655 15th Street, N.W.
Washington, DC 20005-5701
Tel: (202) 452-8444
Fax: (202) 429-4519
e-mail: fmi@fmi.org
Website: www.fmi.org

April 26, 2002

Via Messenger

U.S. Department of Health and Human Services
Office for Civil Rights
Attn: Privacy 2
Hubert H. Humphrey Building
Room 425A
200 Independence Avenue, S.W.
Washington, D. C. 20201

Re: Standards for Privacy of Individually Identifiable Health Information; 45 C.F.R., Parts 160 and 164

Dear Sir or Madam:

The Food Marketing Institute (FMI) respectfully submits the following comments in response to the Department of Health and Human Services' (HHS's) proposal to modify certain standards in the "Standards for Privacy of Individually Identifiable Health Information" rule (the "Privacy Rule"). See 67 Fed. Reg. 14775 (March 27, 2002); 45 CFR, Parts 160, 164. The Privacy Rule implements the privacy requirements of the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996. P.L. 104-191.

For your information, FMI is a non-profit association that conducts programs in research, education, industry relations and public affairs on behalf of its 2,300 members and their subsidiaries. Our membership includes food retailers and wholesalers, as well as their customers, in the United States and around the world. FMI's domestic member companies operate approximately 26,000 retail food stores with a combined annual sales volume of $340 billion, which represents three-quarters of all grocery store sales in the United States.

I's retail members also operate approximately 8,800 in-store pharmacy departments. We estimate that supermarket pharmacies account for nearly 14 percent of all outpatient prescription drugs dispensed in the United States. Based on current industry trends toward larger store formats and the convenience of one-stop shopping, we anticipate that the number of pharmacies located in supermarkets will continue to increase in the coming years as will the number of prescriptions that are dispensed on an outpatient basis from these community settings.

As HHS knows from our two previous comments on these regulations, FMI strongly supports many of the goals and objectives of the Privacy Rule as our industry fully understands the importance of safeguarding the sensitive personal health information of our customers and employees. FMI firmly believes that the modifications that HHS has proposed to the Privacy Rule will not compromise or undermine the protections afforded by the regulation. In fact, the modifications are critically important as they will remove some of the unintended barriers in the current regulation that hinder patient access to quality health care; the proposed changes will also simplify the regulations somewhat, thereby enhancing the ability of covered entities to provide the protections sought in the rule. Accordingly, FMI commends the Department for proposing these modifications to the Privacy Rule and we offer the following comments.

Consent – HHS has proposed significant amendments to the consent requirement of the current Privacy Rule as it applies to health care providers, such as community pharmacists, who have a direct treatment relationship with patients. Under the current Privacy Rule, providers with a direct treatment relationship with an individual are required to obtain a patient's consent before any treatment, payment, or health care operations can be undertaken on the patient's behalf. 45 CFR § 164.506.

As we indicated in our comments to the Department on March 30, 2001, FMI is very concerned about the impact that the written consent requirement in the current Privacy Rule would have on patients and supermarkets that have in-store pharmacies. If left unchanged, this particular requirement would prevent pharmacists from initiating any of the functions relating to the filling and dispensing a prescription – including eligibility verification, insurance coverage, drug utilization review, counseling and other activities – until written consent is given. As a result, it would take much longer for pharmacists to dispense medications and patients would be unnecessarily inconvenienced.

In response to comments submitted by FMI and many others, the Department has proposed to amend Section 164.506 to provide for the use or disclosure of protected health information for treatment, payment or health care operations without first obtaining a patient's consent. Proposed 164.506(a). The proposal would allow covered entities to obtain the patient's consent at the covered entity's discretion. In conjunction, as discussed more fully below, the proposal strengthens the notice requirements.

The proposed revision strikes the right balance between the need to provide strong privacy protection for patients and the need to minimize the barriers to effective health care. Therefore, FMI strongly supports the Department's proposed modification to the consent requirement of the Privacy Rule. We urge its adoption.

Notice - In order to preserve some of the benefits that HHS perceived from the consent requirement that the Department is proposing to remove, HHS is also proposing to modify the notice requirement to require a health care provider who has a direct treatment relationship with individuals to make a good faith effort to obtain an individual's written acknowledgment of receipt of the provider's notice of privacy practices. See Proposed 164.520. FMI believes that this proposed modification is reasonable because it will allow providers to treat patients even if the individual has refused to acknowledge receipt of the notice.

The proposed notice requirement also calls for a high degree of flexibility with respect to the manner in which a health care provider seeks to obtain the individual's acknowledgment of receipt of the notice. See 67 Fed. Reg. 14784. For example, the amendment would not require an individual's signature but allows for acknowledgment by having the patient initial a cover sheet of the notice or other appropriate forms that are used by a health care provider. Id.

For these reasons, we strongly support the proposed changes relating to the notice requirement. However, FMI urges HHS to clarify that a covered entity would not be restricted from payment and health care operations in situations where an individual refuses to acknowledge receipt of the notice. We seek this clarification because the proposed modification refers only to treatment when an individual refuses to acknowledge the notice.

Oral Communications – As expressed more fully in our previous comments to the Department, FMI has and continues to have substantial concerns regarding the inclusion of oral communications in the regulatory definition of "protected health information." In our opinion, HIPAA authorizes the Department to regulate only health information that is transmitted or maintained by electronic media.

One of the key reasons that Congress enacted HIPAA was to address various opportunities and challenges presented by the health care industry's increasing use of and reliance on electronic technology. Indeed, the express purpose of Subtitle F, which directs HHS to promulgate medical privacy regulations, is "…to improve … the efficiency and effectiveness of the health care system, by encouraging the development of a health information system through the establishment *of standards and requirements for the electronic transmission of certain health information*." 42 U.S.C. § 1320d, note; HIPAA § 261 (emphasis added).

With respect to regulatory protections for privacy, HIPAA directs the Department to submit recommendations to Congress regarding the following: the privacy of certain health information (including the rights that an individual who is the subject of individually identifiable health information should have); the procedures that should be established for the exercise of such rights; and the uses and disclosures of such information that should be authorized or required. 42 U.S.C. § 1320d-2, note; HIPAA § 264(b). If Congress fails to develop legislation "governing standards with respect to the privacy of individually identifiable health information *transmitted in connection with the transactions described in section 1173(a) of the Social Security Act . . ., the Secretary of Health and Human Services shall promulgate final regulations containing such standards*." Id. (emphasis added). Section 1173(a), which is subtitled "Standards to Enable *Electronic* Exchange," requires the Secretary to "adopt standards for transactions, and data elements for such transactions to enable health information *to be exchanged electronically*." 42 U.S.C. § 1320d-2 (emphasis added); HIPAA § 262(a) (emphasis added).

The legislative history confirms that the purpose of the regulations was to ensure the privacy of certain health information that was transmitted in electronic form. H.R. Rep. No. 496, 104 Cong., 2d Sess. 99-101, reprinted in 1996 U.S. Code Cong. & Admin. News 1865, 1900-01; HR. Cong. Rep. No. 736, 104 Cong., 2d Sess. 265, reprinted in 1996 U.S. Code Cong. & Admin. News 1990, 2078. As the foregoing demonstrates, HIPAA only authorizes HHS to regulate health information that is transmitted or maintained in electronic format; the Department's authority under HIPAA does not extend to information transmitted or maintained in other media.[1]

We are disappointed that the Department chose not to revisit this issue in the proposed amendments to the Privacy Rule, but continue to assert that HIPAA only grants HHS the authority to issue privacy regulations governing those medical records that are maintained or transmitted in electronic media. Nonetheless, FMI appreciates the Department's technical guidance on this subject, as well as the proposed modifications regarding incidental uses and disclosures, discussed below.

Minimum Necessary Standard - In an effort to reduce confusion surrounding the application of the "minimum necessary" standard and exceptions relating to uses and disclosures made pursuant to an authorization, HHS has proposed several significant modifications to the regulations. Specifically, the proposal adds an important new provision relative to incidental disclosures, as well as an exception from the minimum necessary standard for any uses or disclosures made pursuant to an authorization required under Section 164.508. See Proposed 45 CFR §§ 164.502(a)(1)(iii), 164.502(b)(2).

---

[1] Indeed, as we noted in our March 2001 comments, the preamble suggests that HHS expects a judicial challenge to the provision. See 65 Fed. Reg. 82462, 82496 (Dec. 28, 2000) ("protected health information" definition structured in three parts "so that, if a court were to disagree with our view of our authority in this area, the rule would still be operational, albeit with respect to a more limited universe of information").

With respect to incidental disclosures, the preamble explains that the Privacy Rule is not intended to impede customary and necessary health care communications or practices, nor to require that all risk of incidental use or disclosure be eliminated to satisfy its standards. 67 Fed. Reg. at 14785. In this regard, the proposed amendment to Section 164.502(a) provides that uses and disclosures incidental to those that are otherwise allowed or required by the Privacy Rule will be permitted, provided that certain required protections have been implemented. Proposed 45 CFR § 164.502(a)(1)(iii). We believe that the proposed clarification will assist supermarket pharmacies in terms of oral communications that occur between pharmacists, physicians and patients. Oral communications regarding treatment should not be restricted or discouraged by the Privacy Rule, provided that reasonable safeguards have been implemented.

Moreover, the proposed exemption from the minimum necessary requirement for disclosures made pursuant to an authorization should help to avoid delays in reimbursement.

The preamble to the proposal discusses the recommendations of the National Committee for Vital and Health Statistics (NCVHS) that the Department should issue advisory opinions, publish best practices, and make available model policies, procedures and forms to assist in alleviating the cost and administrative burden that will be incurred when developing policies and procedures as required by the minimum necessary standard. 67 Fed. Reg. at 14786-87. FMI strongly concurs with this recommendation and urges HHS to provide further guidance and technical assistance to help covered entities comply with these provisions.

Business Associates - The Privacy Rule requires covered entities to obtain satisfactory assurances from a business associate that protected health information will be appropriately safeguarded. 45 CFR § 164.502(e). Such assurances must be provided in the form of a written contract or other writing between a covered entity and the business associate.

In recognition of the fact that many covered entities have contractual arrangements with a significant number of business associates – such as third party administrators, pharmacy benefit managers, insurance companies, vendors, suppliers and others – the Department is proposing a new transition period that would allow covered entities to continue operating under existing contracts with business associates for an additional year, or up until April 14, 2004. Proposed 45 CFR § 164.532(d); see also 67 Fed. Reg. at 14787-89. We believe that the proposed transition period will allow covered entities to undertake the contractual renegotiation required by the Privacy Rule in a more considered manner that will ultimately produce more efficient commercial relationships and better patient privacy protections. Therefore, FMI fully supports the proposed one-year transition period.

Uses and Disclosures of Protected Health Information for Marketing - HHS is proposing several important modifications to the Privacy Rule's provisions related to "marketing." Among others, the Department would amend the definition of "marketing" (1) to explicitly exclude certain classes of information, including "case management or care coordination" materials and (2) to eliminate the distinction pertaining to written communications for which a covered entity is compensated by a third party. Proposed 45 CFR § 164.501.

The proposal clarifies that certain written communications made by a health care provider, such as a pharmacist, as part of a patient's treatment for which the covered entity receives compensation from a third party would not be considered "marketing." HHS has indicated that it does not want to impose an authorization requirement on a covered entity for disease management communications, prescription refill reminders, appointment notifications, wellness promotion, and other educational information. 67 Fed. Reg. at 14790. Thus, these written communications would be considered "treatment," rather than "marketing," even if the covered entity was compensated; as "treatment," these communications would not be subject to the authorization requirement.

FMI supports the proposed modification to the "marketing" definition, and urges its adoption. In response to the Department's request for specific types of communications that should not be considered marketing, such a list could be rather lengthy, but we believe that general health information, such as newsletters and brochures or similar type information, that is made available to a patient by a health care provider or electronically from the website of a covered entity, should not be considered "marketing."

Changes of Legal Ownership - The Department has proposed to amend the definition of "health care operations" to include "the sale, transfer, merger, or consolidation of all or part of a covered entity with another covered entity, or an entity that following such activity will become a covered entity and due diligence related to such activity." Proposed 45 CFR § 164.501. The purpose of the amendment is to prevent the Privacy Rule from interfering with necessary treatment or payment activities upon the sale of a covered entity or its assets. 67 Fed. Reg. at 14800.

FMI supports the proposed revision because the Privacy Rule in its present form does not expressly provide for the transfer of protected health information upon the sale or transfer to a successor. Thus, if left unchanged, the Privacy Rule would not allow for treatment or payment activities following the sale of a business or its assets. Recognizing that our industry is currently experiencing considerable activity relating to mergers and acquisitions of stores and pharmacies and the purchase of prescription files, FMI endorses the proposed modification.

Accounting of Disclosures of Protected Health Information - Section 164.528 of the Privacy Rule grants individuals the right to receive an accounting of protected health

information (PHI) disclosures made by the covered entity, with certain exceptions, including disclosures made to carry out treatment, payment or healthcare operations and disclosures to individuals of protected health information about them. See, also, 67 Fed. Reg. at 14801. In response to concerns expressed by the public regarding the high costs and administrative burdens associated with these accounting requirements, HHS is proposing to exempt from the accounting requirement any disclosures that have been authorized by an individual pursuant to Section 164.508. See Proposed 45 CFR § 164.528(a)(1).

FMI fully supports the proposed modification because the individual authorized – and, therefore, already knows of – the disclosures. Thus, the requirement in the existing rule is unduly burdensome without providing a concomitant benefit to individuals and should be removed.

Hybrid Entities - The Privacy Rule currently defines a "hybrid entity" as an entity "whose covered functions are not its primary functions." 45 CFR § 164.504(a). In response to comments regarding the difficulty inherent in determining whether an entity's covered functions are "primary," HHS is now proposing to delete "primary" from the definition. Accordingly, any covered entity that is a single legal entity that performs both covered and non-covered functions may designate itself to be a hybrid entity, regardless of whether the non-covered functions represent that entity's primary function. 67 Fed. Reg. at 14803.

As the preamble discusses, advantages and disadvantages are associated with each status – covered entity and hybrid entity – and PHI will be subject to substantial protections regardless of each entity's ultimate designation. 67 Fed. Reg. at 14803. Covered entities, though, are in the best position to determine which status will allow them to best satisfy their obligations under the Privacy Rule. FMI members who operate in-store pharmacy departments will benefit from the flexibility provided by the proposal. We, therefore, support the proposed change to the definition of a "hybrid entity."

Employment Records – The Department proposes to amend the definition of "protected health information" to expressly exclude individually identifiable health information in employment records held by a covered entity in its role as an employer. Proposed 45 CFR § 164.501(a). The exception will not apply to individually identifiable health information held by a covered entity when carrying out its health plan or health care provider functions; such information would be protected health information. 67 Fed. Reg. at 14804.

FMI agrees that employment records should be expressly excluded from the Privacy Rule's definition of "protected health information." We understand that, under the proposal, records regarding, for example, an employee's absence from work due to an illness, would fall outside the "protected health information" definition as proposed and, therefore, would not be subject to the regulation's restrictions. The modification,

herefore, will reduce the administrative burden and costs associated with companies' handling and safeguard of employment records, a result that we support.

Preemption of State Laws - HIPAA includes express provisions regarding the relationship between the federal medical privacy standards and state law. Specifically, the statute provides that federal standards will "supersede any contrary provision of State law," unless one of the enumerated statutory exceptions applies. 42 U.S.C. Section 1320d-7: HIPAA Section 262 (Social Security Act (SSA) Section 1178(a)). For instance, a contrary State standard will not be preempted "if the provision of State law imposes requirements, standards, or implementation specifications that are more stringent than (those) imposed under the federal regulation." Id. Additionally, State standards shall not be superseded if the Secretary determines that the State standard is necessary for one of several specific purposes enumerated in the statute, such as to prevent fraud and abuse. Id.

Subpart B of Part 160 reiterates the statutory preemption standards and sets forth a process for requesting exception determinations. However, the regulatory process does not apply to determinations of whether a State law related to the privacy of health information is more stringent that the federal standard. See 45 CFR Section 160.204.

FMI strongly supports a national standard to protect the integrity and confidentiality of an individual's medical information. FMI's position has been expressed before Congress and in two sets of comments that have been filed with HHS on this issue. In our view, a uniform national standard is the only way to achieve practical protections for sensitive health information. Even though HIPAA provides some room for contrary state laws,[2] we continue to strongly recommend that the Department engage in the following practical efforts to minimize the confusion that is likely to occur, given the differences in federal and state laws on medical privacy.

Specifically, although HIPAA does not expressly require the Secretary to conduct determinations as to whether a "contrary" state law is more stringent than the federal standards, FMI urges the Department to accept this responsibility. Numerous privacy laws have already been adopted by the states and more medical privacy legislation is actively under consideration at the state level. Covered entities do not have the expertise to determine whether a given state standard is more or less stringent than the federal standards. Therefore, we firmly believe that the Department should provide guidance on the effect of each new state privacy initiative that is enacted in relationship to the federal

---

[2] Congress's failure to preempt all state action in this area will create countless difficulties for covered entities. For example, although the federal medical privacy regulations specifically allow covered entities to use and disclose information as provided in Section 164.512 without consent, authorization or the opportunity to agree or object, HHS states that this section will not preempt any state or other requirements for an individual's concurrence under the same circumstances. See 65 Fed. Reg. at 82524. Similarly, HHS states that Section 164.512(j), which permits use or disclosure of protected health information in order to prevent or lessen serious and imminent threats to health or safety, would not be effective in states that prohibit such disclosures. See 65 Fed. Reg. at 82538.

regulations. This important guidance would assist patients in understanding the protections that apply to their health information and would facilitate compliance by covered entities with the applicable federal regulations and/or state requirements. Such guidance should be posted on the HHS web site along with the preemption determinations that the Secretary must make under Section 160.203(a).

Compliance Date - HIPAA requires the Department to conduct rulemaking on a significant number of related subjects beyond the standards relating to the Privacy Rule. Based on information presented by HHS staff at a February 2002 meeting, we understand that there are eight other HIPAA Administrative Simplification regulations pending in addition to the standards for the Privacy of Individually Identifiable Health Information, but only one of these regulations has been finalized by the Department. In brief, they relate to the establishment of standards for electronic transactions, security, claims attachments, health plan identifiers and others.

The current Privacy Rule requires covered entities to be in full compliance by April 14, 2003, even though eight related regulations have not been promulgated and the Privacy Rule is still being amended. See 45 CFR § 164.534. Due to the extraordinarily complex and challenging nature of this entire initiative, FMI believes that the April 14, 2003 deadline for compliance with the Privacy Rule is unrealistic. Accordingly, we recommend that the Department extend the compliance date of the Privacy Rule so that it will be consistent with the compliance date for regulations that are expected on security standards for health information.

As FMI recommended in comments filed with the Department on March 30, 2001, the issuance of such standards in tandem will facilitate coordination and a smooth transition. Consistent compliance dates between these related regulations would be extremely helpful to covered entities in terms of purchasing or upgrading computer systems, making revisions to business practices, and conducting necessary personnel training. FMI, therefore, urges the Department to delay compliance with the Privacy Rule for at least 24 months after both the privacy standards and the security standards are in place.

* * *

FMI appreciates the opportunity to provide comments on this important initiative relating to the privacy of medical records.

Sincerely,

Tim Hammonds
President and CEO