HHS ISSUES FINAL MODIFICATIONS TO THE HIPAA PRIVACY RULE

After years of sometimes heated controversy and major attention from two Administrations, Congress and the health care and consumer communities, the Department of Health and Human Services (HHS) has finalized regulations that govern the treatment of confidential patient information by the health care industry. On August 9, 2002, Secretary of HHS, Tommy G. Thompson announced final amendments to the Privacy Rule (Amended Privacy Rule) mandated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which governs the confidentiality of health information. Consumers and health care providers alike have been anxiously awaiting the final amendments since the March 21, 2002 Notice of Proposed Rule Making (NPRM) that proposed a number of changes to the original privacy regulations issued in December 2000 by HHS under HIPAA (Privacy Rule or Rule). Most health care providers are covered entities under the Rule and will be required to comply with the Rule by April 14, 2003. The amendments, published on August 14, 2002, do not change that compliance date.

In announcing the amendments, Secretary Thompson stated,

Patients now will have a strong foundation of federal protections for the personal medical information that they share with their doctors, hospitals and others who provide their care and pay for it. The rule protects the confidentiality of Americans’ medical records without creating new barriers to receiving quality health care. It strikes a common sense balance by providing consumers with personal privacy protections and access to high quality care.

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The Amended Privacy Rule represents a significant change from the Rule as originally introduced by the Clinton Administration in December 2000. The Amended Privacy Rule tightens loopholes, corrects serious unintended consequences, clarifies important definitions and restrictions regarding marketing of personal health information and significantly eases administrative burdens for health care providers.

More specifically, the amendments change the Privacy Rule in the following areas:

1. Consent and notice;
2. Disclosures of protected health information (PHI) for the treatment, payment and health care operations of another entity;
3. Marketing;
4. The minimum necessary requirement;
5. Incidental uses and disclosures of PHI;
6. Business associates;
7. Parents and minors;
8. Uses and disclosures of PHI for which authorizations are required;
9. Uses and disclosures of PHI for research purposes; and
10. Minor modifications to other sections of the Rule.

This Advisory highlights and explains the significant modifications that were made to the Privacy Rule, describes the impacts on affected companies and suggests a series of action items designed to help companies meet the April 14, 2003 compliance deadline.

**MAJOR CHANGES**

**Consent v. Acknowledgment**

One of the most important and controversial changes proposed in the NPRM was the removal of the requirement that a direct treatment provider obtain a patient’s consent to use PHI for treatment, payment and health care operations (TPO). Under the Privacy Rule, a direct treatment provider was required to obtain a patient’s written consent to use or disclose his or her PHI prior to rendering treatment, seeking payment or undertaking health care operations. The Amended Privacy Rule removes this obligation, making consents optional. Instead of requiring written consents, covered entities must provide patients with notice of (i) the patient’s privacy rights, and (ii) the privacy practices of the covered entity. It must then obtain a written acknowledgment of receipt of the notice.

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of patient rights and privacy practices (Privacy Notice). Direct treatment providers are required to make a good faith attempt to obtain this acknowledgment, in writing, at the time of first delivering services to the patient. In emergency situations, however, the Privacy Notice need not be provided until it is reasonably practicable to do so. All efforts to provide the Privacy Notice and to obtain an acknowledgment must be documented. Providers also must document those instances when an acknowledgment was not obtained. While fairly rigid in requiring documentation of efforts to provide the Privacy Notice and obtain an acknowledgment, the Amended Privacy Rule remains flexible in the form the acknowledgment can take. Although the acknowledgment must be in writing, no specific form is required. Therefore, the health care provider could have the patient sign a tear-off sheet, initial the front page of the Privacy Notice or even provide an electronic acknowledgment.

HHS chose to replace the consent requirement with the acknowledgment of Privacy Notice because of the outcry from the health care industry that the consent requirement would significantly interfere with operations. By removing the consent requirement, a number of operational burdens also are removed. For example, a covered entity is no longer required to maintain a system to track whether a patient has amended, restricted or revoked his or her consent. Covered entities will need only to implement a system to document the provider’s good faith efforts to obtain an acknowledgment of its Privacy Notice. It is important to note that covered entities still are permitted to obtain consent for uses and disclosures of PHI. However, if they do so, they must continue to abide by the consent provisions, which contain numerous administrative requirements.

**Notice of Privacy Practices**

As noted, the Amended Privacy Rule requires a direct treatment provider to make a good faith effort to obtain a patient’s written acknowledgment of receipt of the provider’s Privacy Notice. The purpose of the requirement is to promote the individual’s understanding of the privacy practices of the provider. The Amended Privacy Rule does not change the original notice requirements. However, HHS does suggest in the Preamble to the Amended Privacy Rule that the use of a layered Privacy Notice is permissible. This new interpretation allows a summary of the Privacy Notice to be placed at the beginning of a more detailed Privacy Notice containing all the required Privacy Notice elements.

Through the Privacy Notice and acknowledgment requirements, HHS hopes to provide an opportunity for the patient to learn of and ask questions about his or her privacy

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7 45 C.F.R. §§ 164.502, 164.506, and 164.520.
8 45 C.F.R. § 164.520(e).
9 45 C.F.R. § 164.506.
10 45 C.F.R. § 164.520(e).
The allowance of a summary in addition to the actual notice should serve to ease confusion for patients receiving a large packet of information at one time.

**Disclosures of PHI to Another Entity**

The Privacy Rule permitted disclosures of PHI to another entity, within the scope of the patient’s general consent, for treatment purposes. The Privacy Rule did not allow disclosure of PHI for the payment and health care operations purposes of another entity. Disclosures of PHI for any purpose other than treatment required a patient authorization. This requirement overlooked the realities of the health care industry, including, for example, the situation when a provider such as an ambulance company, needs information from a hospital to submit its own claims for reimbursement, or when a hospital needs records from another hospital for peer review or physician credentialing purposes.

The Amended Privacy Rule corrects this by providing covered entities with greater flexibility in using or disclosing PHI for payment and health care operations without requiring patient authorization. For payment purposes, the Amended Privacy Rule permits a covered entity to disclose PHI to any health care provider (whether or not it is a covered entity) to assist the provider in obtaining payment for its services.\(^{12}\) This alleviates the problem presented in the above example involving the ambulance company that would have required a patient authorization before the hospital could release information to the ambulance company. For health care operations, the Amended Privacy Rule allows a covered entity to disclose PHI to another covered entity (but not to another provider that is not a covered entity) for limited operations purposes, including peer review and quality assurance. By eliminating the consent requirement, as well as authorization requirements for payment or health care operation purposes, the Amended Privacy Rule greatly eases administrative burdens for health care providers.\(^{13}\)

The Amended Privacy Rule also clarifies certain questions concerning disclosures of PHI by covered entities participating in an “organized health care arrangement” (OHCA). The Amended Privacy Rule explicitly states that covered entities participating in an OHCA, such as a hospital and the doctors on its medical staff or the members of an IPA, can exchange PHI for the health care operations of the OHCA regardless of whether the covered entity making the disclosure has a relationship with the individual. This clarification should assist those entities making up an OHCA – especially in the areas of peer review, credentialing and quality management.\(^{14}\)

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\(^{12}\) 45 C.F.R. § 164.506(c)(3).

\(^{13}\) 45 C.F.R. § 164.506(c)(4).

\(^{14}\) 45 C.F.R. § 164.506(c)(5).
Marketing

To close loopholes in the marketing provisions of the Privacy Rule, HHS further clarified what constitutes marketing uses of PHI that may only be done with patient authorization and it altered the definition of marketing. The Amended Privacy Rule carries forward the requirement that a covered entity must obtain an individual’s prior written authorization to use PHI for marketing purposes. However, it narrows the exceptions to this requirement to include only: (1) communications in face-to-face encounters, and (2) communications involving promotional gifts of nominal value.\(^\text{15}\) The Amended Privacy Rule also clarifies the definition of marketing by stating that an intent to market something is irrelevant. What matters is whether the communication about a product or service, on its face, encourages the recipient of the communication to purchase or use that product or service. Additionally, the definition of marketing now includes:

An arrangement between a covered entity and any other entity [including business associates] whereby the covered entity discloses protected health information to the other entity, in exchange for direct or indirect remuneration, for the other entity or its affiliate to make a communication about its own product or service that encourages recipients of the communication to purchase or use that product or service.\(^\text{16}\)

Exempted from the definition are communications to a patient concerning:

1. The participating providers and health plans in a network, the services offered by a provider, or the benefits covered by a health plan;
2. The individual’s treatment; or
3. Case management or care conditions for that individual, or directions or recommendations for alternative treatments, therapies, health care providers or settings of care to that individual.\(^\text{17}\)

HHS clarifies that a covered entity is prohibited from selling lists of patients or enrollees to third parties and from disclosing PHI to a third person for marketing activities of the third party, without each patient’s authorization. Furthermore, the Amended Privacy Rule clarifies that communications between covered entities and patients about treatment options or the covered entity’s own health-related products and services or benefits is not considered marketing. For example, health care plans can inform patients about additional health plan coverage and value-added items and services, such as discounts on prescription drugs or eyeglasses. Similarly, doctors writing prescriptions or referring patients to specialists are deemed to be engaging in a treatment communication, which is not considered marketing.

\(^{15}\) 45 C.F.R. §§ 164.501 and 164.508(a)(3).

\(^{16}\) 45 C.F.R. § 164.501.

\(^{17}\) 45 C.F.R. § 164.508(a)(3).
**Minimum Necessary Standard**

The Privacy Rule generally requires a covered entity to make reasonable efforts to use or disclose only the “minimum necessary” amount of PHI to accomplish its intended purpose.\(^{18}\) Members of the health care community stressed that the standard is unnecessary when an authorization has been obtained since authorizations are required to specify what information will be used. Based on this rationale, the Amended Privacy Rule exempts from the application of the minimum necessary standard any uses or disclosures for which a covered entity has received an authorization.\(^{19}\)

**Incidental Uses and Disclosures**

The July 2001 Guidance on the Privacy Rule issued by the Office for Civil Rights of HHS indicated that most incidental uses and disclosures of PHI do not violate the Privacy Rule.\(^{20}\) Still, providers and consumers alike desired greater clarification. Therefore, in response to the overwhelming support of commenters, HHS adopted a new provision to the HIPAA Privacy Rule. The Amended Privacy Rule explicitly permits certain incidental uses and disclosures that occur as by-products of a use or disclosure otherwise permitted under the Privacy Rule. According to the Amended Privacy Rule, permitted incidental uses and disclosures of PHI include such things as waiting room sign-in sheets, patient charts located at the bedside, doctors talking to patients in semi-private rooms, and hospital personnel conferring at a nurses’ station. None of these activities violate the Privacy Rule, provided that the covered entity has employed reasonable safeguards and implemented the minimum necessary standard where applicable.\(^{21}\) Although this new provision alleviates concerns about certain types of unavoidable incidental disclosures of PHI, it imposes a burden on providers to consider when and where such disclosures may occur and to take reasonable measures to avoid or minimize those disclosures.\(^{22}\)

**Business Associates**

The Privacy Rule permits a covered entity to disclose PHI to a business associate as long as the covered entity and business associate enter into a contract that contains

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19 45 C.F.R. §§ 164.502(b)(2)(iii) and 164.514(d).


21 45 C.F.R. §§ 164.528(a)(iii) and 164.530(c)(2)(ii).

22 Examples of “reasonable safeguards” given by HHS are curtains in patient treatment areas, cubicles and dividers in areas where patient-staff communications often occur, and asking customers at a pharmacy to stand back when a patient is being counseled.
specific safeguards. A business associate is an entity that performs a function on behalf of, or provides a service to, the covered entity that involves the creation, use or disclosure of PHI. The business associate requirements led to considerable concern in the health care industry that there is not enough time to implement the required agreements. In response, the Amended Privacy Rule allows covered entities to continue to operate under existing contracts with business associates for up to one year beyond the April 14, 2003 compliance date. Covered entities are permitted to utilize this extension if they have existing contracts or other written arrangements with business associates, and the contracts are not renewed or modified between October 15, 2002 and April 14, 2003.

The Amended Privacy Rule contains a set of model business associate provisions that are revised somewhat from the version contained in the NPRM. The modified Model Agreement contains new language providing that a business associate may use or disclose PHI on behalf of, or to provide services to, a covered entity if such use or disclosure of PHI would not violate the Privacy Rule if done by that covered entity itself or the minimum necessary policies and procedures of that covered entity. Although this new language appears innocuous, in fact it will impose a significant burden on the business associate to keep current with and manage its workforce to adhere to the necessarily complex and detailed minimum necessary policies and procedures of the covered entity.

**Parents as Personal Representatives of Unemancipated Minors**

Under the original Privacy Rule, parents, as the personal representatives of their minor children, were given broad rights with respect to their children’s PHI. Generally, parents have the ability to access and control the PHI of their children. Exceptions are provided where state or other applicable laws permit minor children to obtain care without parental consent or special circumstances exist (e.g., child abuse). The Amended Privacy Rule clarifies the extent to which parents have access to PHI of minors. Specifically, the Rule is modified in three situations:

1. Where state or other law expressly identifies the parent’s or child’s rights;
2. Where state or other applicable law is silent and the parent is the personal representative of the minor; and
3. Where state or other applicable law is silent and the parent is not the personal representative of the child.

In the first situation, the Amended Privacy Rule defers to state law. In the second situation, the Amended Privacy Rule defers to the wishes of the child’s personal rep-

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23 45 C.F.R. § 164.532(d) and (e).

24 Id.

resentative. State law determines when the parent is the personal representative of the child. In the third situation, health care providers are permitted to use discretion to provide or deny a parent access to the minor’s PHI so long as that decision is consistent with state or other applicable law. By specifically stating its deference to state law, the Amended Privacy Rule is intended to allow providers to continue current practices regarding parents’ authority with respect to the PHI of their minor children. However, providers should assess whether their current practices regarding a minor’s health information are consistent with state law.

**Uses and Disclosures for which Authorization Is Required**

The original Privacy Rule required patient authorizations for most uses and disclosures of PHI for purposes other than TPO. The Amended Privacy Rule simplifies the authorization requirements by adopting a single set of requirements. So while the Amended Privacy Rule still requires that written authorization be obtained in advance of each non-TPO use or disclosure, it eliminates the need for different types of authorizations for different purposes. For researchers, an authorization can be combined with any other legal permission related to the research, such as an informed consent document.

As a general rule, a covered entity cannot condition treatment on receipt of an authorization. However, the Privacy Rule contains an exception for research-related treatment. The Amended Privacy Rule also adds an exception to allow a health plan to condition enrollment on a prospective enrollee’s authorization to use or disclose PHI for the plan’s underwriting activities.

**Uses and Disclosures for Research Purposes**

Almost from the outset, providers and researchers alike criticized the Privacy Rule and expressed concern that the numerous administrative requirements would hamper research. HHS recognized and addressed these concerns by allowing researchers to use a single form that combines informed consent with a privacy authorization. The Amended Privacy Rule also replaces many of the original requirements, including those applicable to waivers of authorization with requirements that more closely mirror the “Common Rule” that governs federally-funded research. The Amended Privacy Rule

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26 Included in the necessary core elements of a valid authorization are: a description of the information to be used or disclosed; the identification of the persons or class of persons authorized to use or disclose PHI; the identification of the persons or class of persons to whom the covered entity is authorized to make the disclosure; a description of each purpose of the use or disclosure; an expiration date or an event that triggers expiration of the authorization; the individual’s signature and date; if signed by a patient’s personal representative, a description of the representative’s authority to act for the individual; a statement ensuring an individual’s ability to revoke the authorization along with instructions for accomplishing the revocation; a statement that treatment, payment or eligibility for benefits may not be conditioned on obtaining the authorization; and a general statement regarding potential re-disclosures that may occur.

27 45 C.F.R. § 164.532(c).

28 45 C.F.R. §§ 164.508(c), 164.512(i) and 164.532(c).
also allows the expiration date to be an actual date, or a statement such as “end of the research study” or “no expiration date.”

**Limited Data Sets**

Many state medical and hospital associations, as well as researchers, collect and aggregate provider information in order to study patterns of disease or illness and to determine community needs for health facilities and services. HHS recognized the impediments imposed on research under the extensive de-identification requirements in the original Privacy Rule. In response, HHS added a new concept to the Privacy Rule – the “Limited Data Set” (LDS). According to the Amended Privacy Rule, a covered entity can use or disclose LDS information if the covered entity enters into a data use agreement with the LDS recipient. This information may only be used or disclosed for research, public health or health care operations purposes. The covered entity can use the PHI itself to create a LDS, or disclose the PHI to a business associate to create its own LDS, regardless of whether the covered entity is going to use the LDS.

**OTHER PROPOSALS**

**Health Care Operations: Changes of Legal Ownership**

The Amended Privacy Rule provides that the definition of health care operations includes the sale, transfer, merger or consolidation of a covered entity with another entity that is or will become a covered entity upon completion of the transaction, and any related due diligence activities. Therefore, any transfer of records, including patient records, that contain PHI during due diligence in a merger or acquisition also qualifies as a “health care operation” and is permissible without an authorization.

**Protected Health Information: Exclusion for Employment Records**

The Amended Privacy Rule excludes from PHI a covered entity’s own employment records. However, HHS chose not to define “employment record.” Instead, HHS recommends that a covered entity adopt a functional test that asks the covered entity

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29 Id.

30 LDS is defined as PHI that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual: (i) names; (ii) postal address information, other than town or city, state, and zip code; (iii) telephone numbers; (iv) fax numbers; (v) e-mail addresses; (vi) Social Security numbers; (vii) medical record numbers; (viii) health plan beneficiary numbers; (ix) account numbers; (x) certificate/license numbers; (xi) vehicle identifiers and serial numbers; (xii) device identifiers and serial numbers; (xiii) URL address; (xiv) IP addresses; (xv) biometric identifiers including finger and voice prints; and (xvi) photographic images. It is important to note, the catchall “and any other unique identifying number, characteristic or code” is not a part of this definition, nor are dates, cities, states and zip codes.

31 45 C.F.R. § 164.514(e).

32 Id.

33 45 C.F.R. § 164.501.
to distinguish its role as an employer from its role as a health care provider.\textsuperscript{34} For example, blood screening test results are PHI when a provider administers the test to an employee, but will not be PHI when, pursuant to the employee’s authorization, those test results are disclosed to the provider acting as an employer for placement in the employee’s employment record.

\textit{Hybrid Entities}

Under the original Rule, a hybrid entity was permitted to define and designate those parts of the entity engaged in covered functions as one or more health care component(s) if its health care activities were not its primary business activities. The Amended Privacy Rule permits any entity that performs covered and non-covered functions to elect hybrid entity treatment and provides that entity with additional discretion in designating its health care components.\textsuperscript{35} However, if an entity designates health care components and thereby elects treatment as a hybrid entity, it must then designate any component that would meet the definition of “covered entity,” if it were separately incorporated, as a health care component.

\textit{Group Health Plan Disclosures}

The Amended Privacy Rule allows a group health plan, a health insurance issuer or HMO acting for a group health plan to disclose to a plan sponsor (such as an employer) information on whether an individual is enrolled in or has disenrolled from a plan offered by the sponsor without amending the plan documents.

\textit{Accounting of Disclosures of Protected Health Information}

The Amended Privacy Rule exempts from the accounting requirements, disclosures made pursuant to an authorization. The change was based on the idea that the authorization process itself protects individual privacy by assuring that the individual’s permission is given both knowingly and voluntarily. The Amended Privacy Rule also exempts from the accounting requirements incidental disclosures and disclosures that are made in connection with a Limited Data Set. Finally, the Amended Privacy Rule provides a simplified alternative approach for accounting for multiple research disclosures that includes providing a description of the research for which an individual’s PHI may have been disclosed and providing contact information.\textsuperscript{36}

\textit{Uses and Disclosures Regarding FDA-Regulated Products and Activities}

The Amended Privacy Rule clarifies that covered entities are permitted to continue to disclose to non-government entities subject to FDA jurisdiction information about

\textsuperscript{34} 45 C.F.R. § 164.501.

\textsuperscript{35} 45 C.F.R. § 164.504.

\textsuperscript{36} 45 C.F.R. § 164.528(b)(4).
quality, safety and effectiveness of FDA-regulated products and activities – such as reporting adverse events related to prescription drugs.\(^{37}\)

**OBSERVATIONS AND COMMENTS**

The majority of the changes in the Amended Privacy Rule serve to tighten loopholes or correct unintended consequences created in the original Rule and to reflect the realities of the daily operations of health care entities. The changes, by and large, are based on common sense and protect the privacy interests of the patient while attempting to make the provisions more workable for health care businesses. As with the initial version of the Privacy Rule, the Amended Privacy Rule contains requirements that are already part of the practices of many health care providers.

The Privacy Rule now has been finalized and many questions and areas of confusion have been clarified. While far from perfect, a few burdens have been lifted. Since the government cannot modify the Privacy Rule again for at least 12 months, the requirements for implementation of the Privacy Rule are now fixed until after the April 14, 2003 compliance date. Therefore, the way should be clear for providers to take the necessary steps to ensure their compliance with HIPAA privacy requirements by the rapidly approaching compliance date – less than eight months away.

**ACTION ITEMS**

*Assemble Privacy Team and Learn the HIPAA Rules*

To begin the process of meeting the April 14, 2003 deadline for complying with the Privacy Rule, covered entities should assemble an internal HIPAA Privacy Team, appoint a Privacy Officer and create a compliance agenda. Members of the Privacy Team should include delegates from a variety of departments including human resources and information technology. Team members should be educated on the Privacy Rule, a privacy budget should be established, and an internal timeline and meeting schedule should be set. Because the Amended Privacy Rule is now the final Privacy Rule, it is important to incorporate all of the recent changes into the covered entity’s compliance efforts.

*Evaluate PHI Uses and Disclosures and Implement HIPAA Safeguards*

The Privacy Team should map and catalog the covered entity’s uses and disclosures of PHI. This analysis will help determine who has access to PHI and what safeguards must be constructed to ensure Privacy Rule compliance.

*Assess Information Security*

The proposed HIPAA Security Regulations are not yet finalized. However, the Privacy Rule requires covered entities to employ reasonable safeguards to protect the security

\(^{37}\) 45 C.F.R. § 164.512(b)(iii).
of PHI maintained or transmitted by the covered entity. Therefore, covered entities must assess their current levels of information security to determine that reasonable safeguards are in place.

**Assess Business Associate Relationships**

Covered entities must review their third-party relationships to determine if the third parties are their business associates. If the third party receives PHI in the course of performing an activity or function on behalf of the covered entity; or the third party performs one of a number of activities enumerated in the Privacy Rule and such activities necessitate the release of PHI to the third party, under the Privacy Rule, these entities are considered business associates. Covered entities must develop business associate agreements with their business associates and must ensure that the agreements comply with the Privacy Rule.

**Develop and Implement Required Policies and Procedures**

Covered entities must develop detailed policies and procedures to address the Privacy Rule requirements governing the uses and disclosures of PHI.

**Educate Your Workforce**

The Privacy Rule requires each covered entity to train all members of its workforce on the Privacy Rule. A covered entity’s workforce includes employees, volunteers, trainees and any other person whose conduct, in the performance of work for the covered entity, is in the direct control of the covered entity, whether or not they are paid by the covered entity.

**File for an Extension by October 15, 2002 for HIPAA Electronic Data Interchange (EDI) Requirements**

In addition to the Privacy Rule and Security Regulation requirements discussed above, HIPAA Transaction Standards requirements require covered entities to utilize specified transaction codes when conducting certain health care transactions (e.g., filing health claims). The compliance date for the EDI requirements is October 16, 2002. A covered entity can file for an extension by submitting a compliance plan with the Centers for Medicare & Medicaid Services (CMS). The extension should be filed with CMS no later than October 15, 2002. Covered entities that file for an extension by the October 15 deadline will be granted a one-year extension to comply with the Transaction Standards rule. The compliance form can be obtained and submitted through the CMS Web site, which can be accessed at [www.cms.hhs.gov/hipaa](http://www.cms.hhs.gov/hipaa).

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