Proposed Modifications to HIPAA’s Privacy Rule

On March 27, 2002, the U.S. Department of Health and Human Services (“HHS”) published proposed modifications to the privacy regulations under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”). The following summary of these proposed modifications sets forth the relevant provisions of the current HIPAA privacy regulations (the “Current Rule”), describes how these provisions would be modified by the proposed modifications (the “Proposed Rule”), and concludes with a brief analysis of the impact of the Proposed Rule.

Please keep in mind that the modifications in the Proposed Rule have merely been proposed and are subject to a 30-day comment period and further revision by HHS before becoming final.

Proposed Modifications. The Proposed Rule would eliminate the consent requirement and replace it with an obligation to make a good faith effort to obtain the individual’s acknowledgment of receipt of the provider’s notice of privacy practices at the time of the first service delivery. The Proposed Rule states a covered entity may, without prior consent or authorization: (i) use or disclose PHI for its own treatment, payment, or health care operations purposes, (ii) disclose PHI for treatment activities of another health care provider, (iii) disclose PHI to another covered entity or health care provider to allow the recipient entity to seek payment, (iv) disclose PHI to another covered entity for the recipient entity’s health care operations if both covered entities have a relationship with the subject of the PHI and the disclosure is for certain purposes, including quality assessment and improvement activities, peer review or similar evaluations, and fraud and abuse compliance or detection, and (v) disclose PHI for the purpose of the health care operations of an organized health care arrangement in which the covered entity participates. The Proposed Rule would allow providers to obtain consents for the use or disclosure of PHI, but the regulations would no longer specify the content and format of the consents.

Impact. The Proposed Rule’s removal of the consent requirement is in response to criticism that the consent process could impede the efficient delivery of health care (e.g., not allow pharmacies to fill phoned-in prescriptions or allow hospitals to schedule and prepare for first-time patients). The
elimination of the consent requirement is clearly a significant change and, according to estimates by HHS, will reduce the cost of HIPAA compliance by $103 million over 10 years. The changes would resolve the problems the consent requirement created for first-time encounters with patients and remove some of the initial burden of obtaining and maintaining documentation of consents. As discussed below, however, much of the administrative burden of documenting and maintaining records with respect to privacy issues has been shifted to the notice of privacy practices.

**Notice of Privacy Practices (45 C.F.R. § 164.520)**

**Current Rule.** Under the Current Rule, each covered entity is required to maintain a notice of privacy practices (the “Notice”) that details the uses and disclosures of PHI that may be made by the covered entity. The Current Rule contains specific provisions regarding the contents of the Notice and when it must be provided to patients and enrollees whose PHI is covered by such Notice. There is no requirement that the Notice be signed by an individual; rather, an individual executes a consent that acknowledges the existence of the Notice and the right to review the Notice before executing the consent.

**Proposed Modifications.** In conjunction with the proposed elimination of the consent requirement, HHS proposes to use the Notice to preserve certain qualities of the consent. Under the Proposed Rule, direct health care providers will be required to: (1) provide the Notice no later than the date of the first delivery of service (which is not a change from the Current Rule) or, in an emergency treatment situation, as soon as reasonably practicable after the emergency treatment and (2) except in an emergency treatment situation, use a “good faith effort to obtain a written acknowledgment of receipt” of the Notice. If an acknowledgement is not obtained, the covered entity must document its good faith effort and the reason why the acknowledgment was not obtained. The covered entity must document compliance with the Notice requirement by maintaining any written acknowledgments of receipt of the Notice and any documentation regarding unsuccessful good faith efforts to obtain an acknowledgment. HHS has stated that it intends the acknowledgment requirement to “be simple and not impose a significant burden” on the covered entity or the individual.

**Impact.** The acknowledgment of the Notice is one of the most significant changes under the Proposed Rule. The acknowledgment procedure is arguably less onerous than the consent requirements under the Current Rule, because a covered entity can comply with the Notice requirements by obtaining a written acknowledgment or documenting its good faith efforts to obtain one. Unlike the consent requirements under the Current Rule, the form of the acknowledgment is left to the discretion of the covered entity, provided, however, that the acknowledgment must be “written.” While HHS expressed a preference for covered entities to require individuals to sign a copy of the Notice, HHS indicated it “would not limit the manner” in which an acknowledgment is obtained. Although we believe that an electronic acknowledgment should be sufficient, this remains as open issue. From a practical perspective, by requiring that covered entities retain “any written acknowledgments of receipt of notice or documentation of [unsuccessful] good faith efforts to obtain such written acknowledgement,” HHS has shifted the administrative burden of maintaining records from the consent provisions to the Notice provisions.

**Minimum Necessary Standard (45 C.F.R. §§ 164.502(b) and 164.514(d))**

**Current Rule.** The Current Rule’s “minimum necessary” standard requires that covered entities make reasonable efforts to limit a use or disclosure
of (or a request for) PHI to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request. The minimum necessary requirement does not apply to disclosures to or requests by a health care provider for treatment or for disclosures made to the individual. Further, the minimum necessary standards do not apply to uses or disclosures made pursuant to certain authorizations, disclosures made to the Secretary of HHS pursuant to HIPAA, or other disclosures that are required by law. In the implementation guidelines for the minimum necessary standards, the Current Rule requires that covered entities (1) “reasonably ensure” that the minimum necessary standards are met, (2) take reasonable steps to limit its workforce’s access to PHI to the minimum necessary amount for its workforce to perform its duties, and (3) implement policies and procedures to assess and process requests for PHI to ensure that the PHI disclosed is limited to the amount reasonably necessary to achieve the purpose of the disclosure.

**Proposed Modifications.** The Proposed Rule would modify the minimum necessary standard by amending the scope of permitted uses and disclosures to include incidental disclosures, as long as (1) the incidental use or disclosure is incident to an otherwise permissible or required use or disclosure, (2) the covered entity meets the minimum necessary requirements, and (3) the covered entity uses reasonable safeguards to minimize the chance of incidental disclosures. The Proposed Rule would further modify the minimum necessary standard by deleting the “reasonably ensure” language from the implementation guidelines in order to clarify that HHS desires the minimum necessary standard to be flexible and not imply that an “absolute, strict standard” applies. Finally, uses and disclosures made pursuant to any authorization would be added to the list of uses and disclosures excepted from the minimum necessary standard.

**Impact.** As discussed in the guidance issued by HHS on July 6, 2001, the Proposed Rule provides further evidence that HHS believes that a covered entity will be in compliance with the minimum necessary standard if it uses reasonable efforts to limit their uses and disclosures of (and requests for) PHI to the minimum amount necessary to accomplish the purpose of the use, disclosure, or request. The Proposed Rule makes certain incidental uses and disclosures of PHI permissible, which is helpful, but it does not resolve the problems faced by covered entities when trying to determine what will be required for compliance. Because the incidental disclosure language (which appears in the permitted uses and disclosures of PHI section of the Proposed Rule) requires compliance with the minimum necessary standard, there seems to be a problem of circularity of definitions. Additionally, because the incidental disclosure language requires covered entities to “reasonably safeguard” PHI to limit incidental uses and disclosures, the re-introduction of a “reasonableness” standard brings with it the same uncertainty that exists in the Current Rule. HHS provided some guidance in the preamble to the Proposed Rule by discussing a few examples of the application of the minimum necessary standard, but HHS seems to remain committed to the subjective reasonableness standard. Following its hearings, the National Committee on Vital and Health Statistics (an advisory board to HHS) recommended that HHS provide advisory opinions concerning the minimum necessary standard. HHS did not directly respond to the Committee’s recommendation but did indicate that it plans on issuing additional guidance and technical materials to assist covered entities in complying with the minimum necessary standard. Under the Current Rule and the Proposed Rule (if adopted), covered entities should use their best judgment in determining what is “reasonable” in the context of
the minimum necessary standard and in establishing safeguards to prevent impermissible disclosures of PHI.

Business Associates (45 C.F.R. §§ 164.502(e) and 164.504(e))

**Current Rule.** The Current Rule defines a “business associate” as a party that performs functions or services 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 Current Rule requires that covered entities and their business associates have contracts with specified provisions addressing the use and disclosure of PHI.

**Proposed Modifications.** Although no substantive changes are set forth in the Proposed Rule, there is a one-year extension of the compliance date with respect to certain business associate contracts. In addition to the one-year extension, the Proposed Rule also includes form “boilerplate” contractual provisions for business associate contracts. The one-year extension does not apply to all contracts with business associates. If a covered entity has an existing contract with a business associate prior to the effective date of the Proposed Rule, and such contract is not renewed or modified between the effective date of the Proposed Rule 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 the effective date of the Proposed Rule will still be required to meet the 2003 compliance date with respect to such contracts. The preamble does note that “evergreen” contracts that automatically renew after the effective date of the Proposed Rule would be eligible for the extension.

**Impact.** The Proposed Rule’s extension would provide a welcomed reprieve for many covered entities facing the daunting task of amending hundreds of written agreements. However, it is important to note that covered entities would still need to be responsible for providing information to individuals with respect to their PHI, including information held by business associates. The boilerplate provisions, although helpful, are not mandated provisions. Covered entities should be cautious in applying these form provisions because some of the provisions may not be appropriate in every situation.

Marketing (45 C.F.R. §§ 164.501 and 164.514(e))

**Current Rule.** The Current Rule’s provisions governing marketing are, to most readers, confusing. The Current Rule prohibits the use of PHI for the purpose of marketing products or services that are not health related without the express authorization of the individual. However, excepted from the definition of “marketing” are certain communications that may be part of the covered entity’s treatment of the individual or the covered entity’s health care operations. These exceptions do not apply if the covered entity is compensated by a third party. No authorization is required for communications that fall within the exceptions. In addition, the Current Rule permits, without authorization, communications that utilize an individual’s PHI that fall within the definition of marketing provided certain requirements are met, including a mechanism for the targeted individual to “opt out” of receiving further communications.

**Proposed Modifications.** The Proposed Rule contains three important elements and some clarifications. First and foremost, any communication using PHI that would fall under the definition of marketing would require authorization by the individual. The “opt-out” mechanism would be replaced with an “opt-in” mechanism. In addition, if the covered entity
expects to be remunerated for marketing, the authorization must disclose this fact. Secondly, the definition of marketing would be revised so that a determination of whether a communication is marketing would turn on the effect of the communication rather than the intent of the person making the communication. Lastly, the exceptions to the definition would be revised to use terms that are used elsewhere in the Current Rule, but these revisions are not intended to expand the exceptions to the Current Rule. HHS also specifically clarified in the preamble to the Proposed Rule that it considers certain health care communications, such as disease management, prescription refill reminders, and appointment notifications, as being excepted from the definition of “marketing.”

**Impact.** The most significant aspect of the marketing provisions of the Proposed Rule is the replacement of the opt-out procedure with an opt-in requirement. The Proposed Rule would obligate covered entities to obtain an authorization prior to using PHI for marketing purposes unless the communication falls within an exception. This obligation would likely require many providers to change their current marketing practices.

**Parents as Personal Representatives of Unemancipated Minors (45 C.F.R. § 164.502(g))**

**Current Rule.** Under the Current Rule, a parent, guardian, or other person acting in loco parentis (collectively referred to herein as “parent”) generally has the ability to access and control the PHI of a minor child. There are limited exceptions to this general rule. First, the covered entity may not treat the parent as a representative for the minor if the minor consents to the health care service, no other consent is required, and the minor has not requested that the parent be treated as a personal representative. Second, the covered entity may not treat the parent as a personal representative if the minor lawfully obtains the health care services without the parent’s consent and the minor, a court, or other authorized person consents to the service. The Current Rule also recognizes an exception if the parent assents to an agreement of confidentiality between a covered health care provider and the minor. Finally, the Current Rule allows a covered health care provider to choose not to disclose information to a parent when the provider is concerned about abuse or harm to the minor.

**Proposed Modifications.** Under the Proposed Rule, HHS reiterates that it will continue to defer to state law regarding the requirements for disclosure or access to a minor’s PHI. While this was the intent of the Current Rule, HHS felt in certain situations (e.g., where state law was silent or provided discretion on disclosure requirements), the Current Rule did not achieve this goal. Therefore, in addition to reorganizing the provisions addressing minors’ PHI, the Proposed Rule modifies several provisions of the Current Rule. The Proposed Rule would modify the Current Rule by clarifying that state law (including statutes, regulations, and case law) governs disclosures in which a provider has discretion in determining whether a disclosure should be made to a parent. The Proposed Rule would also add a new provision pertaining to the right of access to PHI to take into account situations where a parent is not the personal representative of the minor.

**Impact.** The Proposed Rule clarifies that the Current Rule defers to state law concerning the rights of parents with respect to access to their minor children’s PHI. These changes are helpful clarifications and should not significantly change a covered entity’s approach to addressing the handling of unemancipated minors’ PHI.

**Research (45 C.F.R. §§ 164.512(i), 164.508, and 164.532)**

**Current Rule.** Under the Current Rule, 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. Research
authorizations must meet the requirements that are applicable to all authorizations under the Current Rule, and if the research also involves treatment, must meet additional requirements. Waiver is permitted if the use or disclosure involves no more than "minimal risk" to the individuals and the research could not practically be conducted without the waiver.

**Proposed Modifications.** In response to complaints that the waiver criteria were confusing, internally inconsistent, and required simplification, particularly for institutions subject to the rules applicable to federally funded research (such as the "Common Rule"), HHS proposed minor modifications to the waiver procedure. The Proposed Rule would promote consistency with the Common Rule, but most of the criteria would remain in place.

The Proposed Rule offers more substantial changes with respect to the authorization requirements. The Proposed Rule would eliminate the special requirements applicable to research that involves treatment and would permit research authorizations to be combined in a single document with other consents relating to the same research study. The Proposed Rule would simplify the transition provisions with respect to the treatment of PHI created or received in connection with research studies commenced before April 14, 2003. HHS also stated its intention to provide "additional interpretation, guidance, and technical assistance to help the research community in understanding the relationship between the Current Rule and the Common Rule."

**Impact.** The Proposed Rule provides some clarification. However, the requirements surrounding use of PHI in research remain complex, and it is not clear how the Current Rule (even as amended by the Proposed Rule) will affect studies that seek access to existing PHI for which no authorization has been granted.

**Authorization (45 C.F.R. § 164.508) Current Rule.** Under the Current Rule, an authorization is required for uses and disclosures of PHI, except for disclosures for purposes of treatment, payment, or health care operations and a few other limited exceptions. All authorizations have certain similar components, but certain types of authorizations (e.g., authorizations requested by a covered entity) have additional requirements. Certain types of authorizations are subject to the minimum necessary standards discussed above.

**Proposed Modifications.** The Proposed Rule would retain the core requirements for authorizations, largely unchanged. More significantly, it would eliminate the distinctions among different types of authorizations and would place the same requirements on all authorizations. As noted above, all uses and disclosures made pursuant to an authorization would be exempt from the minimum necessary requirement.

**Impact.** The Proposed Rule would simplify the authorization process and would relieve some of the administrative burden on covered entities because a standard authorization form could be developed and a minimum necessary analysis would not need to be made before responding to a request for a disclosure of PHI.

**De-Identification of Protected Health Information (45 C.F.R. § 164.512(a) - (c)) Current Rule.** The Current Rule provides that a covered entity may use and disclose health information that has been "de-identified" without a consent or authorization. The Current Rule provides two methods by which the information can be "de-identified." The first method by which a covered entity can demonstrate that it has met the standard for de-identification is if an expert in "generally accepted statistical and scientific principles and methods" determines that the risk for identification of the individuals is "very small" and can document
the justification for the determination. In the alternative, the covered entity can utilize the Current Rule's safe harbor by removing a total of 18 possible enumerated identifiers from the health information. Under the safe harbor, the covered entity may not have actual knowledge that the information could be used to identify the individual. The Current Rule includes a method by which the covered entity can 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.

**Proposed Modifications.** The Proposed Rule does not alter either of the two methods for de-identification. Rather, the Proposed Rule requests comments on a possible alternative approach that would allow the use and disclosure of a limited data set that would include certain identifiers. The limited data set would still exclude information considered as direct identifiers such as: name, street address, telephone and fax numbers, e-mail address, social security number, certificate/license number, vehicle identifiers and serial numbers, URLs and IP addresses, and full face photos and any other comparable images. The proposed limited data set would, however, include the following identifiable information: admission, discharge, and service dates; date of death; age (including age 90 or over); and five-digit zip code. The disclosure of the limited data set would be limited to use for research, public health, and health care operations purposes.

The Proposed Rule provides two clarifications with regard to de-identified information. First, the Proposed Rule would clarify that a re-identification code was not intended to be considered as one of the enumerated identifiers in the safe harbor that would need to be removed. Second, the preamble to the Proposed Rule clarifies that disclosure of an individual's age, expressed as age in months, days, or hours, is permissible.

**Impact.** While the Proposed Rule does not make any substantive changes to the use of de-identified information or definition thereof, it provides covered entities an opportunity to comment on possible methods of modifying the safe harbor standard for de-identified information for a limited data set. The proposed limited data set would seemingly provide additional useful data elements for covered entities that conduct research, share individually identifiable information with other covered entities for health care operations (subject to conditions discussed in Uses and Disclosures of PHI for Treatment, Payment, and Health Care Operations, above), or perform public health reporting.

**Technical Corrections and Other Clarifications**

**Proposed Modifications.** Changes of Legal Ownership. The Proposed Rule would expand the definition of "health care operations" (in a manner consistent with the preamble to the final regulations) to include the sale, transfer, merger, or consolidation of all or part of a covered entity to or with another covered entity (or an entity that will become a covered entity after such transaction). This modification is intended to permit the transfer of records upon a sale, transfer, merger, or consolidation and to modify the Current Rule so that it will not interfere "with necessary treatment or payment activities upon the sale of a covered entity or its assets."

Enrollment and disenrollment disclosures. The Proposed Rule would modify the Current Rule explicitly to allow group health plans to share enrollment and disenrollment information with plan sponsors without amending the plan documents. This policy was expressed in the preamble to the final regulations but was not explicitly included in the regulations.
Accounting for Disclosures of PHI. The Proposed Rule would modify the Current Rule by expanding the instances in which a covered entity is not required to account for disclosures of PHI. Under the proposed modification, covered entities will not have to account for disclosures made pursuant to an authorization. Therefore, under the Proposed Rule, covered entities would not be required to account for disclosures made for payment, treatment, or health care operations or pursuant to an authorization.

Uses and Disclosures regarding FDA-Regulated Products and Activities. The Proposed Rule would modify the Current Rule by replacing existing language that appears to limit FDA-related disclosures (made without an authorization). In response to comments that the Current Rule could have a chilling effect on reporting of adverse events or problems with products, the Proposed Rule would broaden the scope of permitted disclosures in an attempt to “recognize and preserve current public health activities” while “not diminishing the health information privacy protections for individuals.” HHS has requested that interested parties provide comments to determine whether the Proposed Rule is sufficient to ensure that health information can flow to the FDA.

Hybrid Entities. The Proposed Rule would modify the Current Rule by amending the definition of “hybrid entity” to allow flexibility to entities that undertake covered and noncovered activities. Under the Proposed Rule, an entity would have the discretion to designate itself as a covered entity or a hybrid entity for purposes of the Current Rule, regardless of the extent of its covered activities. If an entity designates itself a covered entity, all components of its operations must comply with HIPAA’s privacy rule. If an entity designates itself a hybrid entity, it must identify those health care components of its operations that will be treated as covered entities. Hybrid entities must include in the health care components those components that, if standing alone, would be a covered entity. Health care components must treat non-health care components as if they were separate legal entities (e.g., a health care component cannot disclose PHI to a non-health care component unless such disclosure is permitted under HIPAA’s privacy rule). Based on the Proposed Rule, it would be advantageous for a hybrid entity to designate its components that would be “business associates” of its health care components as health care components. Because HHS has indicated that a hybrid entity cannot have a business associate contract with itself, a health care component could not disclose PHI to a business associate component without an authorization unless the business associate component was designated a health care component.

Protected Health Information. The Proposed Rule would modify the Current Rule by amending the definition of PHI to carve out employment records. Under the Proposed Rule, employment records that contain individually identifiable health information would not be PHI if they are held by an entity in its role of employer of the individual. The preamble to the Proposed Rule clarifies that employment records would not include individually identifiable health information held by an entity when it is carrying out its health plan or health care provider activities.

Conclusion

It is unclear whether any or all of the Proposed Rule will become final, and what form the final rule will take. Senator Kennedy has announced that he will hold hearings in the Senate on the Proposed Rule and it appears likely that he will oppose at least some aspects of the Proposed Rule. Additionally, we cannot predict what revisions will be made to the Proposed Rule by HHS in response to comments received during the comment period. It is clear that covered entities need to be prepared to comply with
the Current Rule by April 2003 while remaining flexible enough to cope with any modifications to the Current Rule.

Further Information
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