

Modifications to HIPAA Privacy Rules Under the HITECH Act

An Opinion from Our Fellows
August 30, 2010

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45 CFR Parts 160 through 164, As Proposed: Modifications to the HIPAA Privacy, Security and Enforcement Rules under the Health Information Technology for Economic and Clinical Health Act

The Foundation for HealthSMART Consumers (The Foundation) supports modifications to the statutory amendments under the Health Information Technology for Economic and Clinical Health (HITECH) Act to strengthen the privacy and security protection of health information, and to improve the workability and effectiveness of the Health Insurance Portability and Accountability Act (HIPAA).

The Foundation believes, however, that any modifications to HITECH should consider patients' rights to receive health information and be provided access to resources that can help them manage their health care costs — two primary concerns as our nation seeks to transform and bend cost trends over time. The Foundation seeks to disseminate important information to health consumers, particularly information that enables the consumer to better manage his and her health responsibility and care accountability. It is essential to communicate information about health and care options that offer cost alternatives, represent new and improved condition management solutions, or introduce product/service enhancements that may be of value to the consumer.

Therefore, we support the continuation of the three HIPAA marketing exceptions for communications regarding treatment and/or health care options with the caveat that such exceptions are only valid if the covered entity does not receive direct financial remuneration for the communication. We believe it is essential that covered entities continue to deliver educational and informational communications which provide value to the consumer.

The Foundation also supports clarity regarding remuneration; to establish this as financial remuneration, or a payment made, in exchange for

making the communication itself, from or on behalf of the entity whose product is being described.

Further, The Foundation supports the language which identifies the appropriateness of charitable organizations, such as foundations, to fund a covered entity's mailing to patients as long as the payment is reasonable in amount. We support the work of charitable organizations which are dedicated to improving the health and care competency of consumers.

Marketing Exceptions and Scope

The Foundation agrees with the continuation of HIPAA marketing exceptions for those communications which (1) describe a health-related product or service (or payment for a product or service) that is provided by or included in a plan of benefits of the covered entity making the communication; (2) is made for the treatment of the individual; or (3) is made for case management or care coordination, or to direct or recommend alternative treatments, therapies, health care providers, or settings-of-care to the individual. We support the restriction of these exceptions to only those communications which meet these criteria and for which the covered entity does not receive direct financial payment. We feel it is important to allow covered entities to provide consumers with the information they need for smart health and care decision-making.

The Foundation will submit comment to HHS about the exception to marketing that concerns "a drug or biologic currently being prescribed, if the payment is reasonably related to the covered entity's cost of making the communication." We see value in allowing communications about "drugs that are related to the drug being currently prescribed." It is the responsibility of the covered entity to ensure consumer knowledge of treatment alternatives. In particular, we believe the consumer should be regularly educated on the availability of over-the-counter treatment alternatives for self-care conditions, since these

medications, once available by prescription only, have been approved by the FDA for direct consumer access due to the safety profile.

This is particularly important in therapeutic classes where both Rx and OTC options are available (e.g., pain, allergy, digestive health, etc.) and in classes or categories where current Rx medications may be switching to OTC status in coming years (e.g., migraine, cholesterol lowering, overactive bladder, etc.). Therefore, we support an allowance for communications about class and therapeutic category equivalents (i.e., generics, over-the-counter formulations, and behind-the-counter formulations) and new formulations, delivery devices and/or other innovation that benefits the consumer's self-care competency. Again, this is all important information for a HealthSMART Consumer.

In terms of reasonable costs, we believe the cost of printing, processing and mailing should be included in the definition of a reasonable cost.

Financial Remuneration Clarification

We support the definition that clarifies remuneration as strictly a financial payment in exchange for making a communication. We also support the deletion of any reference to "indirect remuneration," thus eliminating any confusion about the indirect value of a consumer offer or coupon to the covered entity.

We believe this modification protects health consumers' ability to receive offers that will help promote health and/or reduce costs for particular goods and services. Coupons and discounts for products and services are important to consumers and should be made available by covered entities for use at the consumer's choice.

Modification for Communications Funded by Charitable Organizations

As we interpret the modification for charitable organizations, an authorization would not be required if a charitable foundation funded the covered entity's mailing to patients about the availability of new treatments and/or treatment alternatives, and may include a coupon or extend an optional discount to the individual, as long as the covered entity would not be receiving remuneration by or on behalf of the entity

whose product or service was being described.

We are recommending a statement in the final regulations that clearly affirms that any communication funded by a charitable organization for the treatment or education of the individual, and which may or may not include a discount or coupon offer, be exempt as long as the covered entity is not receiving direct financial payment from the entity whose product or service is described. We will request that the term "local" be removed before charitable organization.

We support the modification mandating that communications from a charitable organization do not require individuals to be 'opted in' to receive the communication. This would pose unnecessary confusion for some consumers and result in additional paperwork for all parties involved. It also might prevent consumers from receiving important information about products and services or keep them from receiving cost-saving items that charitable organizations often distribute to health consumers and patients.

Conclusion

The Foundation for HealthSMART Consumers supports efforts to clarify health care policy in the interest of avoiding consumer confusion in its implementation. We believe this point of view supports the effort to protect consumers' privacy interests and protects consumers' rights to receive sound information and cost-saving materials regarding medical products and services without complicated processes that might impede the dissemination of that information.

The Fellows

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Dr. Michael A. Kaufman is a senior health care executive with extensive experience in both Commercial Insurance and Medicare. His core competencies are in the areas of business planning, regulatory compliance, reimbursement strategies and health care consumerism.

Joseph McGovern



Joseph McGovern is an accomplished pharmaceutical executive with extensive experience in strategic management of global health care businesses, including portfolio management, product launches, Rx-to-OTC switches, and acquiring new products through business development.

Jim Parker



Jim Parker is a senior health care executive with 20 years of experience leading organizations through mergers and acquisitions, driving market share, revenue growth, and building high-performing organizations.

About The Foundation

The Foundation for HealthSMART Consumers is a not-for-profit organization dedicated to activating health care consumers by informing them about their health responsibility and care accountability, with an emphasis in the realm of self-care. The Foundation believes consumers need to be better educated about the decisions they make to manage their own personal health and the health of other family members so that they can achieve wellness and avoid unnecessary health care costs. Consumers want to be active and need to be confident in their ability to create health. The Foundation also conducts research to educate consumers and its partners on policy, social, and economic trends that may impact the progression of smart health care consumers.

www.healthsmartconsumers.org

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