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Dear Hearing Care Professional:

Updates this year to the Health Insurance Portability and Accountability Act ("HIPAA") are generating questions from Hearing Care Professionals (you) about whether you are required to change the way in which you market to your patients about the health care products and services offered by your business. What these changes mean for your business depends on how any specific marketing program is structured so you may wish to consult with your lawyer or association for guidance.

Many marketing programs are jointly sponsored by Hearing Care Professionals and hearing aid manufacturers, who are members of the Hearing Industries Association ("HIA"). As such, HIA is pleased to provide you with the following basic information about the 2013 changes to HIPAA. These changes have a compliance date of September 23, 2013.

What's New

The key feature of the new 2013 HIPAA marketing rule is "financial remuneration." If you receive financial remuneration (direct or indirect) from a third party, e.g., a hearing aid manufacturer, in exchange for sending a communication to your patients that describes or promotes the manufacturer's products, then you need to obtain written authorizations from your patients before sending the communication to them.

If you do not receive any such financial remuneration in exchange for sending out a treatment or health care communication – even if it describes or promotes a manufacturer's products -- you do not need an authorization. Also, if you do not use patient information, e.g., names, street or email addresses, to send a communication, you do not need an authorization (HIPAA does not apply if you don't use patient information in your marketing activities, for example, if you send a communication to people on a generic direct mail list that does not include your patients).

If you use money from a fund established by a manufacturer for your business to pay for a marketing communication (in whole or in part) to your patients in which the manufacturer's products are described or promoted, you *may or may* not need patient authorizations under the new HIPAA marketing rule. The answer will in each case depend on the manner in which the funds are available to you per your agreement with the manufacturer. However, as long as a particular marketing communication is not funded by a manufacturer or through funds earmarked for funding marketing communications regarding a manufacturer's products, you will not need patient authorizations under the new rules. Please discuss specific questions about joint marketing programs directly with your lawyer and/or hearing aid supplier.

What's Not New

HIPAA was enacted in 1996 and the original compliance date was 2003. Some related long-standing HIPAA rules governing marketing activities were not changed by the 2013 updates. For example, the following communications and activities are still outside the HIPAA definition of "marketing," and do not require authorization:

- Face-to-face communications between you and your patients (for example, you may hand your patients brochures even if the manufacturer has paid to produce the brochure), and
- Promotional gifts of nominal value that you provide to your patients.

In addition, <u>so long as there is no financial remuneration</u>, the following types of communications are not considered "marketing" and *do not require patient authorization:*

Communications for treatment or health care operations purposes such as:

- (i) treatment of an individual, case management, care coordination, or recommending alternative treatments, therapies, health care providers, or settings of care.
- (ii) to describe a health-related product or service (or payment for such product or service) that is provided by the provider making the communication.
- (iii) to provide information about treatment alternatives and related functions to the extent not covered under the definition of "treatment." Refer to 45 C.F.R. § 164.501, para. (1) (i), (ii), (iii) under Marketing definition.

For all other marketing communications, authorization is required. This would include a mailing to patients promoting products or services that do not satisfy the definition of "treatment or health care operations purposes." Refer to 45 C.F.R. § 164.501, para. (2) under *Marketing* definition.

This summary includes general high-level guidance only, and is not intended to cover every specific situation. Additional information regarding HIPAA is available at:

 Department of Health & Human Services: <u>http://www.hhs.gov/ocr/privacy/index.html</u>

Sincerely,

Hearing Industries Association