



VIA: <http://www.regulations.gov>

May 18, 2010

The Honorable Georgina Verdugo  
U.S. Department of Health and Human Services  
Office for Civil Rights  
200 Independence Avenue, S.W.  
Hubert H. Humphrey Building, Room 509F  
Washington, DC 20201

Dear Director Verdugo:

Re: HIPAA Privacy Rule Accounting of Disclosures Under the Health  
Information Technology for Economic and Clinical Health Act;  
Request for Information

413 North Lee Street  
P.O. Box 1417-D49  
Alexandria, Virginia  
22313-1480

The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to share with the Department of Health and Human Services Office for Civil Rights (OCR) information to help inform you as you draft regulations with respect to the expansion of the accounting of disclosures requirement under the HITECH Act.

NACDS represents 154 traditional drug stores, supermarkets, and mass merchants with pharmacies – from regional chains with four stores to national companies. NACDS members also include more than 900 pharmacy and front-end suppliers, and over 70 international members from 24 countries. Chains operate 37,000 pharmacies, and employ more than 2.5 million employees, including 118,000 full-time pharmacists. They fill more than 2.5 billion prescriptions annually, which is more than 72 percent of annual prescriptions in the United States. The total economic impact of all retail stores with pharmacies transcends their \$815 billion in annual sales. Every \$1 spent in these stores creates a ripple effect of \$3.82 in other industries, for a total economic impact of \$3.11 trillion, equal to 26 percent of GDP. For more information about NACDS, visit [www.NACDS.org](http://www.NACDS.org).

**Scope of Provision**

We believe that as OCR considers the expansion of the accounting of disclosures requirement, OCR must first consider the scope of this expansion. In particular, just because health information is stored in, or disclosed through a computer does not equate that computer system to an electronic health record.

As OCR properly recognizes in the Federal Register notice, under the HITECH Act, the exemption from the accounting of disclosures requirement under the HIPAA Privacy Rule for disclosures to carry out treatment, payment, and health care operations no longer applies to disclosures *through an electronic health record*. Section 13400 of the

HITECH Act provides an extremely broad definition of “electronic health record.” As such, OCR should be guided by Congressional intent when determining what falls under the definition of “electronic health record.”

Congressional intent can be determined by reviewing the HITECH Act as a whole. Notably, the HITECH Act provides grant funding for certain providers to adopt electronic health records and provides a mechanism for the development of criteria for determining eligibility for such funding. It is logical to conclude that Congress intends for the expanded accounting of disclosures functionality (i.e. removal of exemption) to apply to providers who are eligible to receive funding for, and actually adopt, electronic health records as they are envisioned under the provisions of the HITECH Act. Since not all health care providers are eligible for grant funding for the adoption of electronic records, it is clear that Congress intended for certain providers to adopt a certain type of electronic health record, and for specific requirements to attach to those electronic health records.

The logic that the expanded accounting of disclosure requirement applies to providers who are eligible to receive funding for, and actually adopt, electronic health records as they are envisioned under the provisions of the HITECH Act is supported by the historical record of the HIPAA Privacy Rule. Specifically, HHS recognized under the original final HIPAA Privacy Rule that “the additional information that would be gained from including these disclosures would not outweigh the added burdens on covered entities.”<sup>1</sup> Since most covered entities, including pharmacies, are using the same, or substantially similar, computer systems as they did when the original HIPAA Privacy Rule was finalized, OCR would have to reach the same conclusions with regard to burden versus benefit for these computer systems as they did in December 2000. The only alternative would be to disavow nearly ten years of OCR policy.

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<sup>1</sup> At 65 Fed Reg 250, p. 82739; HHS recognizes the following:

“While including all disclosures within the accounting would provide more information to individuals about to whom their information has been disclosed, we believe that documenting all disclosures made for treatment, payment, and health care operations purposes would be unduly burdensome on entities and would result in accountings so voluminous as to be of questionable value. Individuals who seek treatment and payment expect that their information will be used and disclosed for these purposes. In many cases, under this final rule, the individual will have consented to these uses and disclosures. Thus, the additional information that would be gained from including these disclosures would not outweigh the added burdens on covered entities. We believe that retaining the exclusion of disclosures to carry out treatment, payment, and health care operations makes for a manageable accounting both from the point of view of entities and of individuals.”

As OCR is aware, pharmacies are not among the entities that are eligible for grant funding under the HITECH Act for the adoption of electronic health records. Moreover, we refer OCR to a recent letter submitted to Department of Health and Human Services Office of the National Coordinator for Health Information Technology (ONC) regarding existing pharmacy computer systems, which stated the following:

It is critical to ensure that all health care providers have access to an interoperable exchange of health information through certified EHRs and other HIT systems. Specifically, in pharmacy, computerized records are considered databases that are generally not interoperable in a manner to meet the objectives described for certified EHR technology.<sup>2</sup>

Consequently, we believe that pharmacy computer systems are not “electronic health records” as such term is defined under the HITECH Act.

However, if OCR should somehow disagree with our opinion, we would like to share the following comments and concerns:

**Pharmacies Already Provide Patients with the Information they Need**

Pharmacies have been using computer systems to maintain prescription records and to bill payers for over twenty years. NACDS members have the ability to provide patients with a copy of their prescription records upon request, which they frequently do provide. Our patients do not generally complain that the information we currently provide is insufficient for their needs. To require pharmacies to provide patients with an accounting of every disclosure would be confusing to patients and unnecessary, considering the information that is currently available to them.

Since the HIPAA Privacy Rule became effective, pharmacies have received few requests for an accounting of disclosures. We ask OCR to contrast this with patients’ requests for a copy of their prescription records, which is a fairly common request from patients. From this experience, we find the arguments that more patients would request more accountings if they knew they were available to be specious and without merit. Patients currently receive the information they need from pharmacies, as we have developed systems over the past few decades to respond to their needs and requests.

Coincidentally, the prescription records that our members provide do allow a patient to infer the disclosures made electronically, as the record would show the payer that was billed and identity of the prescriber.

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<sup>2</sup> Letter to Department of Health and Human Services Office of the National Coordinator for Health Information Technology from Academy of Managed Care Pharmacy, American Pharmacists Association, American Society of Consultant Pharmacists, American Society of Health-System Pharmacists, and National Community Pharmacists Association; May 10, 2010; page 3.

### **Notice of Privacy Practices**

As required under the HIPAA Privacy Rules, our members clearly notify patients that an accounting of non-routine disclosures is available upon request. Despite this, patients routinely seek copies of their prescription records, which ironically pharmacies do not always clearly notify patients of the availability of such. We view this as further evidence that patients are not afraid to request the information that they seek (and they are not seeking an expanded accounting of disclosures from their pharmacies).

### **Compliance by January 2011 Not Possible**

Finally, if despite our commentary, OCR believes that pharmacies must provide patients with an expanded accounting of disclosures pursuant to the HITECH Act, then we must urge OCR to delay implementation for all pharmacies until the statutory maximum of 2016. Currently, there exists no mechanism for a pharmacy to comply with the expanded HITECH requirement, nor are we aware of any electronic systems being developed or considered.

This expanded HITECH accounting requirement would require pharmacy computer systems to be completely redesigned and redeployed. This would require years of research, design, development, testing, rollout, and training. The cost to the pharmacy industry would be staggering and is impossible to quantify with any reasonable certainty.

### **OCR's Specific Questions**

To ensure we are providing OCR with requested information, our specific answers to the RFI's questions are below:

- 1. What are the benefits to the individual of an accounting of disclosures, particularly of disclosures made for treatment, payment, and health care operations purposes?** We believe the benefit to an individual would be to understand how their sensitive information is being shared and whether sharing such information poses any concerns. However, we believe that existing requirements, notices and provisions meet the needs of individuals. In addition to the notice of privacy practices and the availability of patient prescription records, we comply with breach notification rules, in addition to all the HIPAA Privacy Requirements, including the marketing rules, business associate requirements, and provide accountings of non-routine disclosures.
- 2. Are individuals aware of their current right to receive an accounting of disclosures? Yes. On what do you base this assessment?** The notice of privacy practices is available at our members' pharmacies, and also online for some pharmacies.
- 3. If you are a covered entity, how do you make clear to individuals their right to receive an accounting of disclosures?** It is provided in the notice of privacy

practices. **How many requests for an accounting have you received from individuals?** Random sampling of our pharmacy members indicates that our small and regional chains have received zero to few requests since 2003, which is a tiny fraction of the number of patients served since 2003. The larger, national chains have received requests in similar percentages, that is, tiny fractions of patients served.

4. **For individuals that have received an accounting of disclosures, did the accounting provide the individual with the information he or she was seeking? Are you aware of how individuals use this information once obtained?** Our pharmacy members were generally not aware of the purposes for the requests.
5. **With respect to treatment, payment, and health care operations disclosures, 45 CFR § 170.210(e) currently provides the standard that an electronic health record system record the date, time, patient identification, user identification, and a description of the disclosure. In response to its interim final rule, the Office of the National Coordinator for Health Information Technology received comments on this standard and the corresponding certification criterion suggesting that the standard also include to whom a disclosure was made (i.e., recipient) and the reason or purpose for the disclosure. Should an accounting for treatment, payment, and health care operations disclosures include these or other elements and, if so, why? No. We believe that expanding the type of information to be included in an accounting would be impractical and of questionable value to the patient. Documenting this additional information does not support existing clinical workflows and would be of limited value considering the few requests for accountings that our member pharmacies receive. How important is it to individuals to know the *specific* purpose of a disclosure – i.e., would it be sufficient to describe the purpose generally (e.g., for “for treatment,” “for payment,” or “for health care operations purposes”), or is more detail necessary for the accounting to be of value? Please see previous response. To what extent are individuals familiar with the different activities that may constitute “health care operations?” Most individuals are unaware. On what do you base this assessment? Most patients are concerned about value, efficiency, customer service, safety, and quality, not about the operations of the pharmacy.**
6. **For existing electronic health record systems:**
  - a) **Is the system able to distinguish between “uses” and “disclosures” as those terms are defined under the HIPAA Privacy Rule? Generally, no.**
  - b) **If the system is limited to only recording access to information without regard to whether it is a use or disclosure, such as certain audit logs, what information is recorded? Generally, that a change was made and who made it, not the specific change. How long is such information retained? Varies, based on state and federal requirements. What would be the burden to retain the information for three years? Depends on the information required to be retained.**
  - e) **Is there a single, centralized electronic health record system? Or is it a decentralized system (e.g.,**

**different departments maintain different electronic health record systems and an accounting of disclosures for treatment, payment, and health care operations would need to be tracked for each system)?** Systems vary among pharmacy chains. **f) Does the system automatically generate an accounting for disclosures under the current HIPAA Privacy Rule (i.e., does the system account for disclosures other than to carry out treatment, payment, and health care operations)?** Generally, no. Manual processes are used to track non-routine disclosures. **i. If yes, what would be the additional burden to also account for disclosures to carry out treatment, payment, and health care operations? Would there be additional hardware requirements (e.g., to store such accounting information)?** Yes, significant hardware/software requirements. **Would such an accounting feature impact system performance?** Yes, but the greater impact would be to pharmacy workflow and productivity. **ii. If not, is there a different automated system for accounting for disclosures, and does it interface with the electronic health record system?** Generally, manual processes are used to track non-routine disclosures.

7. **The HITECH Act provides that a covered entity that has acquired an electronic health record after January 1, 2009 must comply with the new accounting requirement beginning January 1, 2011 (or anytime after that date when it acquires an electronic health record), unless we extend this compliance deadline to no later than 2013. Will covered entities be able to begin accounting for disclosures through an electronic health record to carry out treatment, payment, and health care operations by January 1, 2011?** No, our members would need to implement completely new systems. **If not, how much time would it take vendors of electronic health record systems to design and implement such a feature?** Generally, a number of years. **Once such a feature is available, how much time would it take for a covered entity to install an updated electronic health record system with this feature?** Generally, one to two years.
8. **What is the feasibility of an electronic health record module that is exclusively dedicated to accounting for disclosures (both disclosures that must be tracked for the purpose of accounting under the current HIPAA Privacy Rule and disclosures to carry out treatment, payment, and health care operations)? Would such a module work with covered entities that maintain decentralized electronic health record systems?** Unfortunately, it is impossible to develop answers to these questions in the time allotted for responding to the RFI.

**Conclusion**

We appreciate the opportunity to share information and concerns with OCR regarding the HITECH Act's expanded accounting of disclosures requirement. Considering the very few requests for an accounting of non-routine disclosures, the availability of the notice of privacy practices that already provides patients with summary information about how the pharmacy may share PHI for routine disclosures, and the availability of detailed prescription records, we believe that accounting for every individual routine disclosure is impractical.

We believe that this expanded requirement applies only to electronic health records as envisioned by the totality of the HITECH Act and not to *any and all* computer systems from which PHI is disclosed. Moreover, we believe this position is wholly supported by HHS' existing philosophy that requiring an accounting of routine disclosures would not benefit patients while also being unduly burdensome.

Please do not hesitate to contact us if we can provide further assistance. I can be reached at 703-837-4183 or [knicholson@nacds.org](mailto:knicholson@nacds.org).

Sincerely,

/s/

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