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MEMORANDUM

Date: September 24, 2013

TO: All FMI Members

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Executive Director, FMI Foundation

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RE: **Newly Issued Guidance On Sponsored, Retail Pharmacy-Based Patient Communications Programs**

This memorandum discusses the guidance issued by the Department of Health and Human Services (HHS) Office for Civil Rights (OCR) on September 19, 2013, entitled "The HIPAA Privacy Rule and Refill Reminders and Other Communications about a Drug or Biologic Currently Being Prescribed for the Individual" (available at: http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/marketingrefillreminder.html).

The guidance interprets – and substantially expands – provisions of HHS's revised final medical privacy regulations, as published in the *Federal Register* on January 25, 2013 (available at: http://www.gpo.gov/fdsys/pkg/FR-2013-01-25/pdf/2013-01073.pdf). (Those requirements were summarized in our March 2013 webinar) As discussed below, the newly issued guidance should allow many sponsored "refill reminder" patient-specific communications programs that are delivered outside the retail pharmacy to continue without patient authorization (affirmative opt-in). For sponsored in-pharmacy communications, the guidance reinforces the conclusion that messages can be delivered to patients in a face-to-face encounter without authorization and without regard for either message content or compensation limits.

In the interest of brevity, this memorandum does not include legal citations.

Guidance On "Refill Reminders"

A sponsored "refill reminder" (or similar communication) that is delivered to the patient outside of the retail pharmacy setting (*e.g.*, by mail, E-mail, text, fax, or telephone) does not need patient authorization if it complies with HHS requirements regarding the subject of the

communication ***and*** compensation received by the pharmacy. These issues are discussed separately below.

Scope Of Permitted Communications

Under HHS's January 2013 final rule, "refill reminders" and similar communications about a prescription drug that is "currently being prescribed" for the patient may be exempt from authorization requirements. HHS's rulemaking preamble provides three examples of sponsored communications that are regarded as refill reminders:

- Materials about the "generic equivalent" of a prescribed drug.
- "Adherence communications encouraging individuals to take their prescribed medications as directed."
- Information "regarding all aspects of a drug delivery system, including, for example, an insulin pump."

The guidance adds to that list, by including sponsored communications about a prescription that has lapsed within the last 90 calendar days. Sponsored communications about prescriptions that have lapsed by more than 90 days are not regarded as appropriate "refill reminder" messages.

HHS clarified that sponsored communications about ***specific*** new formulations of the currently prescribed medicine, ***specific*** adjunctive drugs related to the currently prescribed medicine, and ***specific*** alternative ("switch") drugs are ***not*** within the scope of the "refill reminder" exception to authorization. Importantly, however, OCR recognized that sponsored "ask your doctor" communications related to these issues may be provided without patient authorization as long as a specific product is not mentioned. For example, HHS stated in connection with adjunctive drugs:

> However, covered entities may communicate in a general manner to individuals regarding the availability of adjunctive drugs related to the drug that is currently being prescribed to the individual without triggering the marketing requirements. For example, a pharmacy could send a communication to an individual alerting the individual to possible side effects from her currently prescribed medication, and suggesting the individual go ask her doctor about a medication to treat the side effects if she experiences them, without naming a particular medication.

OCR made a similar comment about sponsored communications regarding a new formulation (*e.g.*, different dosing schedule or form) of a currently prescribed medicine. These sponsored, "ask your doctor" communications that do not reference a specific product may provide

additional business opportunities for FMI members that operate retail pharmacies and their business partners.

"Reasonable" Costs

The "refill reminder" exception is subject to a statutory and regulatory limit on compensation received by the pharmacy: that compensation must be "reasonably related" to the pharmacy's costs of making the communication. OCR clarified several important issues related to "reasonable" costs.

Direct And Indirect Costs (Including Capital And Overhead)

In its guidance, OCR stated that permissible costs include:

> [P]ayments to a covered entity by a pharmaceutical manufacturer or other third party whose product is being described in the communication that cover only the reasonable direct and indirect costs related to the refill reminder or medication adherence program, or other accepted communications, including labor, materials, and supplies, as well as capital and overhead costs.

OCR's clarifications on permissible costs for which a sponsoring pharmaceutical company can reimburse the pharmacy reflect a substantial expansion of HHS's January 2013 preamble language.

Business Associate Costs – Fair Market Value

OCR also clarified that a pharmacy may utilize the services of an independent business associate to assist in making refill reminder and similar communications without patient authorization, provided that:

> [A] business associate only may receive, whether directly from the third party or through the covered entity from the financial remuneration the covered entity receives from the third party, payments not to exceed the fair market value of its services.

Although OCR did not expressly state that a third party business associate can make a reasonable "profit" in providing services to a pharmacy for a "refill reminder" program, we believe that conclusion is implicit in OCR's recognition that a business associate can be compensated on a fair market value basis for services provided, as a reasonable profit is inherent in the concept of fair market value.

The OCR guidance recognizes that the details of payment flow to the covered entity or to a business associate are of no regulatory significance.

"In Kind" Benefits

HHS's January 2013 rulemaking preamble states that "non-financial benefits, such as in-kind benefits," need not be taken into account in determining reasonable costs, but did not elaborate. In its guidance, OCR clarified that "supplies, computers, or other materials" are examples of "in-kind" remuneration.

Payments From Health Plans

The guidance also clarifies that "[p]ayment from a party other than the third party (or other than on behalf of the third party) whose product or service is being described in the communication, such as payment from a health plan," is not subject to the reasonable compensation limit.

Delayed Compliance Date

Separately, OCR announced that it would not enforce the "refill reminder" and related provisions of its January 2013 rule for another 45 days, until November 7, 2013. This time period should allow pharmacies and their business partners to evaluate current and planned programs under the interpretation set forth in the new guidance.

Guidance On "Face-To-Face" Communications That Do Not Need Patient Authorization

HHS's January 2013 final rule did not change the face-to-face exception from authorization. If anything, HHS's preamble discussion (reiterated in the September 19 guidance) strengthened the exception, by expressly recognizing that the exception covers a situation where the pharmacy communicates with the patient "by ***handing*** the individual ***written materials such as a pamphlet***, that the individual take a specific alternative medication, even if the provider is otherwise paid by a third party to make such communications" (emphasis added). HHS's preamble language recognizes that a "face-to-face" communication may involve written materials that are "handed" to the individual; HHS does not require that a verbal discussion take place to get the benefit of the exception.

Consistent with the January 2013 preamble, the guidance expressly recognizes that sponsored communications about adjunctive drugs, new formulations of a currently prescribed drug, and alternative ("switch") drugs can be made without patient authorization in a face-to-face setting. The guidance also reinforces the preamble discussion, that written materials handed to a pharmacy patient qualify for the face-to-face exception from authorization.

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This memorandum is for general informational purposes only and is not intended to provide specific legal advice to any FMI member. Each member with existing or contemplated retail

pharmacy operations should consult with its in-house or outside legal counsel and regulatory compliance advisors to ensure that it is in timely compliance with the revised HIPAA Privacy Rule and with OCR's interpretations.

Please direct any general questions regarding this memorandum to Cathy Polley at 202-220-0631 or cpolley@fmi.org.