

VIA Electronic Submission to <http://www.regulations.gov>

May 18, 2010

The Honorable Georgina Verdugo
U.S. Department of Health and Human Services
Office for Civil Rights
Attention: HITECH Accounting of Disclosures
Hubert H. Humphrey Building, Room 509F
200 Independence Ave., S.W.
Washington, D.C. 20201

Re: Document ID: RIN 0991-AB62. HIPAA Privacy Rule Accounting of Disclosures under the Health Information Technology for Economic and Clinical Health Act; Request for Information [45 CFR Parts 160 and 164]

Dear Director Verdugo:

Thank you for the opportunity to submit our comments on the above-referenced Request for Information. The National Community Pharmacists Association (NCPA) represents America's community pharmacists, including the owners of more than 23,000 community pharmacies, pharmacy franchises, and chains. Together they employ over 300,000 full-time employees and dispense nearly half of the nation's retail prescription medicines.

Section 13405 (c) of the HITECH Act requires the Department of Health and Human Services to revise the HIPAA Privacy Rule to require covered entities to account for disclosures of protected health information to carry out treatment, payment and health care operations if such disclosures are through an electronic health record.

It is the position of NCPA that at the present time, pharmacy management systems used to fill and process prescriptions and manage inventory, are not "Electronic Health Records" for the

purposes of the HITECH Act and thus pharmacies would not be required to account for disclosures made for treatment, payment and health care operations.

The computerized pharmacy management systems currently employed by many community pharmacies to process new prescriptions, manage inventory, allow for electronic transmission of prescriptions, track drug allergies and interactions and refill requests and approvals, are not “Electronic Health Records” when one considers the interplay between the overly broad definition of Electronic Health Record found at Section 13400 of the HITECH Act in conjunction with the subset of eligible health care professionals who may receive significant financial incentives or bonuses under Medicare and Medicaid provided they demonstrate “meaningful use” of Electronic Health Records.

Section 13400 of the Act defines “Electronic Health Record” as “an electronic record of health-related information on an individual that is created, gathered, managed and consulted by authorized health care clinicians and staff.” This definition could conceivably refer to any and all records or notes from any health care provider ranging from typewritten notes on a word processor to the most sophisticated interoperable health care information exchange system. In order to identify with any specificity a workable definition of Electronic Health Record (EHR), we feel it imperative to look to other, related sections of the Act, to narrow down the specific health care providers envisioned by the HITECH Act drafters to take the lead with respect to the initial adoption and implementation of EHRs for the purposes of accounting of disclosures.

The HITECH ACT does not include pharmacists in the list of eligible health care professionals that may qualify for Medicare or Medicaid incentive payments for the adoption and implementation of EHRs able to comply with “meaningful use” requirements, accounting of disclosures and other priority components.

Under the HITECH Act, non-hospital based physicians and hospitals may qualify for Medicare incentive payments for the adoption and implementation of EHRs. In addition, the HITECH Act also provides Medicaid incentive payments to a broader group of health care professionals who adopt and implement EHRs. The healthcare professionals eligible for such incentives under Medicaid include physicians, dentists, certified nurse-midwives, nurse practitioners and physician assistants—but not pharmacists. In addition, the HITECH Act also establishes 70 regional centers to help promote EHR adoption. These regional centers have been designed to offer “technical assistance, guidance and information on best practices to support and accelerate health care providers’ efforts to become meaningful users of Electronic Health Records.” At the present time, 100,000 primary health care providers will be supported by the regional centers. It seems apparent that the initial focus of federal efforts to encourage and assist in the establishment of EHRs has been upon physicians or related primary care

providers—but not pharmacists. The pharmacy management systems currently in use by community pharmacists would need significant technological upgrades to ensure the needed interoperability and the additional functionalities to serve as EHRs.

NCPA does recognize the importance of the integration of all medical information and the inherent value of melding medical data with medication information. NCPA members certainly wish to provide medication/prescription data to medical providers and likewise have access to EHRs or elements of such records such as lab values, diagnoses and immunization histories in order to ensure that patients receive optimal and integrated health care.

At the present time, it is NCPA's position that the information generated by pharmacy management systems constitute a valuable addition or module to an EHR but are not sufficient to serve as a stand-alone EHR. NCPA recognizes that moving forward, in order to achieve optimal patient care and outcomes, bidirectional interoperability and functionality between pharmacy information systems and EHRs will be necessary. NCPA does anticipate that at some point in the future, pharmacy management systems will evolve and pharmacy practitioners will be provided with the support and necessary incentives to adopt systems with additional functionalities.

The independent pharmacies represented by NCPA comprise most of the 17,500 pharmacies with revenues under \$7 million per year and thus meet the Small Business Administration's definition of small entity. The financial burden for independent pharmacy owners to sufficiently upgrade current pharmacy management systems to address the accounting of disclosures in the absence of any federal assistance or incentives would be virtually insurmountable.

At the present time, pharmacy providers receive very few requests for an accounting of disclosures at all under the current Privacy Rule that requires only the capacity to produce accounting of disclosures reports for non-routine disclosures.

At the present time, pharmacy patients are made aware of their current right to receive an accounting of disclosures when they sign the notice of privacy practices provided by their community pharmacy. Based on an informal survey, none of the NCPA member pharmacists that responded indicated that they had ever been asked for an accounting of disclosures under the current Privacy Rule. In fact, the only information that we were able to determine that current pharmacy patients do request with any frequency is for a prescription fill history—something that pharmacy management systems in their current iterations are easily able to produce. From what we have been able to ascertain, most pharmacy patients that request this information do so to calculate the amount of money spent on co-pays for the purposes of their varied health care savings-related accounts.

If it were determined that some components of pharmacy management systems do in fact constitute electronic health records, the current state of such systems do not allow for the automatic capture of information for the purposes of disclosures and are not able to distinguish between “uses” and “disclosures.”

In order for pharmacy systems to provide an accounting of disclosures for payment, treatment and operations (PTO), significant technological outlays would be required in order to comply with the increased demand on data collection and storage. In addition, virtually all disclosures of prescription information are made for the purposes of PTO and in fact, in most instances, multiple disclosures are necessary for any one prescription. Taking into account the fact that the average independent pharmacy fills approximately 200 prescriptions a day—and estimating that each prescription generates approximately four disclosures for PTO, this would translate into 800 disclosures per day, most likely as a minimum amount. The sheer volume or number of disclosures that would be required to be accounted for would be overwhelming to all parties involved.

In Conclusion

As you gather information from all of the interested stakeholders on the accounting of disclosures for treatment, payment and health care operations, NCPA respectfully urges you to consider these issues. We appreciate the opportunity to share our concerns and recommendations with you.

Sincerely,

A handwritten signature in cursive script that reads "John M. Coster".

John M. Coster, Ph.D., RPh.
Senior Vice President, Government Affairs