

August 27, 2009

Susan D. McAndrew, J.D.
Deputy Director for Health Information Privacy
Office for Civil Rights
U.S. Department of Health and Human Services
Hubert Humphrey Building, Room 515F
200 Independence Avenue SW
Washington, DC 20201

Dear Ms. McAndrew:

Thank you for the opportunity to meet with you and your staff to discuss the HITECH Act privacy provisions in relation to the independent community pharmacy industry and patients we serve. The pharmacy profession has been on the leading edge of the adoption of health information technology (HIT) for many years and is ahead of the vast majority of other health care providers. We have been actively involved in fostering the use of technology to improve the quality of patient care and developing standards to allow the growth of HIT in pharmacy practice. As so, it is very important that community pharmacy be able to continue providing communications necessary to ensure quality patient care, while assuring protections for protected health information (PHI). On behalf of the National Community Pharmacists Association (NCPA) and our members, I wanted to follow up regarding several issues we discussed at our meeting on July 24, 2009.

Accounting of disclosures

Section 13405(c) of the HITECH Act newly requires covered entities (CEs) that use or maintain an Electronic Health Record (EHR) to provide, upon request, an accounting of disclosures made for treatment, payment and health care operations purposes through an EHR over a three-year period. This provision expands significantly a Health Information Portability and Accountability Act (HIPAA) privacy rule requirement that physicians, hospitals, and other covered entities prepare an accounting of all “non-routine” disclosures of a patient’s personal health information. Under the new law, entities would have to account for *all* disclosures of information.

Independent community pharmacies make thousands of disclosures every day in order to provide a high level of quality care for our patients and process claims for payment. Not all pharmacy information systems utilized by our members have been designed to comply with this type of requirement for the billions of transactions affected. Our members who have invested heavily in technology may be forced to abandon existing systems for brand new systems that would comply with the mandate. To do so would prove too costly for many independent pharmacists.

NCPA contends that so few patients have sought an accounting of disclosures under current HIPAA requirements that, instead of providing an expansive listing of disclosures in the future, a better approach would be to require a CE to provide a patient, upon request, a listing to whom they disclose PHI for payment, treatment, and operations purposes. The few patients who seek more details could talk with the pharmacist or their designee for more information. Taking this approach provides patients who request an accounting with information that will help them understand to whom the pharmacy discloses their PHI.

Patient requested restrictions on disclosures

CEs, including independent pharmacies, will be required to comply with requests from individuals that their PHI not be disclosed to a health plan if the purpose is for payment or health care operations and pertains to an item or service for which the provider has been paid out of pocket in full. There could be instances when a patient requests that their pharmacist not disclose payment or operations information to the health plan if they pay out of pocket for a prescription, but the pharmacy is contractually bound to submit this information based on specific contractual arrangements between them and the plan.

Furthermore, in the case of Medicare Part D and the coverage gap between the initial coverage limit and catastrophic coverage threshold (“donut hole”), pharmacies are required to adjudicate a Part D claim to the health plan so that true out-of-pocket (TrOOP) costs can be calculated. In these instances, Medicare Part D beneficiaries pay 100% of the cost of prescription drugs. In this scenario, if a patient requests that their PHI not be disclosed to the Part D plan, calculation of out-of-pocket costs could be affected.

In the routine practice of pharmacy, our members submit claims to health plans related to payment, operations and treatment in one adjudication process. We want to make you aware that it may not always be possible to separate a claim for payment or operations from one for treatment upon patient request. We will be working with our technology vendor and health plan partners as the rulemaking process progresses related to this provision.

Business associates and updated agreements

The HITECH Act requires that BAs must comply directly with the HIPAA Security Rule and use and disclosure requirements of the HIPAA Privacy Rule. Our members will need to update their existing contracts with BAs to account for these changes. It may be difficult for our members, as small business owners, to secure updated contracts from the much larger corporate entities with which they contract, especially for our members who do not participate as part of a Pharmacy Services Administration Organization (PSAO), who contract on their behalf. We would ask that there be exceptions provided for CEs operating small practices when there has been a good faith effort made to obtain updated BA contracts but the CE is unable to obtain such agreement from the BA.

Prohibition on payment for exchange of data

CEs and BAs are not able to directly or indirectly receive remuneration for the exchange of PHI without a valid individual authorization. The law provides for an exception in the cases of “treatment” and we ask that this exception be interpreted as applying for circumstances such as the exchange of monies in order to transmit PHI electronically. This is especially important in the case of electronic prescribing, where pharmacies pay a fee to participate in electronic exchange of PHI between the pharmacy and prescriber, and in the case of transmittal of pharmacy claims, where pharmacies pay a transaction fee to adjudicate claims.

Also, when a pharmacy closes and prescription records are sold to another pharmacy, there is an exchange of monies for the transaction. This practice is specifically included in the “health care operations” exception listed in statute at 45 CFR § 164.501.

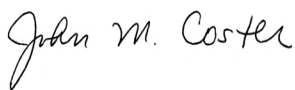
New enforcement provisions

New enforcement provisions in the HITECH Act would allow state attorneys general to bring civil actions in federal court to enforce the HIPAA rules. NCPA contends that the federal government already has enforcement powers under HIPAA and states have powers under state privacy laws, thus this may lead to conflicting outcomes and varied civil actions incurring needless legal expenses. We ask that the original intent of HIPAA enforcement, which focused on ongoing compliance and not corrective action, be followed.

In closing, although pharmacies have been on the leading edge of adoption of HIT, our members will have to make significant modifications and upgrades to their existing systems to comply with many of the HITECH Act’s privacy provisions, such as the breach notification requirement, the accounting of disclosures requirement, and patient-requested restrictions on disclosures. Small independent pharmacies will be adversely impacted as they may be more resource challenged than others.

We will continue to participate in discussions with our technology vendor partners, as they will be integral to compliance, and we would like to suggest a meeting with you and our technology partners at a future date. NCPA appreciates your willingness to keep an open dialog related to these matters. If you have any questions, please contact me at (703) 683-8200 or john.coster@ncpanet.org.

Sincerely,



John M. Coster, Ph.D., R.Ph.
Senior Vice President, Government Affairs
National Community Pharmacists Association