FOOD MARKETING INSTITUTE

September 13, 2010

Submitted Electronically

U.S. Department of Health & Human Services
Office for Civil Rights
Attention: HITECH Privacy and Security Rule Modifications
Hubert H. Humphrey Building
Room 509F
200 Independence Ave. SW
Washington, DC 20201

Re: Modifications to HIPAA Privacy, Security, and Enforcement Rules Under the Health Information Technology for Economic and Clinical Health Act; Proposed Rule, 45 CFR Parts 160 and 164, 75 Fed. Reg. 40,868 (July 14, 2010)

Docket No: RIN-0991-AB57

The Food Marketing Institute (FMI) appreciates the opportunity to respond to the Department of Health and Human Services (HHS) Notice of Proposed Rulemaking to modify the HIPAA Privacy, Security and Enforcement Rules 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 15,000 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.

The Food Marketing Institute supports efforts to promote greater use of information technology to enhance healthcare while ensuring the privacy of sensitive patient information. HHS is seeking comments to inform the agency's rulemaking process to implement recent statutory amendments under the HITECH Act, to strengthen the privacy and security protection of health information, and to improve the workability and effectiveness of these HIPAA rules.

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FMI wants to express the need for an appropriate balance between protections for patient health information and the delivery of important pharmacy services to patients. As such, we offer the following comments:

Authorization Versus Notice/Disclosure/Opt-Out Requirements: Treatment, Marketing and Health Care Operations

FMI strongly supports HHS' proposed revisions to the current definition of "treatment" in 45 CFR 164.501 and the Department's decision not to require authorization for treatment communications. We believe the existing HIPAA Privacy Rule, with no additional requirements for "treatment" communications, has worked well in protecting the privacy of pharmacy patients. However, subject to the specific comments below, FMI supports the proposed notice, disclosure, and opt-out regulatory scheme for sponsored treatment communications.

FMI requests confirmation in the final rule that all current HHS statements on what is a "treatment" communication continue to be valid.

We also request the final rule confirm that refill reminders can qualify as "treatment" if notice/disclosure/opt-out requirements set forth in the rule are met.

FMI supports HHS' distinction in the proposed rule between treatment and health care operations communications. The proposed rule explains a sponsored "treatment" communication would not need authorization, but is subject to the new notice/disclosure/opt-out requirements. In comparison, a sponsored healthcare operation communication would require authorization with notable exceptions for refill reminders.

Face-to-face Communications

We strongly support HHS' decision to maintain the "face-to-face" exception from the marketing authorization requirement. The "face-to-face" exception is based on the policy that the healthcare provider should be able to communicate important health information to the patient in a "face-to-face" setting *and* that the patient can terminate the conversation or disregard the written material if he or she chooses to. In the explanation of its version of the HIPAA Final Rule ten years ago, the Clinton Administration HHS explained the face-to-face exemption, saying it:

> permits a covered entity to use or disclose protected health information without individual authorization to make a marketing communication if the communication occurs in a face-to-face encounter with the individual. This provision would permit a covered entity to discuss any services and products, including those of a third-party, without restriction during a face-to-face

> communication. A covered entity also could give the individual sample products or other information in this setting.[1]

The Bush Administration HHS retained the face-to-face exemption in its version of the Final Rule in August 2002, explaining its reasoning by saying that it was retaining "this exception so that the marketing provisions would not interfere with the relationship and dialogue between health care providers and individuals."[2]

FMI's member companies have professional pharmacists and pharmacist assistants working in 15,000 retail locations around the country. Federal law requires pharmacists to offer to counsel Medicaid patients. These pharmacists have a professional obligation to counsel patients about their prescriptions and conditions. This requirement has been extended by most states to require pharmacists to offer counseling to all patients receiving a new prescription. These are sound reasons to retain the face-to-face exemption, and FMI is pleased that HHS has chosen to do so.

Notice of Privacy Practices (NPP)

FMI supports the general proposal to provide patients with the covered entities Notice of Privacy Practices. We anticipate that the NPP will be given to the patient when he or she picks up their first prescription and thereafter will be available in the store and/or on-line. The NPP will include: (1) a description of whether/how the patient's health information will be used; (2) whether the patient will receive sponsored treatment communications; and (3) how to opt-out.

The NPP provides patients an opportunity to opt-out before receiving any sponsored "treatment" communications. We urge HHS to recognize that any requirements (or guidance) in this area should be very flexible, so as not to discourage pharmacies from engaging in "treatment" communications.

We also ask HHS to be flexible with regard to the requirement that any health care provider that revises their NPP make the NPP available upon request and comply with the requirements of 164.520 (c)(2)(iii) to have the NPP available at the delivery site and posted in a clear and prominent location.

Opt Out

HHS states in the preamble to the proposed rule that the opt-out method provided to an individual "may not cause the individual to incur an undue burden or more than a nominal cost."[3] FMI supports the ability of our members to provide simple, quick and inexpensive ways for patients to opt out of receiving future communications. Mechanisms could include email, a toll-free phone

[1] 65 Fed. Reg. 82,545 (December 28, 2010).
[2] 67 Fed. Reg. 53,185 (August 14, 2002).
[3] 75 Fed. Reg. 40,886 (July 14, 2010).

number, website, or speaking directly with the pharmacy. This is not an exhaustive list of methods and we urge HHS not to adopt prescriptive, inflexible requirements. Though some pharmacies may have the ability to offer multiple opt-out mechanisms, multiple options should not be a requirement of such a system.

Future Sponsored Treatment Communications:
In response to HHS' request for comment on how opt-out should apply to "future" subsidized treatment communications, FMI advocates that the opt-out apply only to the same means of communication (*e.g.*, opt-out from letter program does not apply to e-mail program), due to possible operational considerations. As discussed above, the NPP should specify the types of sponsored communications offered and the available methods to opt-out.

Feasibility of Requirement for Prospective Opt-Out:
FMI opposes a prospective opt-out requirement on the basis that it would deny a pharmacy patient the public health benefit associated with a treatment communication, possibly before the patient has ever seen such a communication. In addition, a prospective opt-out requirement may create operational difficulties. As discussed previously, we anticipate that all covered entities will include details regarding how to opt-out in the NPP which would give patients an opportunity to opt-out before receiving any sponsored "treatment" communications.

Scope of Refill Reminder Exception

Congress expressly exempted from marketing communications regarding refill reminders or otherwise about a drug or biologic that is currently being prescribed for the individual, provided any financial remuneration received by the covered entity for making the communication is reasonably related to the covered entity's cost of making the communication. FMI believes that it would be in the patient's best interest to include other communications related to the drug currently being prescribed, such as communications regarding generics or new formulations of the drug in this exception.

We would also like to see clarification in the final rule that the "drug or biologic currently being prescribed" includes recently lapsed prescription for chronic use drugs, based on well-recognized public health benefits of adherence communications.

"Reasonably Related" Financial Remuneration

We support HHS' decision to reject as too burdensome a requirement that permissible remuneration would be limited to "actual cost" of making the communication. The Food Marketing Institute commissioned Avalere Health to develop a methodology to calculate the cost to the pharmacy to administer patient messaging programs. In February 2010, Avalere Health LLC authored a paper entitled "Methodology to Calculate Pharmacy Costs Related to Patient Messaging Programs" (Attachment A). The methodology distinguishes between the personnel, direct and indirect costs

associated with the most common patient messaging programs; refill reminder letters, in-store printed messaging, and telephone messaging.

We urge HHS to recognize that "reasonably related" costs to provide the communication include personnel, direct and indirect costs of the communication. Personnel costs could include, for example, an allocated portion of relevant retail pharmacy and headquarters salaries. Direct costs could include computer software and hardware, paper, mailing supplies, and postage. Indirect costs could include, among other things, storage, liability insurance, maintenance and repairs.

"Minimum Necessary"

The HITECH Act requires HHS to address by guidance the "minimum necessary" requirements with respect to the use or disclosure of *PHI*. Accordingly, HHS requested public comment on this issue.[4]

FMI urges HHS to approach the guidance in a reasonable and flexible manner. When addressing this issue, we hope HHS recognizes that the type and extent of information used by a pharmacy or physician (and, if appropriate, shared with its *business associate*) must be broad enough to reasonably implement a *treatment* communications program that will provide meaningful information to patients, with its accompanying public health benefits.

Effective/Compliance Dates

A 180-day compliance date could be unduly restrictive and difficult, if not impossible, for many of our members to meet. There may ultimately be substantial differences between the proposed rule and the final rule. In particular, opt-out procedures and NPPs take time to develop and implement or disseminate.

FMI appreciates the opportunity to comment on this important matter.

Sincerely,

Erik R. Lieberman
Regulatory Counsel

[4] 75 Fed. Reg. 40,896 (July 14, 2010).