure of information pertaining to a specific identifiable individual. However, in granting a waiver of authorization, an IRB or Privacy Board is required to obtain "adequate written assurances that the protected

health information will not be reused or disclosed to any other person or entity... .” Where the IRB or Privacy Board also has required that direct identifiers be removed or destroyed by the researcher *before* use of the data for research, for purposes of section 164.512(i)(2)(ii)(A)(2), there is no “reasonable basis to believe that the information can be used to identify the individual” as is required for the reported information to be considered “individually identifiable health information” as defined in 45 C.F.R. 160.103. As such, disclosures of information under a waiver of authorization where the researcher does not maintain the direct identifiers are not considered disclosures of protected health information; they do not relate to a specific individual or affect public or private actions taken with respect to an individual. As such, they are not required to be included in an accounting of disclosures to a specific individual.

**Q6: What types of disclosures of protected health information must be included in an individualized accounting of disclosures provided to an individual?**

**A6:** It is important that an individual be able to obtain information about disclosures that relate to an individual personally or that could affect public or private actions taken with respect to such individual. Specifically, the following disclosures of protected health information must be included in an accounting to an individual: (1) regarding victims of abuse, neglect or domestic violence [*§ 164.512(c)*]; (2) in connection with judicial and administrative proceedings (except where no direct identifiers are disclosed) [*§ 164.512(e)*]; (3) to law enforcement [*§ 164.512(f)*]; (4) to coroners, medical examiners and funeral directors [*§ 164.512(g)*]; (5) for cadaveric organ, eye or tissue donation [*§ 164.512(h)*]; (6) for research pursuant to an IRB or Privacy Board waiver of authorization (except where no direct identifiers are disclosed) [*§ 164.512(i)*]; (7) to avert a serious threat to health or safety [*§ 164.512(j)*]; (8) for military and veterans activities [*§ 164.512(k)(1)*]; (9) for protective services of the President and others [*§ 164.512(k)(3)*]; (10) in connection with medical suitability determinations [*§ 164.512(k)(4)*]; (11) by covered entities that are government programs providing public benefits [*§ 164.512(k)(6)*]; and (12) for workers’ compensation [*§ 164.512(l)*]. Note that an accounting of disclosures for health oversight activities or to law enforcement may need to be temporarily suspended in accordance with *§ 164.528(a)(2)*. Disclosures that are required by law which are not part of the covered entity’s health care operations activities [*§ 164.512(a)*], and disclosures for public health purposes that include direct identifiers also are required to be included in an individual accounting where the covered entity has not elected to use the generalized approach to communicating about public health disclosures.