FOOD MARKETING INSTITUTE

July 29, 2011

Submitted Electronically

The Honorable Kathleen Sebelius
Secretary of Health and Human Services
United States Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: HIPAA Privacy Rule Accounting of Disclosures Under the Health Information Technology for Economic and Clinical Health Act; Proposed Rule[1]

RIN: 0991-AB62

Dear Secretary Sebelius:

The Food Marketing Institute (FMI) appreciates the opportunity to respond to the Department of Health and Human Services (HHS) request for comments on the proposed rule modifying the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule's accounting for disclosure requirement under the Health Information Technology for Economic and Clinical Health Act (HITECH Act).

FMI is the national trade association that conducts programs in public affairs, food safety, research, education and industry relations on behalf of its 1,500 member companies – food retailers and wholesalers – in the United States and around the world. FMI's members in the United States operate approximately 26,000 retail food stores and 14,000 pharmacies. Their combined annual sales volume of $680 billion represents three-quarters of all retail food store sales in the United States. FMI's retail membership is composed of large multi-store chains, regional firms, and independent supermarkets. Our international membership includes 200 companies from more than 50 countries. FMI's associate members include the supplier partners of its retail and wholesale members.

I. Introduction

The proposed rule modifying accounting for disclosures and adding the right of "access reports" for patients will impose very significant burdens on retail pharmacies. Ambiguity exists because the proposed rule does not clarify whether "access reports" are to include accesses only by humans or whether reporting of any electronic accesses is required even if no humans accessed, used or disclosed a patient's personal

[1] 76 Fed. Reg. 31426 (May 31, 2011).

health information (PHI.) The intent of Congress was to protect PHI from unlawful access by living people. A broad interpretation of electronic access to include all computerized access would place enormous burdens on the industry and be virtually impossible to comply with.

II. "Electronic Designated Record Set" Goes Beyond HITECH Act

Modifying the HIPAA Privacy Rule's accounting requirement to include disclosures of PHI made through an "electronic designated record set" needlessly broadens HITECH Act's requirement that accounting rules apply only to those entities that use, maintain and disclose from an electronic health record (EHR), not any electronically stored PHI. HITECH Act requires accounting of disclosures only for EHRs, whereas the proposed rule expands the Privacy Rule accounting requirements to include all uses and disclosures of PHI stored electronically.

If the goal of HHS's proposal is to improve the workability and effectiveness of the existing accounting rule, expanding the scope of the rule to include all electronic uses and disclosures pertaining to treatment, payment and health care operations (TPO) is not the way to achieve it. Congress' intent was to exclude accounting of disclosures for purposes of TPO because cost-benefit analysis showed accounting of such disclosures would be far too burdensome on covered entities; section 164.528 of the Privacy Rule explicitly excludes disclosures for TPO purposes and section 13405(c) of HITECH Act refers to disclosures from EHRs only rather than referring to PHI from designated record sets (DRS).

Furthermore, accounting all electronic access to PHI would be an unreasonable request because much access of PHI occurs though routine computer scans, data sifts and data sweeps, which are situations not involving a living being accessing, using or disclosing data. It would be nonsensical for these disclosures to be included in access reports. Patients would be provided with excessive and unhelpful information. HIPAA was intended to prevent illegal access of PHI by humans, and including accounting of all electronic access would go beyond HIPAA and HITECH Act. The proposed rule is inconsistent with the intent of Congress.

III. Pharmacies Burdened by Expanded Accounting of Disclosures

Broadening the Privacy Rule's accounting of disclosure requirements would create expensive, time-consuming burdens for covered entities and their business associates while providing little or no benefit to individuals. Not only would computer systems need to be changed because most pharmacies have not employed EHR systems, but an expanded electronic system would need to be developed. Developing and implementing a new system would be extraordinarily expensive and time-consuming.

Maintenance of access logs is required under current law, but the proposal adds the burden of maintaining an expensive computer system that turns raw data, including accountings of computer-only access of PHI,

into a substantive access report for patients. Furthermore, expanding accounting requirements to include all electronic PHI disclosures would be superfluous and confusing for individuals because the access report would contain accesses by computer systems that never involved a human. The extra disclosures would have little to no value to patients who desire an access report. Moreover, an insignificant number of requests have been made for accounting of disclosures under the current rule and most patients want only prescription records, which the industry already provides.

Because the proposal eliminates the TPO exception, excessive work of tracking all disclosures will impose enormous burdens on pharmacies. Under the current rule exempting TPO from accounting, pharmacies can easily send out refill reminder letters (a type of TPO disclosure.) In the United States, non-adherence to medication instructions and refills are a major problem; for example, only half of U.S. patients treated for hypertension adhere to prescribed treatment.[2] Patients similarly fail to adhere to medication regimens for other illnesses, many of which are communicable, and this creates a risk for public health. Refill reminders improve adherence and should not be deterred through the burdensome and inefficient proposed rule. Under the proposal, the expense of time and money to track and record such disclosures could lead to many members of the industry eliminating such programs.

The addition of disclosures made by business associates to patients' right to an accounting of disclosures further increases the burden on FMI members. Refill and specialty programs are often conducted by business associates of pharmacies, so on top of needing to account for disclosures made by pharmacists, pharmacy technicians and pharmacy clerks, any disclosure of PHI made by business associates is onerously required as well. Increasing the administrative burden and costs for retail pharmacies to provide an accounting of use and disclosure of PHI, even by business associates, will negatively impact valuable programs and may lead to their elimination.

It is also important to note that individuals are already provided with notice about how pharmacies may share PHI by members of the industry. Because individuals have knowledge of possible disclosure and only a minority of them chooses to request an accounting of disclosures under the current rule, there is no pressing need to expand the rule any further.

IV. **Workable Aspects of Proposed Rule**

We believe that the main provisions of the proposed rule place an excessive burden on retail pharmacies and should be rewritten. That said, there are also aspects of the proposed rule that ease the burden on covered entities and business associates. Requiring accounting for 3 years rather than 6, allowing a general range of dates when there are multiple disclosures to a single recipient for a single purpose and allowing

[2] Adherence to Long-term Therapies – Evidence for Action, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland (2003). ISBN 92 4 154599 2 (NLM classification: W 85).

approximation of access date when it is unknown makes the process less onerous. Reducing the time period for an accounting and access report to 1 year would certainly create less expense and trouble for retail pharmacies.

V. Conclusion

Excessive burdens are placed on the industry under the proposed rule modifying HIPAA's Privacy Rule. The proposal will require access reports to account for uses and disclosures made by computers, even though there was no human access. Access logs are already required by law, and these logs include accounting of disclosures of human access only; therefore, Congress has shown its intent for disclosure of human access only and not for when a computer, without human viewing, has accessed PHI through a data sort or some similar function. Patients likely would not understand nor value an access report that includes each and every access of PHI.

FMI greatly appreciates HHS's consideration of these comments. Please contact me at elieberman@fmi.org or 202-220-0614 if you have any questions.

Sincerely,

Erik R. Lieberman
Regulatory Counsel