

HIPAA AND PATIENT COMMUNICATIONS: WHERE TO GO FROM HERE

A CPM WHITE PAPER

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PLEASE NOTE: The information presented in this paper is based on conversations with attorneys, research, congressional testimony and interpretation of the latest round of proposed changes to HIPAA's medical privacy regulations released by the Department of Health and Human Services on March 21, 2002.

SECTION 1:

EXECUTIVE SUMMARY

Here we go again. When it comes to HIPAA—the Health Insurance Portability and Accountability Act (HIPAA) of 1996—and medical privacy, it seems that nothing is final. Although the Bush administration stated that the medical privacy section was accepted in December 2000 and finalized on April 14, 2001, the U.S. Department of Health and Human Services (HHS), announced proposed changes on March 21, 2002. According to HHS Secretary Tommy Thompson, the changes were proposed to ensure strong privacy protections while correcting unintended consequences that threatened patients’ access to quality health care.

The good news is that the majority of patient communication and relationship efforts that health care providers do today are still allowable under the proposed HIPAA changes. The definition of “marketing” in the proposed changes does not include a description of services or products provided by a covered entity.

The proposed changes to the Privacy Rule are based on the more than 11,000 comments received last year and additional public input. After issuing the proposed changes, Secretary Thompson opened up another 30-day comment period through April 26, 2002. HHS will consider this input to the proposed changes before issuing a final (ahem) rule.

Naturally, health care providers, many of whom had begun HIPAA implementation in earnest to meet the scheduled April 14, 2003 compliance deadline (for most health care entities) have been scrambling to fully understand the proposed changes and where these fit into current HIPAA-related efforts.

We have to keep three things in mind. First, the proposed new rules are not FINAL, and may not go into effect as written. Second, HIPAA regulations and the proposed changes were written for a broad audience including

hospitals, physicians, health plans, device manufacturers and drug stores. Third, while the HIPAA regulations now cover thousands of pages, the medical Privacy Rule dealing with the use of Protected Health Information (PHI) for marketing is covered on just a few pages—14,789 to 14,793—in the Federal Register, available from the National Archives and Records Administration, WWW.NARA.GOV/

This paper summarizes the proposed changes to the Privacy Rule as they relate to marketing and attempts to clarify the modifications with specific examples.

SECTION 2:

WHERE WE STAND TODAY

The proposed new changes to HIPAA cut a broad path through the various sections under the medical privacy portion of the federal regulation. According to HHS Deputy Secretary Claude Allen, the previous marketing regulations satisfied no one because they were too complicated and ambiguous.

In releasing its suggested changes to the HIPAA Privacy Rule on March 21, HHS said in the Federal Register, “the Department proposes to modify the Privacy Rule to make the marketing provisions clearer and simpler.”

According to HHS, “Both industry and consumer groups argued that the marketing provisions were complicated and confusing. Covered entities expressed confusion over the Privacy Rule’s distinction between health care communications that are excepted from the definition of “marketing” versus those that are marketing but permitted subject to the special conditions in Section 164.514(e).”

For example, commenters wanted to know if and when disease management communications or refill reminders were considered “marketing” and as such would require the special disclosure and opt-out provisions specified. In addition, many organizations wanted to know how to characterize various health care operations activities such as general health-related educational and wellness promotional activities.

Also, the issue of third party reimbursement for communications remains controversial, and seems to be the most likely focus of the debate to accept the proposed changes.

THE BOTTOM LINE:

What is the bottom line? We believe that there are two key issues that every health care provider or entity that communicates with its patients must examine:

1. The definition of marketing and what kinds of communications are allowed without authorization. It seems that this proposed definition of “marketing” has hospitals and health care providers worried they can no longer use the information in their patient records, classified as PHI, to inform their patients about health care services or programs that may directly impact their health. However, it appears that most of the types of communications covered entities conduct with their patients are allowable under the current marketing exclusions. Read on for more specific examples.
2. The maintenance and improvement of health is one of the key tenets of a relationship between caregiver and patient. Within this trust relationship, providers should be able to send information to their patients about recommended screenings and immunizations, new procedures, treatments and health-related seminars. The purpose is to improve wellness, disease management, quality of life and longevity. If we as U.S. citizens cannot look to our hospitals and physicians to provide this information, to whom do we turn?

Deputy HHS Secretary Claude Allen corroborated this point of view when he testified before the U.S. Senate Committee on Health Education, Labor and Pensions Oversight Hearing on Medical Privacy on April 16, 2002 that what consumers need most is unimpeded access to quality care. When hospitals, physicians and other care providers offer information to their patients to help maintain their health, they further and advance this goal. In fact, Allen said that patients expect their physicians, hospitals or other direct treatment providers to share medical information for core activities that are essential to the provision of health care.

Allen also stated, “The proposal prohibits explicitly using or disclosing a patient’s information for marketing without the individual’s express authorization. At the same time, the proposal would permit doctors, hospitals, pharmacists and health plans to communicate freely with patients about individual treatment options and other health-related information, including disease management, case management and care coordination.

“We did not want to interfere with valuable communication between patients and doctors over new treatments they feel their patients need to know about. Nor should we interfere with programs that provide important information to those who suffer from chronic diseases such as diabetes. Nor should we stop pharmacists from sending refill reminders to those customers who are on maintenance medications such as blood pressure or cholesterol-lowering drugs.”

WHAT THE PROPOSED CHANGES ALLOW:

HHS confirms in the Federal Register that it does not want the marketing provisions to interfere with the relationship and dialogue between health care providers and individuals, and it appears they do not.

The proposed revised definition of “marketing” is “to make a communication about a product or service to encourage recipients of the communication to purchase or use the product or service.”

This definition **excludes** communications to an individual that:

1. Describe the entities participating in a health care provider network or health plan network, products or services provided by the covered entity, and plan benefits.
2. Pertain to an individual’s treatment.
3. Provide information necessary for case management and care coordination; recommendations for alternative treatments, therapies, health care providers or care settings.

4. Are common health care communications, such as disease management, wellness programs, prescription refill reminders and appointment notifications that individuals expect to receive as part of their care. HHS has clearly stated in the Federal Register it “believes that these types of communications are allowed under the exceptions to the definition of “marketing” in the Privacy Rule and therefore would continue to be allowed under the proposed modification.”

In comments to HHS, the Health Privacy Project at the Institute for Health Care Research and Policy at Georgetown University identified three types of communications that encourage patients to purchase or use products and services. Here’s how they fall under the proposed rule:

1. Communications that are clearly treatment oriented and for which the provider **does not** receive remuneration from a third party for making the communication. *Under the proposed Privacy Rule changes, these types of messages do not require prior authorization because they are treatment related.*
2. Communications that are related to health but are at least partially financially motivated, such as a pharmacy being paid by a drug company to encourage patients to switch to the drug company’s brand. *Even though the entity receives a financial benefit, HHS found that the Privacy Rule was confusing and therefore stated in the proposed changes that previous conditions for these types of communications are no longer necessary.*
3. Communications that are clearly marketing because they do not relate to health (such as vacation advertisements). *According to the proposed changes, prior authorization is necessary and the authorization form must state how the covered entity is using individuals’ PHI for these activities as well as an expiration date.*

One of the reasons HIPAA was written in 1996 was to allow patients to control their health information beyond the health care arena. The proposed rules as written in the Federal Register continue to uphold the “basic prohibition in the Privacy Rule against covered entities selling lists of

patients or enrollees to third parties, or from disclosing protected health information to a third party for the independent marketing activities of a third party, without the express authorization of the individual.”

As is reasonable, the proposed changes also still prohibit the sharing of PHI to employers or insurers for employment and insurance coverage decisions without the express and prior authorization of the individual.

SECTION 3:

EXAMPLES OF WHAT IS ALLOWED

Here are some specific examples of marketing communications between hospitals, physicians and other providers and their patients *that appear to be* allowed under the proposed changes to HIPAA's Privacy Rule. Remember, these are proposed changes and may not go into effect.

Keep in mind that these examples presume that PHI is being used to select a list of individuals who will receive the communication. **Any communication that does not use PHI in the list select is not subject to HIPAA.**

- 1. Example:** A hospital wants to send a notice to its patients who have been diagnosed with hypertension by informing them of the hospital's heart screening services and offering a coupon for a discounted screening.

Reason it is allowed: In HHS's comments in the Federal Register, the agency identifies certain communications, including "disease management" that is excluded under the definition of "marketing" under the proposed modification. In this example, the hospital also is informing the recipients of a service it provides, also excluded from the definition of "marketing."

- 2. Example:** A hospital wants to offer a \$39 baseline EKG to all current patients over 40 who have not had an EKG in the past two years, and who have not previously been treated for heart disease.

Reason it is allowed: This communication would be considered a "wellness" communication because it is designed to keep recipients well by offering a service that could identify problems and therefore indicate early

intervention if needed. Therefore, it is excluded from the definition of “marketing.”

- 3. Example:** A hospital wants to send information on the latest treatment, support groups and other resources it provides for individuals with diabetes, to individuals who have the disease.

Reason it is allowed: In HHS’s comments in the Federal Register, the agency identifies certain communications, including “disease management” as communications that should be permitted under the Privacy Rule. We believe this would fall under that category. Providing this type of information gives patients with diabetes more information that could help them better manage and live with their disease.

- 4. Example:** A physician aims to keep her patients on a regular immunization and screening schedule as recommended by leading health care authorities. She sends birthday letters to her patients, reminding them of the check-up or other tests required.

Reason it is allowed: In HHS Deputy Secretary Claude Allen’s testimony before the Senate Committee on Health, Education, Labor and Pensions, he indicated that when a covered entity wants to ensure its patients have access to the “latest and greatest health information” providing that information to patients is not considered “marketing” under the regulations.

- 5. Example:** A hospital wants to notify all of its patients that the hospital’s radiology department has acquired a PET scanner.

Reason it is allowed: Under the proposed rule, a covered entity is not marketing when it describes its own services.

- 6. Example:** A hospital wants to notify expectant mothers who registered with the hospital, about an infant care and CPR class.

Reason it is allowed: This communication would be allowed under either the “preventive care” or “wellness” categories acknowledged by HHS as falling outside of

“marketing.” It is also an example of a hospital describing its services, an activity that is also exempt from the marketing definition.

- 7. Example:** A hospital wants to notify a certain segment of cancer patients of a new clinical treatment trial that may be of benefit to them.

Reason it is allowed: We believe this also would fall under “care coordination” or “alternative health” and therefore would be allowed. The hospital’s objective is to provide a service that could ultimately improve a patient’s health.

- 8. Example:** A hospital wants to conduct ongoing campaigns to former patients about new physicians, screenings, treatments, facilities or educational programs.

Reason it is allowed: These types of communications fall under “health promotion, preventive care and wellness programs” that have been exempted from the definition of “marketing.”

These are just some of the examples of communications that hospitals or physicians might provide to their patients and other community members that involve PHI and therefore are subject to HIPAA.

Although the proposed Privacy Rule changes no longer require a health care entity to tell why an individual has received a certain communication, it’s still good business practice. Answer the two most important questions for recipients: “Why I am receiving this?” and “What does it mean to me?”

If the hospital is promoting an EKG screening, the message might state what age groups are most likely to have a high risk of heart attack, and how heart disease is treatable when it is discovered early. Therefore, this screening would be beneficial.....etc. Simple direct mail strategy.

DATA USES THAT ARE NOT AFFECTED BY HIPAA:

Any good patient/customer communication program is based on a comprehensive database. The database can be segmented for various uses and list selects for specific messages. While the database includes PHI, which can be used as described in the above examples, there are other sources within the database that do not use PHI and therefore are not subject to HIPAA.

These include:

- Purchased lists that include only geodemographic information. This information doesn't include PHI, but it is useful for New Movers programs, designed to introduce the organization or physician to area newcomers; and for general health newsletters that cover a variety of health topics.
- Aggregate data with a selection process designed to mitigate risk and comply with legislation that separates medical information from names and addresses. Data can be aggregated from "designated record" sets that include, at a minimum, the medical and billing record about individuals maintained by or for the provider. Because selections are generally viewed in the aggregate, not having individually identifiable information does not diminish the database's analytical use. The selection program can generate a set of "links" to the selected names and addresses, which can be used by a separate application that can "see" the names without any medical information. This eliminates the simultaneous viewing of medical information and the identifier.

For example, many diseases are tied to gender and age. Marketing programs to these audiences based on those facts alone—say about breast cancer risk and screening to women, and about prostate cancer risk and screening to men over 40—can be accomplished without the use of PHI. (Age is considered an identifier under HIPAA if the person is over age 89).

- The use of a market/consumer segmentation system, with your data such as the Consumer Healthcare

Utilization Index (CHUI)TM that can score individuals' propensity to need services from the major diagnostic categories (MDC), ICD-9 code groups, and diagnostic related groups (DRG), thus providing more targeted lists. With predictive segmentation, all list selections are based on geography and demography rather than PHI.

SECTION 4:

CONCLUSION

It appears the only constant when it comes to HIPAA and the medical Privacy Rule is change. It's unclear at this point whether or not the proposed changes will stand and whether or not they will be further modified based on the comment period that ended April 26, 2002. We will keep you posted.

For now, the biggest concern health care providers have concerning HIPAA and marketing is how the regulations will affect their ability to communicate with patients about programs and services that could improve their health, and in what situations the use of PHI is permissible to do so. As stated in the Executive Summary and illustrated throughout this paper, **the majority of communications programs health care entities are conducting today are NOT prohibited by the proposed changes to the HIPAA Privacy Rule and do not require prior authorization.**

The maintenance and improvement of health is one of the key tenets of a relationship between caregiver and patient. Within this trust relationship, we believe (as do members of HHS) that providers should be able to send information to their patients about procedures, services, screenings and seminars that could ultimately lead to better quality of life and improved longevity. If we as U.S. citizens cannot look to our hospitals and physicians for this information, then to whom do we turn?

Our hope is that HHS will clarify the proposed modifications to the medical Privacy Rule very soon, and once and for all, so that health care providers can concentrate on their main priority—the health and well-being of their patients.

SECTION 5

ABOUT CPM

Customer Potential Management (CPM) Marketing Group is a pioneer in the development of Customer Relationship Management (CRM) solutions, including information warehousing technology, delivery systems, and portals. Since its inception in 1981, CPM has achieved international recognition for solving health care, financial and telecommunications business problems with this technology and today focuses solely on health care.

CPM's CRM integrated solutions allow businesses to maximize their customer relationships through market analysis, strategic planning and targeted personal communications. The foundation is an accessible, customer-centric web warehouse that includes comprehensive individual and household data. CPM's suite of software tools provide easy and secure access to the data for individual snapshots of customers and prospects on a "segment of one" basis.

Our intelligent CRM pieces fit together seamlessly into an application framework that produces a single, top-level business strategy.

For more information contact us:

**Customer Potential Management (CPM)
Marketing Group**

Intelligent Healthcare Marketing

2500 N. Main Street, Suite 2

East Peoria, IL 61611

800-332-2631/309-698-1037

FAX 309-698-1039

<http://www.cpm.com>

email: sales@cpm.com