Final Modifications to HIPAA's Privacy Rule

On August 14, 2002, the U.S. Department of Health and Human Services (“HHS”) published modifications to the privacy regulations under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”). These modifications were proposed on March 27, 2002, and received 11,000 public comments prior to final publication last month. The final modifications are, with a few exceptions, consistent with the proposed modifications.

The following is a summary of the modifications explaining the relevant provision of the HIPAA privacy rule as published on December 28, 2000 (the “Prior Rule”), the modification thereto (the “Amended Rule”), and a brief discussion of the impact of the modification. This commentary does not purport to fully summarize the privacy regulations under HIPAA. For an in-depth discussion of the privacy rules, please refer to our March 2001 commentary, which is available at www.jonesday.com.

Compliance with the HIPAA privacy rules, as amended, is required by April 14, 2003. It is not anticipated that HHS will further amend the privacy rules prior to that date as it is only authorized to modify the rules not more frequently than once every 12 months. It should be noted that guidance previously published by HHS on the Office for Civil Rights Web site has been removed. HHS has indicated it will post guidance that is consistent with the Amended Rule, but has not yet indicated a date for such posting.

Consents and Acknowledgements
(45 C.F.R. §§ 164.506 and 164.520)

Prior Rule. Under the Prior Rule, providers in a direct treatment relationship with an individual were required to obtain the individual’s signed, written consent before using or disclosing the individual’s protected health information (“PHI”) for payment, treatment, or health care operations. The requirement was subject to limited exceptions, and in most cases the provider could condition treatment on receipt of consent. After consent was obtained, the provider could use or disclose PHI for purposes of the patient’s treatment, for its own payment, or for its own health care operations, unless the consent was revoked by the patient (or the patient’s representative). Covered entities were also required to maintain a notice of privacy practices (the “Notice”) detailing the uses and disclosures of PHI the entity might make and the individual’s rights with respect to PHI. The form of consent prescribed by HHS acknowledged the existence of the Notice and the individual’s right to review it.

Amended Rule. The Amended Rule eliminates the consent requirement. Instead, the Amended Rule only requires direct treatment providers to give individuals a copy of the Notice. The Notice must be delivered no later than the date of the first service delivery on or after April 14, 2003 and the provider must make a good faith effort to obtain the individual’s written acknowledgement of receipt of the Notice. If the individual refuses to execute an acknowledgement, the provider must document its good faith efforts to obtain the acknowledgement...
and the reasons why it was unable to do so. In emergencies, the individual must be provided a copy of the Notice “as soon as reasonably practicable after the emergency,” but there is no requirement to obtain an acknowledgement. If services are provided electronically, the Notice must be sent electronically and acknowledgement may be obtained through a return receipt or other transmission from the individual. Revisions of the Notice must be made available upon request, but it is not necessary to obtain a new acknowledgement. Providers are required to document compliance by retaining the written acknowledgements of receipt or explanations of why an acknowledgement could not be obtained.

The required content of the Notice is unchanged by the Amended Rule. HHS encourages, but does not require, use of a “layered notice.” The first layer would contain a short notice that briefly describes the covered entity’s principal uses and disclosures of PHI and the individual’s rights; the second layer would contain a longer notice that covers all the elements required by the Amended Rule. HHS has indicated that it will issue further guidance on implementation of the Notice provision.

In order to provide flexibility to covered entities, HHS intentionally does not prescribe the form of the acknowledgement in the Amended Rule except to require that it must be in writing. Similarly, HHS does not specify what constitutes a good faith effort to obtain an acknowledgement but has indicated that it expects to provide further guidance on this issue.

Impact. Elimination of the consent requirement facilitates treatment in situations where it is desirable that a provider make use of PHI prior to the first face-to-face encounter with the patient. For example, pharmacists may now fill prescriptions without receiving the patient's prior written consent and hospitals may schedule procedures before the patient arrives without receiving the patient’s prior written consent. Additionally, the tracking of revocations of consents was an area of concern for many hospitals and health systems. Because the acknowledgement cannot be revoked, this potential problem is avoided. Finally, HHS’s acknowledgement that electronic acknowledgement can be obtained without the burdensome “e-signature” requirements of HIPAA is of substantial benefit to any provider that interacts with patients over the Internet. Nevertheless, because direct health care providers must create and retain documentation of the individual’s acknowledgement or the reasons for failure to obtain one, the administrative burden on such providers is largely unchanged.

Authorizations (45 C.F.R. §§ 164.508 and 164.528)

Prior Rule. Under the Prior Rule, a covered entity was required to obtain an authorization for the use or disclosure of PHI for most purposes other than treatment, payment, and health care operations. The Prior Rule contained a list of “core elements and requirements” for authorizations and three sets of specific requirements applicable to authorizations sought by covered entities for particular purposes. Disclosures made pursuant to an authorization were in most cases subject to the minimum necessary standard and were required to be included in the accounting of disclosures requirements of the Prior Rule.

Amended Rule. The Amended Rule simplifies the authorization process by retaining only the core elements and requirements and eliminating the three sets of specific requirements. Almost all distinctions based on the party seeking PHI and for what purpose have been removed. However, where an authorization is sought for purposes of marketing, any direct or indirect remuneration received by the covered entity must be disclosed, and an individual who initiates the authorization may include the statement “at the request of the individual” in lieu of a description of the purposes for which the disclosure is sought.
The Amended Rule specifies that the minimum necessary standard does not apply to disclosures made pursuant to authorizations. In addition, uses and disclosures of PHI made pursuant to an individual’s authorization no longer have to be included as part of the accounting of disclosures.

Impact. Simplifying the requirements associated with obtaining authorizations will reduce the administrative burden on covered entities and will likely reduce errors. Covered entities will be able more easily to create a form authorization. Similarly, exempting disclosures pursuant to authorizations from the minimum necessary standard and accounting of disclosures requirements will ease the burden of compliance.

Marketing
(45 C.F.R. §§ 164.501 and 164.508)
Prior Rule. The Prior Rule’s provisions governing marketing were, to most readers, confusing. The Prior Rule prohibited the use of PHI for the purpose of marketing products or services not health related without the express authorization of the individual. However, excluded from the definition of “marketing” were communications (i) made by the covered entity to describe participating providers or health plan benefits and (ii) made by a health care provider as part of the treatment of the individual. These exceptions only applied if the communication was made orally or, if in writing, without remuneration from a third party. No authorization would have been required for communications that fell within the exceptions. The Prior Rule permitted, without authorization, communications involving PHI that fell within the definition of marketing, provided certain disclosure requirements were met, including a mechanism for the targeted individual to “opt out” of receiving further communications. In addition, the Prior Rule permitted a covered entity to engage in “marketing” without prior authorization if the communication occurred in a face-to-face encounter and involved products or services of nominal value.

Amended Rule. The Amended Rule requires a covered entity to obtain an individual’s prior written authorization for all marketing purposes except face-to-face encounters and communications pertaining to promotional gifts of nominal value. An authorization obtained for marketing purposes must contain a statement describing any remuneration paid to the covered entity by a third party. The detailed disclosure and “opt-out” mechanism have been eliminated. As with the Prior Rule, each authorization must be specific, and blanket authorizations will be considered defective under the Amended Rule.

The definition of marketing has been changed to an objective standard. The communication is marketing if, on its face, it encourages recipients to purchase or use the product or service. The Amended Rule clarifies the exemptions and delineates the three categories of communications excluded from the definition of marketing. Specifically, a covered entity is not engaged in marketing if it is communicating to individuals about: (i) the participating providers and health plans in a network, the products or services offered by a provider, or the benefits covered by a health plan; (ii) the individual’s treatment; or (iii) case management or care coordination for the individual, or recommendations for alternative treatments. The Amended Rule clarifies that a health plan would not be “marketing” when advising enrollees about other available health plan options if the services are health related and add value to the plan’s membership.

The Amended Rule also eliminates the provision set forth in the Prior Rule that would have permitted communications to fall within an exception only if made orally or, if in writing, without any direct or indirect remuneration. HHS states that simple receipt of remuneration does not necessarily transform a treatment communication into a
commercial promotion. If a communication falls within an exception, it is irrelevant to the analysis whether the covered entity is being paid to make the communication by a third party.

The Amended Rules have added language prohibiting parties from using the guise of a business associate relationship to circumvent the requirement that a covered entity obtain a valid authorization prior to using or disclosing PHI under marketing arrangements with a third party. HHS clarifies that “marketing” includes arrangements whereby a covered entity discloses PHI to another entity in exchange for direct or indirect remuneration. The Amended Rules thus close a perceived loophole that could have allowed parties to avoid the authorization requirement by utilizing a business associate arrangement.

HHS also clarifies that the Amended Rule’s marketing provisions in no way amend or modify any state or federal statutes such as anti-kickback laws and anti-self referral laws.

Impact. The Amended Rule is somewhat successful in accomplishing its stated purpose of clarifying and simplifying the marketing provisions of the Prior Rule. However, critics have already surfaced, claiming the Amended Rule allows greater dissemination of medical information for commercial purposes through the use of the exception to the definition of marketing for “case management or care coordination, . . . or to direct or recommend alternative treatments, therapies, health care providers or settings.” In fact, Senator Edward M. Kennedy stated his intent to introduce legislation to regulate more stringently the use of health care information for marketing purposes. The future of this provision may not be settled.

Business Associates
(45 C.F.R. §§ 164.532(d) and (e))

Prior Rule. The Prior Rule defined a “business associate” as a party that performs functions or services for or on behalf of the covered entity that involve the creation, use, or disclosure of PHI. A covered entity may disclose PHI to a business associate if the covered entity obtains “satisfactory assurances” that the business associate will appropriately safeguard the information. The Prior Rule required that covered entities and their business associates have contracts with specified provisions addressing the use and disclosure of PHI by the business associate.

Amended Rule. Although no substantive changes are set forth in the Amended Rule, there is a one-year extension of the compliance date with respect to certain business associate contracts for covered entities other than small health plans. In addition to the one-year extension, the Amended Rule also includes sample contractual provisions for business associate contracts. It is important to note that the one-year extension does not apply to all contracts with business associates. Rather, if a covered entity (other than a small health plan) has an existing business contract with a business associate prior to August 12, 2002, and such contract is not renewed or modified between such date and April 14, 2003, the compliance date will be extended. The contract will be deemed compliant until the earlier of April 14, 2004 or the date of any renewal or amendment to the written agreement. Covered entities entering into new contracts or amending or renewing existing contracts after August 12, 2002 will still be required to meet the 2003 compliance date with respect to such contracts. Similarly, oral agreements are not eligible for the extension. The preamble does note that “evergreen” contracts that automatically renew after August 12, 2002 are eligible for the extension.

Impact. The Amended Rule’s extension provides a welcome reprieve for many covered entities facing the daunting task of amending hundreds of written agreements. However, it is important to note that, although the business associate contract requirements have been extended, covered entities
will nonetheless have responsibilities (as of April 14, 2003) with respect to PHI in the hands of their business associates. For example, a covered entity might be responsible for amending PHI held by its business associate. The covered entity could have difficulty meeting its obligations if it does not have business associate contracts in place by April 14, 2003. The boilerplate provisions set forth in the Amended Rule, although helpful, are not mandated provisions. Covered entities should be cautious in applying these form provisions. Not all of the sample provisions may be appropriate in every situation, and state and federal laws may prescribe specific provisions.

Minimum Necessary Standard and Incidental Uses and Disclosures
(45 C.F.R. §§ 164.502 and 164.514(d))

Prior Rule. Under the Prior Rule, the “minimum necessary” standard required that covered entities make reasonable efforts to limit uses or disclosures of, and requests for, PHI to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request. The Prior Rule contained a number of exceptions to the minimum necessary standard, including disclosures required by law, disclosures made to an individual or pursuant to an authorization initiated by the individual, requests by a health care provider for treatment of individuals, and disclosures made to the individual. The Prior Rule did not explicitly address incidental uses and disclosures.

Amended Rule. Under the Amended Rule, any uses or disclosures made pursuant to an authorization are exempted from the minimum necessary standard. HHS reasoned that because all authorizations must include a specific and meaningful identification of the information to be used and disclosed, individuals are put on sufficient notice. If an individual objects to the breadth of the information covered by the authorization, the individual can refuse to sign the authorization or negotiate a narrower authorization. HHS also clarified that covered entities must implement criteria for their nonroutine and nonrecurring requests to other covered entities for the disclosure of PHI to limit such requests to the minimum necessary to accomplish the intended purpose.

The Amended Rule explicitly permits certain incidental uses and disclosures as long as (i) such use or disclosure is incident to an otherwise permissible or required use or disclosure, (ii) the covered entity meets the minimum necessary requirements, and (iii) the covered entity uses reasonable safeguards to minimize the chance of incidental disclosures. An incidental use or disclosure resulting from failure to apply reasonable safeguards or the minimum necessary standard is a violation of the privacy rules. However, the fact that an incidental disclosure occurs does not, in and of itself, indicate that reasonable safeguards have not been used. The Amended Rule excepts incidental disclosures from the patient accounting requirement.

Impact. The Amended Rule re-emphasizes HHS’s position that the minimum necessary requirements be “reasonable and flexible to accommodate the unique circumstances of the covered entity.” The exemption from the minimum necessary standard for uses and disclosures made pursuant to an authorization is helpful. The Amended Rule’s provision governing incidental uses and disclosures, although welcome, presents the potential for confusion because of the subjective nature of the minimum necessary standard and the use of “reasonable” safeguards. The practical effect of this provision is to change the standard of care for incidental uses and disclosures from one of strict liability to a negligence standard. However, it will often be difficult for a covered entity to determine what is required to avoid being negligent. Guidance from HHS may be of assistance in clarifying these issues.
Research
(45 C.F.R. §§ 164.512(i), 164.508, and 164.532)
Prior Rule. The Prior Rule stated that covered entities may use or disclose PHI for purposes of research if the individual signs an authorization or if an institutional review board or privacy board approves a waiver of the authorization. A waiver is permitted if the use or disclosure involves no more than a “minimal risk” to the individuals and the research could not practicably be conducted without the waiver. The Prior Rule included special requirements for authorizations that included treatment of the individual.

Amended Rule. The Amended Rule eliminates the additional requirements for authorizations relating to research that includes treatment of the individual. The Amended Rule requires a single set of authorization requirements for all types of authorizations and allows research authorizations to be combined with any other type of legal permission relating to the study. The Amended Rule eliminates the requirement for an expiration date for use or disclosure of PHI for research purposes and allows researchers to make a statement on the authorization that the research does not have an expiration date. This will aid researchers who accumulate databases of information with no exact time limit. HHS also clarified that covered entities may continue to use and disclose PHI that was obtained prior to the time an individual revoked his or her authorization as necessary to maintain the integrity of the research study.

Impact. The Amended Rule will make it easier to obtain a research authorization. These changes are helpful clarifications to the privacy rules governing research and will hopefully make compliance less cumbersome.

Parents as Personal Representatives of Unemancipated Minors
(45 C.F.R. § 164.502(g))
Prior Rule. Under the Prior Rule, a parent, guardian or other person acting in loco parentis (collectively referred to herein as “parent”) generally had the ability to access and control the PHI of a minor child. There were limited exceptions to this general rule. First, the covered entity could not treat the parent as a representative for the minor if the minor consented to the health care service, no other consent was required, and the minor had not requested that the parent be treated as a personal representative. Second, the covered entity would not treat the parent as a personal representative if the minor lawfully obtained the health care services without the parent’s consent and the minor, a court, or other authorized person consented to the service. The Prior Rule also recognized an exception if the parent assented to an agreement of confidentiality between the covered health care provider and the minor. Finally, the Prior Rule allowed a covered health care provider to choose not to disclose information to a parent when the provider was concerned about abuse or harm to the minor.

Amended Rule. In the preamble, HHS sets forth three primary goals of the Amended Rule with respect to the parents and minors provision of the privacy rule. The first is to ensure that parents have appropriate access to the health information of their minor children in order to make important health care decisions. This goal is subject, however to HHS’s desire to ensure that the privacy rule does not interfere with a minor’s ability to consent to and obtain health care under state or other applicable law. The second goal identified by HHS is the desire to not interfere with state or other applicable laws related to competency or parental rights in general, or specifically, interfere with a parent’s role in making health care decisions for his or her minor children. Third, HHS stated its deference to the professional requirements of state medical boards or other ethical codes of health care providers pertaining to the confidentiality of health information or to health care practices related to adolescent health care.
In an attempt to achieve these goals and to address the “unintended consequences” of the Prior Rule, HHS adopted two primary changes to the parents and minors provision of the Prior Rule (in addition to reorganizing the placement of the parents and minors provision). First, the Amended Rule permits a covered entity to disclose PHI about a minor to a parent if state or other law permits or requires the disclosure. Similarly, the Amended Rule states that a covered entity may not disclose PHI about a minor to a parent if doing so would be prohibited by state or other law. The Amended Rule makes it clear that deference to state law includes not only statutes or regulations, but case law as well.

Second, in order to clarify HHS’s intent, the Amended Rule includes two provisions addressing access to a minor child’s PHI. Similar to the provision addressing the disclosure of PHI, the Amended Rule provides that state or other applicable law governs when a covered entity is permitted, required, or prohibited from granting access to the PHI of a minor to a parent. Again, HHS will defer not only to state statutes and regulations, but also to applicable case law.

Finally, in order to address situations where the parent is not the personal representative of the minor child and where state or “other law” is not clear, HHS added a new provision. The Amended Rule provides that the covered entity may either provide or deny access to the minor child’s PHI, provided that the action taken is consistent with state or other law. The discretion to provide or deny access to a parent under this provision may only be made by a licensed health care professional “in the exercise of professional judgment.”

Impact. The Amended Rule clarifies and may even simplify adherence to the parents and minors provision. The modifications underscore that state law governs decisions regarding disclosure and access of a minor child’s PHI to a parent. The Amended Rule should simplify the analysis for a covered entity when trying to make decisions related to the disclosure or access of a minor child’s PHI by his/her parent.

**De-Identification of Protected Health Information**

(45 C.F.R. § 164.514(b))

**Prior Rule.** The Prior Rule provided that a covered entity may use and disclose PHI that has been “de-identified.” There were two methods by which the information could be “de-identified.” The first method by which a covered entity could demonstrate that it has met the standard for de-identification was if an expert in “generally accepted statistical and scientific principles and methods” determined that the risk for identification of the individuals was “very small” and could document the justification for the determination. In the alternative, the covered entity could utilize the Prior Rule’s safe harbor by removing a total of 18 possible enumerated identifiers from the health information. Under the safe harbor, the covered entity could not have actual knowledge that the de-identified information could be used to identify the individual. The Prior Rule included a method by which the covered entity could assign codes or other means as a way of allowing the de-identified information (once de-identified by one of the two methods discussed above) to be re-identified.

**Amended Rule.** In the preamble to the Amended Rule, HHS states that due to the nature of the comments received in response to the proposed modifications, HHS was not convinced that there was a need to modify the safe harbor standard for de-identification. (As discussed below, however, HHS did adopt a standard for the use and disclosure of a limited data set.) In the Amended Rule, however, HHS clarifies that insertion of a re-identification code was not intended as one of the enumerated identifiers that would need to be removed in order to satisfy the safe harbor.
Therefore, HHS made a technical modification to the de-identification safe harbor provisions to except the re-identification code (or other means of record identification permitted under the privacy rule) from the listed identifiers. Otherwise, the Prior Rule was not changed.

**Impact.** The technical modification made to the Privacy Rule clarifies that the use of an appropriate re-identification code will not prevent information from being considered de-identified. This change should assist covered entities when trying to satisfy the de-identification safe harbor.

**Limited Data Set (45 C.F.R. § 164.514(e))**

**Prior Rule.** The Prior Rule did not include the limited data set standard.

**Amended Rule.** The adoption of the limited data set standard represents a significant change to the Prior Rule. As part of the proposed modifications, HHS requested comments on an alternative approach to the de-identification safe harbor that would permit uses and disclosures of a limited data set. In response to comments received, HHS determined that the adoption of a standard for the use and disclosure of a limited data set for use in research, public health, and health care operations was warranted. Section 164.514(e) has been added by the Amended Rule to allow the use and disclosure of a limited data set if the covered entity satisfies three requirements. First, the covered entity may only use or disclose a “limited data set.” Second, the covered entity must enter into a data use agreement with the intended recipient of the limited data set. Third, the limited data set may be used or disclosed only for the purposes of research, public health, or health care operations.

For purposes of the privacy rule, a limited data set is defined as PHI that excludes the following direct identifiers of the individual, or relatives, employers, or household members of the individual: (i) names; (ii) postal address information, other than town or city, state, and zip code (i.e., street address must be excluded, but other geographic identifiers are permissible); (iii) telephone and fax numbers; (iv) electronic mail addresses; (v) social security numbers; (vi) medical record numbers; (vii) health plan beneficiary numbers; (viii) account numbers; (ix) certificate/license numbers; (x) vehicle identifiers and serial numbers, including license plate numbers; (xi) device identifiers and serial numbers; (xii) Web Universal Resource Locators (URLs); (xiii) Internet Protocol (IP) address numbers; (xiv) biometric identifiers, including finger and voice prints; and (xv) full-face photographic images and any comparable images. Notably, the Amended Rule allows the use and disclosure of dates of admission and discharge and dates of birth and death for the individual.

Covered entities must enter into a data use agreement with the intended recipient of the limited data set. The data use agreement must (i) establish the permitted uses and disclosures of the limited data set (consistent with the purposes of the research, public health, or health care operations), (ii) establish who can use or receive the limited data set, and (iii) require that the recipient: (a) not use or further disclose the information other than as permitted by the data use agreement or as required by law, (b) use appropriate safeguards to prevent the use or disclosure of the information other than as provided in the data use agreement, (c) report to the covered entity any use or disclosure of the information that is not permitted by the data use agreement of which the recipient becomes aware, (d) ensure any agents or subcontractors of the recipient agree to the restrictions and conditions placed on the recipient, and (e) not identify the information or contact the individual.

As with other disclosures under the privacy regulations, there are other requirements, including, but not limited to, the minimum necessary requirement, that apply to the disclosure of a limited
data set. However, covered entities do not need to include disclosures of limited data sets in any accounting of disclosures of PHI.

Impact. Overall, the limited data set standard will permit covered entities to use and disclose information that will be useful in conducting research, public health, or health care operations. The standard created by HHS is not complicated, but it does require additional action on the part of the covered entity. For example, the covered entity will need to create a data use agreement that includes all of the elements required under section 164.514(e). In connection with the data use agreement, a covered entity should recognize that while it would not be liable for a breach of the data use agreement by the recipient of the limited data set, the covered entity will be required to take appropriate action (similar to requirements associated with business associate agreements) should it learn of a material breach or a violation of the agreement. Finally, covered entities must recognize that use or disclosure of a limited data set does not absolve covered entities from making a minimum necessary determination (which may further limit the amount of information in a given limited data set).

Technical Corrections and Other Clarifications

Disclosure of PHI for Payment and Health Care Operations of the Entity Receiving the Information. Under the Prior Rule, a provider who had obtained the individual’s consent could disclose PHI to other providers for purposes of treatment but could only use PHI for its own payment and health care operations. Section 164.506 has been amended to permit a covered entity to disclose information to other health care providers and covered entities for the payment activities of such providers and other covered entities. This modification was adopted to accommodate providers, such as ambulance companies, that frequently rely on other providers to obtain necessary billing information and to aid in coordination of benefits situations.

In addition, a covered entity may disclose PHI to another covered entity for certain health care operations (e.g., quality assessment and improvement, staff evaluation, licensing, and accreditation) of the recipient covered entity or fraud and abuse detection or compliance, provided both covered entities have or had a relationship with the individual.

Changes of Legal Ownership. Under the Prior Rule, health care operations was defined to include due diligence in connection with the sale or transfer of assets of a covered entity. As amended, section 164.501 defines health care operations to include the sale, transfer, merger, or consolidation of all or part of the covered entity. This modification permits the transfer of records to the new owner who may use and disclose them for purposes of treatment, payment, and health care operations.

Enrollment and Disenrollment Disclosures. Section 164.504(f) has been amended to specifically permit group health plans to share enrollment and disenrollment information with plan sponsors without having to amend the plan documents. This policy was expressed in the preamble to the Prior Rules but was omitted from the text of the regulations.

Accounting for Disclosures of PHI. Section 164.528 has been amended to exempt the following disclosures from the accounting requirement: disclosures of PHI made pursuant to authorizations, disclosures of PHI in connection with limited data sets, and incidental disclosures of PHI.

Uses and Disclosures Regarding FDA-Regulated Products and Activities. The Prior Rule permitted limited disclosures to report adverse events and provide other information concerning FDA-regulated products and activities without the necessity of obtaining an authorization. Because it was felt that the restrictions in the Prior Rule could have a chilling effect on voluntary reporting, section 164.512 was amended to permit covered entities to disclose PHI to a person (subject to the jurisdiction
of the FDA with respect to an FDA-regulated product or activity for which that person has responsibility) for the purpose of activities related to the quality, safety, or effectiveness of such FDA-regulated product or activity. The preamble to the Amended Rule cautions, however, that such disclosures are subject to the minimum necessary standard, and that it may often be possible to make the report without identifying the individual to whom the information relates.

**Hybrid Entities.** An entity that performs both covered and non-covered functions may designate the component(s) that perform covered functions as one or more “health care component(s).” Such entities may include as part of the health care component(s) those staff groups (e.g., accounting) that act in the capacity of business associates to the portion of the entity performing the covered functions. Under the Amended Rule, even an entity whose primary functions are covered activities may designate portions of its business as “a health care component” while carving out other portions as non-covered components. Thus, for example, a pharmacy may designate the portions of its operations that involve dispensing drugs as a health care component and exclude the portion of its operations devoted to sales of food, magazines, and sundries.

If an entity that performs a covered function fails to make a designation, the whole entity is treated as a covered entity, and PHI generally can only be used for purposes of treatment, payment, or health care operations unless the individual has signed an authorization. If a health care component is designated, only the designated component is subject to the privacy rules, but disclosures to other portions of the entity are treated as disclosures to outsiders. Therefore, the designated component must create firewalls to ensure that PHI is not disclosed except to the extent it could be disclosed to a separate entity.

Finally, if a covered entity determines that it is in its best interests to consider itself a hybrid entity, the covered entity should be cognizant of which of its components will be designated as health care components. It is strongly recommended that a hybrid entity include in its designation of health care components those components that provide “business associate” type functions. If the designated health care component does not include those portions of the entity that perform business associate functions on its behalf, the covered components may not disclose PHI to the non-covered component without an authorization for such disclosure. HHS reached this conclusion by reasoning that an entity could not have a business associate agreement with itself. Disclosures within a designated component are subject to the minimum necessary standard, as are any permitted disclosures between the health care component and other portions of the entity.

The Amended Rule generally gives entities greater flexibility to determine whether to designate a health care component and to decide what functions to include within it. However, an entity that chooses to designate a health care component must include within it any component that would meet the definition of a “covered entity” if it were a separate entity.

**Employment Records are not Protected Health Information.** Amendments to the definition of “protected health information” contained in section 164.501 make explicit that information maintained in “employment records held by a covered entity in its role as employer” is not PHI. Thus, when a hospital employee submits a physician’s letter to document sick leave, the information is not protected; on the other hand, if the employee enters the hospital as a patient, information obtained in connection with his/her hospital stay is PHI. HHS chose not to separately define “employment record.”
Conclusion
The Amended Rule represents a positive step toward reducing the administrative burdens imposed on covered entities by the Prior Rule. HHS responded to some of the most severe criticisms from the provider community regarding the impact of certain aspects of the HIPAA privacy regulations. Additionally, the Amended Rule clarifies many of the uncertainties present in the Prior Rule. Nonetheless, there remain many unanswered questions that covered entities must address. Further guidance from HHS may help to answer these questions.

Further Information
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Jones Day has established a task force to assist our clients with all aspects of their HIPAA compliance responsibilities. Questions relating to HIPAA may be e-mailed to our dedicated HIPAA mailbox at hipaaprivacy@jonesday.com. We invite you to visit our Web site at www.jonesday.com.

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