



May 3, 2013

Ms. Susan McAndrew
Deputy Director for Health Information Privacy
Office for Civil Rights
Department of Health and Human Services
200 Independence Avenue, SW
56E 5th Floor
Washington, D.C. 20201

Re: HIPAA/HITECH Privacy Rule – Clarifications Sought Regarding Sponsored
Refill Reminder Programs

Dear Ms. McAndrew:

This letter is submitted by the Food Marketing Institute (FMI) and the National Association of Chain Drug Stores (NACDS).

BACKGROUND

Food Marketing Institute (FMI) conducts programs in public affairs, food safety, research, education and industry relations on behalf of its nearly 1,250 food retail and wholesale member companies in the United States and around the world. FMI's U.S. members operate more than 25,000 retail food stores and almost 22,000 pharmacies with a combined annual sales volume of nearly \$650 billion. FMI's retail membership is composed of large multi-store chains, regional firms and independent operators. Its international membership includes 126 companies from more than 65 countries. FMI's nearly 330 associate members include the supplier partners of its retail and wholesale members.

NACDS represents traditional drug stores, supermarkets, and mass merchants with pharmacies – from regional chains with four stores to national companies. Chains operate more than 41,000 pharmacies and employ more than 3.8 million employees, including 132,000 pharmacists. They fill over 2.7 billion prescriptions annually, which is more than 72 percent of annual prescriptions in the United States. The total economic impact of all retail stores with pharmacies transcends their over \$1 trillion in annual sales. Every \$1 spent in these stores creates a ripple effect of \$1.81 in other industries, for a total economic impact of \$1.81 trillion, equal to 12 percent of GDP. For more information about NACDS, visit www.NACDS.org.

This letter addresses sponsored prescription refill reminder programs. These programs are intended to improve patient adherence and compliance with prescription drug therapy, with their attendant public health benefits. The importance of improving adherence and compliance with prescription drug therapy is well-recognized by OCR's sister agencies in HHS. HHS's Agency for Healthcare Research and Quality participates in efforts to educate the public about the importance of prescription drug adherence and compliance. HHS's Centers for Medicare and Medicaid Services has used its authority to broaden beneficiary eligibility for the Medicare Part D adherence-focused Medication Therapy Management Programs. HHS's Food and Drug Administration has recognized that "[p]atient noncompliance with prescribed drug regimens can be directly related to therapeutic failure." 60 Fed. Reg. 44,182, 44,186 (Aug. 24, 1995). Moreover, as the Congressional Budget Office (CBO) recently concluded, even a small (1%) increase in prescription refills would result in millions of dollars in savings in overall Medicare costs. *See* CBO, OFFSETTING EFFECTS OF PRESCRIPTION DRUG USE ON MEDICARE'S SPENDING FOR MEDICAL SERVICES (Nov. 2012), *available at* <http://www.cbo.gov/sites/default/files/cbofiles/attachments/43741-MedicalOffsets-11-29-12.pdf>.

Sponsored prescription refill reminder programs are an extremely effective tool for improving patient compliance and persistence, thereby enhancing patient health and reducing health care costs.

CLARIFICATIONS SOUGHT

We write to request that OCR clarify (such as in a guidance or FAQ) three aspects of the preamble to its January 25, 2013 final rule (78 Fed. Reg. 5566) related to sponsored refill reminder programs. Specifically, we respectfully request that OCR address the following points, as discussed separately below:

- OCR should clarify that it intends the permitted scope of refill reminder communications to be interpreted broadly. OCR should recognize in its promised guidance that communications about new formulations of the prescribed drug and communications regarding recently lapsed prescriptions can qualify as sponsored refill reminder programs that can be conducted without patient authorization. We also ask OCR to give careful consideration to including "ask your doctor" communications about specific adjunctive drugs related to the currently prescribed drug.
- OCR should clarify that the "reasonable" compensation limit for sponsored refill reminders that can be conducted without patient authorization is intended to be interpreted broadly, so as to more accurately reflect and not improperly hinder, the Congressional intent behind the special statutory exception from authorization for these programs. OCR's rulemaking preamble contains language that is

capable of being misinterpreted to permit only a narrow, restrictive interpretation of reasonable costs, which runs contrary to both Congressional intent and sound public health considerations. OCR should not allow that to happen.

- Finally, OCR should clarify that a pharmacy can utilize the services of an independent third-party business associate to help implement sponsored refill reminder programs without automatically triggering a need for patient authorization, which would be consistent with the subcontractor business associate model. Absent such clarification, the preamble is capable of being misinterpreted, which could have the effect of bringing such programs to an end as well as resulting in a final Privacy Rule that is inconsistent internally and with the Security Rule.

FMI and NACDS are seriously concerned that preamble language, not required by the HITECH Act or the new regulations, will be interpreted to inhibit sponsored compliance and persistence programs without in any way promoting patient privacy.¹

OCR Should Clarify That It Will Interpret The Permitted Scope Of Refill Reminder Communications Broadly

In its rulemaking preamble, OCR stated that it would issue future guidance on the types of communications that qualify for the refill reminder exception from authorization. 78 Fed. Reg. at 5596. As a threshold matter, we appreciate OCR's recognition in the rulemaking preamble that "communications about the generic equivalent of a drug being prescribed to an individual as well as adherence communications encouraging individuals to take their prescribed medication as directed fall within the scope of this exception," as well as recognition that "where an individual is prescribed a self-administered drug or biologic, communications regarding all aspects of a drug delivery system, including, for example, an insulin pump, fall under this exception." 78 Fed. Reg. at 5596. We urge OCR to go further in its promised guidance.

OCR should issue guidance that interprets the scope of the refill reminder exception from authorization broadly. In the introduction to the proposed rule, OCR expressly sought comment on whether "new formulations" of the prescribed drug should be within the scope of this exception. 75 Fed. Reg. 40,868, 40,885 (July 14, 2010). We ask OCR to expressly recognize that communications about an improved version of the prescribed drug (for example, a "new" drug product with the same active ingredient indicated for the same conditions of use that offers a more convenient dosing schedule than the currently prescribed drug) are within the scope of

¹ It should be noted that unlike regulatory (C.F.R.) text, preamble language does not have the force and effect of law; rather, it sets forth the agency's views on how it is likely to interpret statutory and regulatory requirements.

the refill reminder exception. Typically, these “new formulations” improve patient adherence and compliance by offering distinct advantages, such as greater ease of swallowing, a more convenient dosing schedule, or a similar desirable attribute.

We encourage OCR to recognize that the refill reminder exception includes communications about a chronic use prescription drug where the most recent prescription has lapsed. If that prescription is no longer valid under applicable state pharmacy law, under a very technical interpretation of state pharmacy law, the drug is arguably not a “currently prescribed drug,” as required by the HITECH Act, 42 U.S.C. § 17936(a)(2)(A)(i). Nevertheless, in most cases the intent of the prescriber is that the patient continue to take the drug, as previously prescribed and dispensed. Thus, allowing refill reminders about a recently lapsed prescription is consistent with the intent of the refill reminder exception from authorization. The ability to send a refill reminder without patient authorization in this situation serves a definite public health purpose in improving patient adherence and compliance with prescription drug therapy.

We ask OCR to give careful consideration to including “ask your doctor” communications about a specific prescription drug that relates that “adjunctive” drug to the currently prescribed drug. Typically, the adjunctive drug helps treat the patient’s underlying disease or condition or helps address a side effect of the currently prescribed drug. By helping address treatment of the underlying disease or condition or by helping address a side effect of the currently prescribed drug, these communications about an adjunctive drug are also intended to ultimately improve the patient’s adherence and compliance with the currently prescribed drug. Thus, they should be included as permissible refill reminders that can be sent without patient authorization.

OCR Should Clarify That It Will Interpret The “Reasonable” Compensation Limit For Refill Reminders Broadly

We turn to the “reasonable” compensation limit for “refill reminders.” The HITECH Act’s special statutory exception from patient authorization for sponsored refill reminders requires that any payment received by the health care provider must be “reasonable in amount,” 42 U.S.C. § 17936(a)(2)(A)(ii). The January 25, 2013 final rule significantly narrows the flexibility granted by Congress by requiring that “any financial remuneration received by the covered entity in exchange for making the communication is *reasonably related to the covered entity’s cost in making the communication.*” 45 C.F.R. § 164.501 (definition of “marketing,” provision (2)(i)) (emphasis added). Nothing in the statutory or regulatory language indicates that “reasonable” compensation should be interpreted so narrowly.

Moreover, nothing in the formal or informal legislative history of this provision of which we are aware provides any indication that Congress wanted the “reasonable in amount” criteria to be interpreted narrowly. Otherwise, Congress would have provided such in the statute itself. We are unable to come up with a rationale – whether based in public policy, legal considerations, or financial considerations – for tying specifically an exception from patient authorization in a medical privacy regulation to a limitation on compensation received by the covered entity to make a treatment communication. Given the lack of a rationale that relates medical privacy and calculation of any payment to the covered entity, we think OCR should interpret the “reasonable” compensation limitation on refill reminders as broadly as possible, so as to help achieve the public health advantages of refill reminders and similar adherence and compliance communications. Nothing indicates that Congress intended otherwise.

In the rulemaking preamble, OCR stated that permissible costs “are those which cover *only* the cost of labor, supplies, and postage to make the communication.” 78 Fed. Reg. at 5997 (emphasis added). OCR also stated that “*only* the pharmacy’s cost of drafting, printing, and mailing the refill reminders” may be taken into account. *Id.* (emphasis added). We are concerned that the quoted preamble language could be interpreted very narrowly by both potential sponsors of refill reminders and by pharmacies, thereby effectively denying pharmacy patients the widely accepted benefits associated with communications to improve their adherence and compliance with prescription drug therapy. We urge OCR to clarify that narrow, restrictive interpretations of the preamble language were never intended.

To prevent misinterpretation, we expressly ask OCR to clarify that the cost of “labor,” and the “cost of drafting, printing, and mailing” encompass a wide range of direct and indirect costs associated with refill reminder programs. For example, “labor” costs should include an allocated portion of the labor cost of a wide range of pharmacy personnel, whether located at retail pharmacy locations or at pharmacy chain corporate headquarters. These costs include labor costs associated with developing and reviewing communications content; developing criteria to ascertain which patients will receive which communications; matching appropriate communications and specific patients; determining whether specific contemplated programs qualify as refill reminder programs that can be conducted without patient authorization; setting up and maintaining file format communications methodology; addressing patient comments and questions stemming from communications received; maintaining and updating patient records; managing “accompanying information” and stationery; printing, sorting, inserting, and delivering letters to the post office (and comparable labor costs for messages delivered by E-mail, text, or other means); maintaining automated systems used for the above functions; and training and overseeing employees performing the above-mentioned functions.

Labor costs include those of pharmacists, pharmacy technicians, physicians, attorneys, management personnel, human resources personnel, information technology specialists, and administrative and support personnel performing the above-mentioned functions, allocated as appropriate. In addition, OCR should recognize that “labor” costs include a pro rata portion of total benefits, taxes, and other “overhead” items typically taken into account by government and industry in ascertaining total employee costs. OCR should also recognize that the professional fees and expenses of outside counsel, accountants, physicians, technical specialists, and others needed to assist pharmacy personnel can be taken into account. By analogy, standard accounting rules allow for consideration of such indirect costs under the category of SG&A – Selling, General and Administrative costs.

We also request that OCR recognize that permissible costs include the cost of purchasing or leasing appropriate computer hardware and software associated with refill reminder programs and the cost of purchasing or leasing printing and mail handling equipment (or comparable equipment for communications delivered by other means), including depreciation, maintenance, electricity, insurance, and associated property taxes.

Our request that OCR clarify and recognize that a broad range of a pharmacy’s costs, as detailed above, may be taken into account in determining whether payments to the pharmacy are “reasonable” is generally consistent with other requirements enforced by HHS. For example, in enforcing the federal Medicare/Medicaid anti-kickback statute, 42 U.S.C. § 1320a-7b(b)(2), HHS’s Office of Inspector General has recognized that payments from pharmaceutical companies to healthcare providers are generally not of anti-kickback enforcement concern if the payments do not exceed fair market value of any legitimate service rendered to the payer. 59 Fed. Reg. 65,372, 65,376 (Dec. 19, 1994). To use this as a standard to determine the “reasonableness” of the remuneration not only allows for the healthcare improvements available through better adherence and compliance of patients related to, among other things, such communications, it also permits covered entities to align compliance programs to ensure that compliance with the Privacy Rule does not create non-compliance with anti-kickback obligations.

Further, our request that OCR clarify that “reasonable” costs include a broad range of costs (and look to consistency with the anti-kickback model of fair market value) is supported by a study conducted in 2010 by Avalere Health LLC, an expert pharmacoeconomic consulting firm that FMI and NACDS independently submitted to the rulemaking docket for OCR’s July 14, 2010 proposed rule. In particular, costs associated with refill reminder programs are discussed at pages 7-10 of that report, a copy of which is enclosed for your convenience.

Today, pharmacies do utilize the services of independent business associates to help them send sponsored refill reminders (and similar prescription drug compliance and adherence communications) to their patients. Many pharmacies utilize the services of independent companies that specialize in developing effective communications programs, as well as assisting them in selecting which patients should receive which communications and when. The services of these companies are often essential in helping smaller pharmacy chains, which typically do not have the resources or scale to run their own communications programs, to provide these valuable services to their patients. Other pharmacies may utilize the services of independent business associates that carry out more ministerial functions, such as printing, sorting, and mail fulfillment. All of these business associates are an integral part of sponsored, patient-specific refill reminder programs run by pharmacies for their patients. Without the assistance of business associates, the great majority of these sponsored communications programs would not exist today.

OCR should recognize that independent business associate costs, as paid by the pharmacy, are permissible costs. We do not believe that the notion of “profit” for independent third party business associates should have any bearing in determining whether a cost actually borne by a pharmacy or physician is “reasonable.” Like other business entities, independent business associates that assist pharmacies are in business to make a reasonable profit. If a pharmacy cannot utilize the services of an independent, for-profit business associate, such as a mail fulfillment house, sponsored refill reminder programs that run without patient authorization will, as a practical matter, come to a halt. Congress could not have intended that result when it created the special statutory exception from authorization for sponsored refill reminders. Congress simply required that the payments had to be “reasonable in amount.”

In considering what is “reasonable” costs, because of both the need for consistency with other healthcare enforcement and to ensure consistency for the use of business associates, a greater range of costs should be clarified and the use of fair market value will work to align the different rules with the understanding of “reasonableness.”

OCR Should Clarify That A Pharmacy Can Utilize The Services Of An Independent Business Associate To Help Fulfill A Refill Reminder Program Without Automatically Triggering The Need For Patient Authorization

The preamble to the final rule includes language in two separate places that, when read in isolation, appears to effectively preclude a pharmacy from using a business associate to help it send its patients any sponsored communications that promote the sponsor’s specific product or service unless the pharmacy obtains patient authorization. This preamble language could have the unintended consequence of preventing a pharmacy from using the services of a business associate to help deliver a communication that would otherwise qualify for the statutory refill reminder exception from patient authorization. This is inconsistent with the basic concept in the

Privacy Rule and the Security Rule that a business associate may assist in patient communications, provided common requirements for engaging a business associate are fulfilled.

Specifically, our concern is with the following two preamble excerpts:

We also clarify that where a business associate (including a subcontractor), as opposed to the covered entity itself, receives financial remuneration from a third party in exchange for making a communication about a product or service, such communication requires prior authorization from the individual.

78 Fed. Reg. at 5595.

Even where a business associate of a covered entity, such as a mailing house, rather than the covered entity itself, receives the financial remuneration from the entity whose product or service is being promoted to health plan members, the communication is a marketing communication for which prior authorization is required.

Id. at 5597.²

When the relevant pages of the preamble regarding sponsored communications (*id.* at 5595-97) are read as a whole, we think it is evident that OCR did not intend to preclude the payment of compensation by the sponsor of a communication to the covered entity's business associate for a communications program that does not otherwise require patient authorization. Rather, the quoted language only set forth OCR's views on a basic principle that is not in dispute, namely, a business associate cannot carry out an activity that could not be carried out by the covered entity itself and the covered entity has not authorized the business associate to perform on its behalf. In other words, OCR was only explaining that a business associate cannot conduct programs directly for a sponsor where the covered entity could not conduct such programs itself.

The language quoted above is capable of being misinterpreted by both potential sponsors of refill reminder communications and by pharmacies (and other covered entities) so as to effectively preclude the use of business associates in helping to facilitate refill reminders that do not require patient authorization. This misinterpretation is clearly contrary to the express intent of Congress in establishing a specific refill reminder exception from authorization and would

² Although the quoted language responded to a comment that concerned health plans, it appears to be equally applicable to other covered entities, such as pharmacies.

prevent patients from receiving the important public health benefits associated with these sponsored communications.

Compensation to a business associate for its participation in a communications program, whether flowing directly or indirectly, should not lead to the pharmacy's automatic disqualification from using the statutory refill reminder exception from authorization. We are not aware of any legal or policy reason related to the protection of patient medical privacy that should prevent a pharmacy (or other health care provider) from using the services of an independent business associate, such as a mail fulfillment house, to help it carry out a refill reminder communications program that does not require patient authorization.

CONCLUSION

We respectfully urge OCR to issue clarification (such as in a guidance or FAQ) on the three points discussed above. OCR should do so as soon as reasonably possible so as not to hinder refill reminder programs after the September 23, 2013 compliance date of the final rule. We welcome an opportunity to discuss the issues raised by this letter with you and your colleagues in person.

We appreciate OCR's consideration of this request.

Respectfully submitted,



Kevin N. Nicholson, R.Ph., J.D.
Vice President
Government Affairs and Public Policy
NACDS



Catherine M. Polley, RPh
Vice President, Health & Wellness
Executive Director, FMI Foundation
Food Marketing Institute

Enclosure