
# HHS Issues Guidance on Communications about Drugs and Biologics under HIPAA and HITECH

By: Jennifer J. Daniels

Just in time for the September 23 enforcement deadline under the HIPAA Omnibus Final Rule, the Department of Health and Human Services ("HHS") Office of Civil Rights ("OCR") has issued Guidance (the "Guidance") regarding communications with individuals about drugs or biologics.

You may recall that the Final Rule requires that a covered entity obtain an authorization for all treatment and healthcare operations communications where the covered entity receives financial remuneration for making the communication from the third party whose product or service is described in the communication. There is no general exception for treatment communications, but there is an exception for refill reminders or other communications about a drug or biologic currently being prescribed to the individual, so long as the financial remuneration paid to the covered entity is reasonably related to the covered entity's cost of making the communication.

The Guidance reinforces some concepts that were already discussed by OCR in the preamble to the Final Rule (which are covered at the end of this Alert), but some interpretations by OCR in this Guidance are new:

1. **Delay in Enforcement:** Since the publication of the Final Rule, OCR has come under attack from adherence program vendors, pharmacies, and the Specialty Pharmacy Association of America for having gone too far in restricting refill reminders and adherence communications. Adheris Inc., a vendor to pharmaceutical manufacturers that sends refill reminders and adherence communications, brought suit against the agency and sought a preliminary injunction against the implementation of the Final Rule on September 23. OCR argued to the court that no injunction was necessary because it had decided to suspend enforcement of its restrictions on refill reminders and other communications until November in anticipation of the issuance of this Guidance.

Oddly, the main body of the Guidance does not include a general statement indicating OCR's intent to delay enforcement of the Final Rule with respect to manufacturer-funded refill reminder and adherence communications. Rather, OCR raises the delay in enforcement in response to an FAQ regarding a specialty pharmacy program that makes manufacturer-sponsored communications to patients for prescribed drugs for chronic and complex diseases that require complicated therapies. The pharmacy in the FAQ has taken the approach with new patients of getting authorizations when they enroll in the program, but existing patients have not signed such authorizations. The FAQ asks whether existing patients must either sign authorizations or be terminated from the program. **OCR responded that it will not determine that a covered entity is in violation of the marketing provisions of the Final Rule where authorizations are not obtained by the covered entity from existing patients to whom it is making such communications by September 23, 2013, so long as (i) the patients from whom authorizations have not been obtained have not opted out of or objected to the receipt of the communications, and (ii) the authorizations are obtained by the next time their prescriptions are renewed or by September 23, 2014, whichever is earlier.** Presumably this delay in enforcement with respect to the "marketing provisions" applies only to the refill reminder exception, and does not apply more broadly to the larger change in the Final Rule that expanded marketing to include communications about a product where remuneration is received by a third party (though this is not entirely clear). Further, it seems from OCR's response that this delay in enforcement applies to all refill reminders or other communications about drugs or biologics that are currently prescribed to the individual, and not just to these programs geared toward individuals who require complex drug therapies (but, again, it is not entirely clear).

2. **Fair Market Value Payment to a Business Associate:** OCR explains in the Guidance that remuneration is acceptable under the marketing exception (and "reasonably related" to the covered entity's cost of making the communication) if it involves payments made to a business associate carrying out the communication and such payments are no more than the fair market value of the business associate's services. Further, such payments may be made directly by the manufacturer to the business associate or through the covered entity to the business associate. Accordingly, while the exception does not permit the covered entity to make a profit from making such communications, the business associate may make a profit so long as the business associate is only charging a fair market value fee for its services. This change in interpretation by OCR may give business associates like Adheris some new comfort, so long as they are charging a fee for their services that a third party would pay in an arms-length transaction.

3. **Costs of Capital and Overhead are Reasonably Related to the Cost of Making the Communication:** A communication about a drug or biologic currently being prescribed to the individual is not marketing, so long as any remuneration received by the covered entity from the manufacturer is reasonably related to the cost of making the communication. In the preamble to the Final Rule, OCR stated that it considered permissible costs for which a covered entity could receive remuneration under the exception to be those that covered only the costs of labor, supplies and postage to make the communication. OCR stated, "Where the financial remuneration…generates a profit or includes payment for other costs, such financial remuneration would run afoul of the Act's 'reasonable in amount' language." In the Guidance, OCR states that a payment is "reasonable in amount" if it covers labor, materials, and supplies, ***as well as capital and overhead costs.*** Including capital and overhead costs is an expansion of OCR's interpretation of the types of costs that were permitted under the preamble to the Final Rule.

4. **Recently Lapsed Prescriptions:** The exception to the marketing rule is for communications about drugs or biologics that are "currently prescribed" to the individual. In the Guidance, OCR clarifies that this includes communications about a recently lapsed prescription, so long as the prescription has lapsed within the last 90 calendar days.

3. **New Formulations of Currently Prescribed Drugs:** OCR explains in the Guidance that communications about new formulations of a currently prescribed medicine do not fall within the marketing exception for communications about currently prescribed drugs. However, OCR explains that a pharmacy could send an adherence communication to an individual that is permitted by the exception without an authorization, and then also include information in that same communication about the availability of a product with a more convenient dosing schedule or in a liquid form without naming the particular medication, and this would not be considered marketing. This interpretation could open some possibilities for marketing communications that do not name the specific product being marketed.

5. **Risk Evaluation and Mitigation Strategy ("REMS") Communications:** OCR makes clear in the Guidance that communications by a covered entity to a patient about a prescribed drug that are required by the FDA under a REMS program are not marketing, even if they are funded by the manufacturer.

As noted above, the Guidance covers some of the same ground that was already discussed in the preamble to the Final Rule, including:

1. **Drug Delivery Systems:** Where an individual is prescribed a self-administered drug or biologic, communications regarding all aspects of the drug delivery system, including, for example, an insulin pump, fall within the exception for communications about a drug or biologic that is currently prescribed to the individual.

2. **Face-to-Face Communications:** Face-to-face communications are not marketing. So, if the pharmacist provides a refill reminder to a patient face-to-face, no authorization is required even if the pharmacy receives financial remuneration that is in excess of the pharmacy's costs. Similarly, a manufacturer can provide a physician with pamphlets about the manufacturer's product, and the physician can distribute those pamphlets when meeting with patients in his or her office without an authorization, even if the physician is paid by the manufacturer to make the communication. The same communication over the phone or by mail would require an authorization.

3. **In-Kind Benefits Not Remuneration:** OCR again emphasizes that financial remuneration does not include non-financial compensation, such as in-kind benefits provided to the covered entity in exchange for making a communication about a product or service. Rather, financial remuneration is payment made in exchange for the communication.

4. **Payment Not from Manufacturer Is Not Remuneration:** If payment is made for the communication from a third party who is not the party whose product or service is being promoted, such as a health plan paying for the communication by a health care provider, then the communication is not marketing. "Financial remuneration" is "direct or indirect payment from or on behalf of a third party whose product or service is being described."

5. **Communications about Generic Equivalents:** OCR restates that communications about a generic equivalent of the drug currently prescribed to the individual falls within the marketing exception for communications about a currently prescribed medication.

For more information please contact:

Jennifer J. Daniels
212.885.5575 • Daniels@BlankRome.com