

Health Information Compliance Alert

HIPAA Compliance: Are You Complying With The 'Refill Reminder' Rules?

Could your prescription drug communications land you in hot water?

If you want to stay out of trouble for making HIPAA-prohibited communications, you'd better take a closer look at your practices for prescription refill reminders. Specifically, you need to ensure that your communications meet a two-part test for the refill reminder exception.

Background: Refill reminders came under scrutiny when the HHS Office for Civil Rights (OCR) released the HIPAA Omnibus Final Rule, which, among many other things, placed severe limits on sending marketing communications to patients.

How Remuneration, Current Prescriptions Influence Compliance

The Final Rule provided an exemption for refill reminders or other information about a drug or biologic that is currently prescribed to a patient, notes Jim Sheldon-Dean, founder and director of compliance services for Lewis Creek Systems, LLC, based in Charlotte, VT.

Then, OCR released some much-needed guidance explaining when refill reminders and other communications about drugs or biologics do not constitute "marketing," according to a recent blog posting by Martin Dix a Tallahassee-based partner with the law firm Akerman LLP. This "refill reminder exception" allows for certain situations in which a provider does not need to obtain prior patient authorization in order to send refill- or drug-related communications.

Also in the guidance, OCR pushed back the compliance/enforcement date for the refill reminders restrictions until Nov. 7, 2013, Dix added. And OCR provided a "test" to determine whether refill reminder communications are excepted under the Rule.

Crucial: According to Dix, the refill reminder exception "test" involves two questions:

- 1. Is the communication about a currently prescribed drug or biologic?
- 2. If there is remuneration for the communication, is it reasonable?

What 'Reasonable' Means for Remuneration

Simplified: "Under the Omnibus Rule, any communication to an individual by a covered entity [CE] or its business associate [BA] about a drug or biologic currently prescribed to that individual does not generally require prior authorization," stated a recent analysis by law firm **Ropes & Gray LLP**. "So long as any financial remuneration provided by the third party whose product is being described is 'reasonably related' to the covered entity's cost of making the communication."

"The Omnibus Rule was a departure from OCR's proposed rule and prior practice, in which communications regarding treatment were exempt from the definition of marketing, regardless of whether any remuneration was involved," Ropes & Gray explained.

Pay attention: And when OCR further defined "reasonably related" costs, it provided a definition that differed depending upon whether a CE or a BA is receiving a direct or indirect payment from a pharmaceutical manufacturer in exchange for making the communication, said Ropes & Gray.

Payment to a CE is limited to the reasonable direct or indirect costs related to the labor, materials, supply, and capital and overhead costs of making the communication, Ropes & Gray explained. But when a BA receives the payment, "such payment may be up to the fair market value for the services provided" by the BA.

What Communications are Okay

According to OCR, within the exception for the first question (Is the communication about a currently prescribed drug or biologic?) are the following:

- Refill reminders;
- Communications about generic equivalents of a drug being prescribed;
- Communications about a recently lapsed prescription (one that has lapsed within the last 90 calendar days);
- Adherence communications encouraging individuals to take prescribed medicines as directed; and/or
- Communications regarding all aspects of a drug delivery system, where an individual is prescribed a self-administered drug.

And within the exception for the second question (Does the communication involve financial remuneration, and if so, is it reasonable?) are the following:

- Communication does not involve remuneration;
- Communication involves only non-financial or in-kind remuneration, such as supplies, computers, or other materials;
- Communication involves only payment 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;
- Remuneration involves payments to the CE by a pharmaceutical manufacturer or other third party whose product is being described that cover the reasonable direct and indirect costs related to the refill reminder or medication adherence program, or other excepted communications, including labor, materials, and supplies, as well as capital and overhead costs; and/or
- Remuneration involves payments to a BA assisting a covered entity in carrying out a refill reminder or medication adherence program, or to make other excepted communications, up to the fair market value of the BA's services. The payments may be made by a third party whose product is being described directly to the BA or through the CE to the BA.

Avoid: What's Not Okay

In its guidance, OCR then lists situations that are not within the exception and would require prior patient authorization:

- Communication involves financial remuneration other than as described above;
- Communications about specific new formulations of a currently prescribed medicine;
- Communications about specific adjunctive drugs related to the currently prescribed medicine; and/or
- Communications encouraging an individual to switch from a prescribed medicine to an alternative medicine.

Pay Attention to Scope, Timing of Authorizations

OCR also clarified in the guidance the timing of when you must obtain authorizations from existing patients, as well as the scope and content of these authorizations, according to Ropes & Gray. For existing patients, you must obtain the authorization by Sept. 24, 2014 or by the next prescription renewal, whichever occurs first.

You don't need to limit the authorization's scope to a single drug or biologic, and you don't need to re-obtain the authorization at each subsequent prescription renewal, Ropes & Gray advised. But you must include in the authorization a disclosure stating that you, as the CE, will receive financial remuneration from one or more pharmaceutical manufacturers in exchange for making the communication, and that the individual may revoke the authorization at any time.

