



August 1, 2011

NAQC Board

- AARP
- American Association of Colleges of Nursing
- American Academy of Nursing
- American Academy of Nurse Practitioners
- American College of Nurse-Midwives
- American Nurses Association
- Association of Nurses in AIDS Care
- Association of periOperative Registered Nurses
- Consumers Advancing Patient Safety
- National League for Nursing
- American Organization of Nurse Executives
- Mothers Against Medical Error
- National Council of State Boards of Nursing
- National Organization of Nurse Practitioner Faculties
- National Quality Forum

Secretary Sebelius,
 U.S. Department of Health and Human Services, Office of Civil Rights
 Attention: HIPAA Privacy Rules Accounting of Disclosures
 Hubert H Humphrey Building, Room 509F
 200 Independence Avenue SW
 Washington, DC 20201

Submitted electronically to [Http://www.regulations.gov](http://www.regulations.gov)

Re: HIPAA Privacy Rule Accounting of Disclosures Under the Health Information Technology for Economic and Clinical Health Act
 RIN 0991-AB62; 45 Fed. Reg. Part 164, May 31, 2011.

Dear Secretary Sebelius:

The Nursing Alliance for Quality Care (NAQC) welcomes the opportunity to offer comments on this proposed rule. NAQC is a partnership among the nation's leading nursing organizations to advance the highest quality, safety and value of consumer-centered health care for all individuals-patients, their families, and their communities. NAQC works to ensure that: patients receive the right care at the right time by the right professional; nurses actively advocate and are accountable for consumer-centered, high quality health care; and that policy makers recognize the contributions of nurses in advancing consumer-centered, high quality health care.

NAQC champions the individual's right to confidentiality in regard to their protected health information, and appreciates the challenges of assuring patient/client confidentiality in view of operational logistics for health care organizations.

NAQC supports the proposed changes to the Accounting of Disclosures, with minor modifications as noted below. This portion of the proposed rule clarifies and streamlines the accounting of disclosures required by HIPAA, and is commendable in many regards.

NAQC opposes the Department's proposed access log and record as described. This discretionary expansion of the accounting beyond that which is provided in statute is well intended but logistically unmanageable and potentially very costly. NAQC strongly encourages the Department to reconsider the requirements related to an access log or record.



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Section IV. Section-by-Section Description of Proposed Rule

A.1. Standard: Right to an Accounting of Disclosures:

NAQC supports the proposed change to the scope of information subject accounting to that within a designated record set. Of particular benefit is the note that a hospital's peer review files fall outside the classification of a designated record set. *NAQC strongly encourages the extension of this classification to all internal Quality Improvement activities which necessitate accessing the EHR.* We believe the existing Privacy Rule and Security Rule as well as the continued application of the Breach Notification Rule provide the critical protection of patient privacy needed for information which falls outside the designated record set.

NAQC supports the proposed reduction in the accounting period from six years to three. This increases consistency within the regulation and reduces administrative burden without significant compromise to consumer interests.

The proposed change to listing the types of disclosures subject to accounting (as well as listing the types subject to exemption) provides good clarification. In particular, the Department's intent to require accounting of disclosures impermissible under the privacy rule (even if they do not constitute a formal breach) provides enhanced protection.

We support continued inclusion of disclosures for:

- public health activities (unless specifically exempted)
- judicial and administrative proceedings
- military and veterans activities
- medical suitability determinations
- government programs providing public benefits
- worker's compensation

We are in favor of the proposed exemptions from disclosure for the following:

- reports of suspected child or elder abuse
- reports of suspected domestic violence
- disclosures for health oversight activities
- disclosures about decedents to coroners, funeral directors and medical examiners
- disclosures for initial contact regarding cadaveric organ, eye, or tissue donation
- disclosures for research purposes
 - In particular, NAQC supports providing an exemption for IRB approved research, which already provides very substantial privacy protection for consumers. HHS should be commended for their incorporation of input from the scientific community and of content from the relevant IOM document in this regard.

NAQC opposes the current proposal that covered entities must provide an accounting of any disclosures made by their business associates (rather than provision of a list of said associates). This requirement is unduly burdensome. It shifts complete responsibility and cost to the covered entity and begs questions of enforcement and accountability.

Additionally, this provision is wasteful in that significant effort may be extended to obtain and report information the individual is not seeking. Recognizing the Department's intent to facilitate consumer access to records of interest, a compromise approach might be to provide

the individual with the listing of business associates, and provide a method for the individual to identify which they would like to have queried.

Our organization has would like to express concern regarding the exemption from disclosure of any reports to public health required by law, but not those "authorized but not required". As a point of patient advocacy, NAQC supports inclusion of any reports not specifically exempted above. Individuals may wish to know that reports naming them have been advanced, whether required by law or not. In addition, this provision has potential for undue administrative burden in that it requires facilities to separate required from authorized disclosures.

Section IV.A.3. Implementation Specification: Provision of Accounting

NAQC objects to the alteration of the timeline for provision of accounting from 60 days to 30 days, which may create significant burden for a covered entity without substantial benefit to consumers. We support the provision of the accounting in the form and format of best use to the consumer if readily producible. Likewise, the use of machine readable or electronic copy if "covered entities are able to do so" allows adequate flexibility for both the agencies and the individual.

Section IV. B. Right to an Access Report-Section 164.528(b)

This portion of the proposal generates a number of critical concerns. The right to confidentiality and privacy is of critical importance to consumers, but the rule as proposed does not adequately address their concerns. What consumers really want is assurance that any access of their protected health care information (electronic or otherwise) was appropriate and necessary. The Department is correct that it would be preferable to provide a "complete picture" of all who accessed the information. Unfortunately, although this is highly desirable, it comes with a disproportionate cost burden. It is more realistic and attainable to hold covered entities responsible for the ability to conduct comprehensive internal investigation upon request (including review of that capability by regulatory or licensing agencies).

Section IV. B.1. Standard: Right to an Access Report

This proposed regulation creates substantial burden and cost for covered entities. HHS considers the burden reasonable, since entities complying with the HIPAA Security Rule are already required to "implement procedures to regularly review records of information system activity, such as audit logs, access reports and security incidence tracking reports". However, the chasm between an audit log for internal investigative procedures and a document of use and value to the consumer is vast. If required in the proposed format, the access report would require very substantial work to generate, including manual merging of information from multiple data streams. The primary increased costs in implementation of this regulation are related to work load, not revision of the privacy notice as described. The consideration of only the cost of revision of the privacy notice is disingenuous.

Section IV. B.2. Implementation Specification: Content of the Access Report

The proposed requirement assumes a level of IT sophistication and integration which currently exists sporadically and which would be costly to implement. It lessens or negates the intent of several of the exemptions from accounting created in the earlier section of the proposed rule. As an example, why exempt researchers if their names and the nature of their access is provided in the access record?

The requirement of the access log creates significant concerns for workforce privacy and security. The report as defined would include the first and last name of all staff members who accessed the record for any purpose, with no provision to limit access by individuals with a history of criminality or other irrational behavior.

The intent of the proposal that an access report include what information was accessed and what action was taken are laudable, but this regulation does not meet the intended needs of consumers. It would undoubtedly raise more questions than it answers for the requesting individual. Any list of persons who accessed the EHR for "treatment, payment, and healthcare operations" for a patient during an acute care hospitalization would easily reach into the thousands. None of that information is meaningful to the individual, who cannot determine legitimacy of the access based on name, or even on job title. In order for this information to be useful, the individual would need to know not only the name and role of the person who accessed the information, but also their work schedule and duties during the period of interest, what portion of the record was viewed, and for what specific purpose.

It is our perspective, based on the above, that the extension of this report to every EHR access made by all individuals within business associates of the covered entity is not feasible.

Section IV. B.3. Implementation Specification: Provision of the Access Report

As noted above, NAQC does not believe the Access Report will accomplish the intended purpose. If regulations require the report as described, the proposed 30 day window for provision of the report is not logistically reasonable.

Section IV. B.5. Accounting for Disclosures Made Through Electronic Health Information Exchange

NAQC supports limitation of the proposed Access Report from disclosures made through Health Information Exchange. As noted, the potential benefit to the requesting individual is outweighed by the difficulty and cost.

Section IV.C. Confidentiality of Patient Safety Work Product

NAQC strongly supports the continued protection of disclosures as provided by the Patient Safety and Quality Improvement Rule.

Conclusion:

NAQC appreciates the opportunity to comment on this important set of proposed rules. If we can be of further assistance, or if you have any questions or comments, please feel free to contact me at 202-994-3484 or at sonmjs@gwumc.edu

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