

Wiggin & Dana

# HIPAA PRIVACY IMPLEMENTATION

Analysis Of Proposed  
Modifications And  
Potential Impact On  
Implementation Tasks

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**On March 27, 2002**, the Department of Health and Human Services (HHS) issued proposed regulations that would modify certain standards in the Privacy Rule. These proposed modifications are contained in a Notice of Proposed Rulemaking (“NPRM”). Most significantly, the NPRM would permit health care providers to use protected health information (“PHI”) for treatment, payment, and health care operations activities (both their own and certain activities of other entities) without patient Consent. The NPRM expands the Privacy Notice requirements by requiring covered entities that provide direct treatment to make good faith efforts to obtain patients’ written acknowledgement of the receipt of the Notice. In addition, the NPRM provides a limited one-year extension for amending certain existing agreements to comply with the business associate standards, explains that “incidental disclosures” of PHI in the course of an otherwise permitted use or disclosure would not violate the Privacy Rule, and makes other changes to various provisions of the Privacy Rule. The analysis that follows breaks down the NPRM’s changes by implementation task, and assesses the impact the proposed changes would have on the implementation process.

Please keep in mind that the proposed modifications remain subject to further consideration and change by HHS. Final language for the Privacy Rule may not be known until October, 2002. In addition, HHS has suggested that it may be issuing further guidance and proposed regulations. Also note that in some places the NPRM contains technical corrections to the Privacy Rule that may affect policy language.

**ANALYSIS OF PROPOSED MODIFICATIONS AND POTENTIAL IMPACT ON IMPLEMENTATION TASKS**

PRIVACY RULE REQUIREMENT	TASKS/DELIVERABLES	IMPACT OF PROPOSED MODIFICATIONS ON TASKS
<p><b>State Preemption: Sections 160.201- 160.205</b></p>	<p>Obtain state law preemption analysis and analysis of the interrelationship of the Privacy Rule with other applicable federal privacy laws</p>	<p><b>A preemption analysis is still necessary, but the NPRM would change some of the content of the analysis.</b> The proposed changes in the NPRM would affect the state law preemption analysis, particularly the provisions of the NPRM that eliminate the Consent requirement. (67 Fed. Reg. 14812).</p>
<p><b>Compliance and Enforcement: Sections 160.300-160.312</b></p>	<p>Designate a contact person within the organization to work with HHS/OCR in the event of an investigation or compliance review</p> <p>Develop response protocol in the event HHS/OCR initiates an investigation or compliance review</p>	<p><b>No changes</b></p> <p><b>No changes</b></p>
<p><b>General Rules Regarding Uses and Disclosures of PHI: Section 164.502</b></p>	<p>Develop policy describing generally permitted and required uses and disclosure of PHI</p>	<p><b>Covered entities must still develop, but the NPRM would require changes in this policy. As proposed:</b></p> <ul style="list-style-type: none"> <li>• Covered health care providers are not required to obtain the individual’s Consent prior to using and disclosing PHI for their own treatment, payment, or health care operations. Prop. Reg. §164.506 (67 Fed. Reg. 14812). Instead, the NPRM adds a requirement for direct treatment providers to obtain written “acknowledgement” of receipt of the Privacy Notice. See discussion pages 8-9. Prop. Reg. §164.520(c)(ii) (67 Fed. Reg. 14814).</li> <li>• Covered health care providers can choose to adopt a voluntary Consent process. Prop. Reg. §164.506(b) (67 Fed. Reg. 14812).</li> </ul> <p><b>New Task:</b> <i>providers must determine whether they wish to adopt such a practice.</i></p> <ul style="list-style-type: none"> <li>• Covered entities can share PHI for the treatment activities of another provider, and can disclose PHI to another health care provider or covered entity for the payment activities of that entity, regardless of whether or not the receiving provider is a covered entity. Covered entities can also disclose PHI for certain, quality-related health care operations of the receiving entity, but only to another covered entity and only if both entities have a relationship with the individual. Patient Consent is not required for these disclosures. Prop. Reg. §164.506(c) (67 Fed. Reg. 14812).</li> </ul> <p><b>New Task:</b> <i>if your organization discloses PHI to other organizations for their own purposes, under the NPRM you must determine whether the organizations are covered entities, and whether disclosures fit into a category of disclosures allowed without Consent.</i></p>
	<p>Develop minimum necessary policy and procedures that address (1) routine uses, disclosures and requests, and (2) non-routine uses, disclosures and requests:</p>	<p><b>The “minimum necessary” standard would remain in force under the NPRM, but the policy should incorporate certain minor changes in the application of this standard.</b></p>

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	<ul style="list-style-type: none"> <li>• For routine use, disclosures and requests, identify: the person needing access and why; the nature of the information required; the appropriate conditions/restrictions; and limit access accordingly.</li> <li>• For non-routine requests, uses and disclosures: develop criteria for individualized review.</li> </ul>	<ul style="list-style-type: none"> <li>• Disclosures in response to an Authorization would be exempted from the minimum necessary requirements. Prop. Reg. §164.502(b)(2)(iii) (67 Fed. Reg. 14811). Accidental disclosures (e.g., care-givers overheard discussing a patient) would not violate the Privacy Rule under the NPRM, if the covered entity has applied the reasonable safeguards listed in §164.530(c) and has implemented the minimum necessary standard where applicable. Prop. Reg. §164.502(a)(1)(iii) (67 Fed. Reg. 14811) The minimum necessary standard is otherwise unchanged.</li> </ul>
	<p>Develop policy and procedures on the use and disclosure of de-identified information that include methods to de-identify PHI, when de-identification is appropriate or necessary, and what qualifies as “de-identified”</p>	<p><b>No immediate changes, but changes to the “de-identification” standard may be forthcoming.</b></p> <ul style="list-style-type: none"> <li>• The NPRM does not modify the standards for “de-identifying” information, but HHS solicits comments on an alternative approach that would allow covered entities to use or disclose a limited data set which retains certain identifiers for research, public health, and health care operations, subject to certain conditions. (67 Fed. Reg. 14799).</li> </ul>
	<p>Develop policies and procedures regarding the creation or amendment of contracts with Business Associates, disclosures to Business Associates and the management of PHI in relation to Business Associates</p>	<p><b>The NPRM would grant a one-year extension to comply with the business associate requirement for existing written contracts.</b></p> <ul style="list-style-type: none"> <li>• The NPRM would allow covered entities (other than small health plans) up to an additional year to amend existing written contracts with business associates to meet the standards for business associate agreements, as long as the contracts at issue are not renewed or modified between the effective date of the regulations (estimated no later than 10/13/2002) and the compliance date of 4/14/2003. Prop. Reg. §164.532(d) (67 Fed. Reg. 14815).</li> <li>• Even if they are eligible for the extension, covered entities still must make PHI maintained or held by the business associate available to the individual and, in any enforcement action, to the Secretary. Prop. Reg. §164.532(e)(3) (67 Fed. Reg. 14815).</li> <li>• The NPRM Appendix includes a Model Business Associate Contract.</li> </ul> <p><b>New Task:</b> <i>analyze contracts to determine which would be eligible for the extension, and determine whether your organization will be able to obtain necessary information from the contractor in case of an enforcement action or a request by the individual. If you decide to take advantage of the extension, develop a procedure for monitoring which contracts are HIPAA compliant and which ones are not.</i></p>

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	Develop policy and procedures regarding health information of incapable patients and the designation and authority of personal representatives	No changes.
	Develop policy and procedures regarding uses and disclosures of PHI concerning health information of deceased individuals	No changes
	Develop policy and procedures regarding health information of minors	<p><b>The NPRM does not change the existing rule except in the situation where the parent is not the personal representative of the minor.</b></p> <ul style="list-style-type: none"> <li>Under the NPRM, in the rare instance where a parent is <i>not</i> the personal representative of a minor, a covered entity could provide to the parent access to the minor's PHI as if he or she <i>were</i> the personal representative, as long as such access is consistent with state law. Covered entities are not required to grant such access under the NPRM. Prop. Reg. §164.502(g)(3)(iii) (67 Fed. Reg. 14811).</li> </ul> <p><i><b>New Task:</b> based on a state law preemption analysis, determine whether it would be consistent with state law to allow a non-personal representative parent to have access to a minor's PHI, and develop the organization's policy for making such decisions.</i></p>
	Develop policy and procedures regarding restricted uses and disclosures and confidential communications	No changes
<b>Organizational Requirements: Section 164.504</b>	<p>Determine if the organization is a hybrid entity, and document hybrid designation and designation of health care components</p> <p>If the organization is a hybrid entity, develop policy and procedures (including safeguards) regarding shared workforce and the use and disclosure of PHI relating to the hybrid entity designation</p>	<p><b>Under the NPRM an organization can choose to be a hybrid entity regardless of the organization's proportion between covered and noncovered functions.</b></p> <ul style="list-style-type: none"> <li>Under the NPRM, any covered entity, if it is a single legal entity that performs both covered and noncovered functions, can choose whether or not it wants to be a hybrid entity. The NPRM eliminates the requirement that noncovered functions must represent that entity's "primary function" for the entity to be a hybrid entity. Prop. Reg. §164.504(a) (67 Fed. Reg. 14812).</li> <li>The NPRM also gives a hybrid entity more discretion in designating its "health care components," although any component that would be a covered entity were it a separate legal entity must be included within the hybrid's health care components. A hybrid entity's "health care component" can include the functions of a health care provider that does not engage in electronic billing, and components of the entity that perform business associate functions, if the hybrid entity chooses.</li> </ul>

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	Determine if the organization qualifies for and desires to be designated as an “affiliated covered entity”	<ul style="list-style-type: none"> <li>If the organization decides to designate itself a hybrid entity, the same documentation and safeguard requirements apply.</li> </ul> <p><b>No changes</b></p>
	If yes, draft Board resolutions and have Board adopt resolution documenting affiliated entities designation to determine other mechanism for designation	<b>No changes</b>
	Determine whether the organized health care arrangement (OHCA) designation applies to relationships with other covered entities in addition to the organization’s medical staff, and whether the organization will invoke the OHCA designation in those circumstances	<p><b>No changes.</b></p> <p>The NPRM expressly allows covered entities that participate in an OHCA to disclose PHI to each other for the OHCA’s health care operations activities. Prop. Reg. §164.506(c)(5) (67 Fed. Reg. 14812).</p>
	Draft Business Associate Addenda/Agreements for existing arrangements	See the discussion on page 2 regarding changes to the Business Associate requirements and the Model Contract included in the NPRM.
	Develop a process for tracking and assessing on an ongoing basis new business associate arrangements	<b>No changes</b> , except that the NPRM would allow a one year extension for written contracts that are not renewed or modified in the period between the effective date and the compliance date (see the discussion on page 2). In the short-term, any contract tracking process could incorporate tracking criteria relating to this possible extension.
	Designate a person responsible for overseeing Business Associate contracting negotiation and management	<b>No changes</b>
	Send addenda/agreements to existing business associates and ensure ongoing execution of addenda/agreements for new arrangements	<p><b>Under the NPRM, any addenda or modifications to existing contracts occurring after the effective date of the proposed modifications may disqualify that contract from the proposed one year extension.</b></p> <p>Covered entities should be aware of this possibility in negotiating with existing business associates. Prop. Reg. §164.532(e)(1)(ii) (67 Fed. Reg. 14815).</p>
	Develop policy and procedures for responding to contract violations by Business Associates	<b>No changes</b>



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	<p>Develop policy and procedures regarding when Authorizations are required and the process for obtaining an Authorization</p> <p>Develop Authorization form(s)</p>	<ul style="list-style-type: none"> <li>• As discussed on page 1, covered entities can disclose PHI to other health care providers and covered entities for certain of the receiving entities’ treatment, payment, and health care operations activities, without patient Consent. Therefore, the special authorization required under the current §164.508(e) for disclosures by other covered entities to the covered entity requesting the Authorization would be eliminated. Prop. Reg. §164.508 (67 Fed. Reg. 14813).</li> <li>• As discussed on page 2, under the NPRM the minimum necessary standard would not apply to disclosures pursuant to an Authorization for any purpose. Prop. Reg. §164.502(b)(2)(iii) (67 Fed. Reg. 14811).</li> <li>• The NPRM would change the requirements for Authorizations for marketing purposes. Authorizations would be needed for <i>all</i> marketing disclosures, except for face-to-face communications and promotional gifts of nominal value. Prop. Reg. §164.508(a)(3) (67 Fed. Reg. 14813). The NPRM would eliminate the exception to the authorization requirement in the current Privacy Rule for certain marketing activities of health-related products and services of the covered entity. (67 Fed. Reg. 14814).</li> </ul> <p><b>Under the NPRM, these policies would be modified to incorporate the changes discussed above.</b></p> <p><b>Under the NPRM, the form of Authorizations would change.</b></p> <ul style="list-style-type: none"> <li>• The “core elements” required for an Authorization would differ under the NPRM, although the “core elements” that are eliminated are simply turned into “required statements.” Prop. Reg. §16.508(c)(1) and (2) (67 Fed. Reg. 14813). Authorizations must also state that treatment, payment, enrollment or eligibility for benefits cannot be conditioned on the provision of an Authorization (except when the Privacy Rule permits such condition). Prop. Reg. §164. 508(c)(2)(ii) (67 Fed.Reg. 14813).</li> <li>• If the Authorization is for a marketing purpose and the marketing is expected to result in remuneration to the covered entity, the Authorization must so state. Prop. Reg. §164.508(a)(3)(ii) (67 Fed. Reg. 14813).</li> <li>• The “special” Authorizations required by §164.508(d) (Authorizations requested by a covered entity for its own uses), (e) (Authorizations requested by a covered entity for disclosures by others), and (f) (Authorizations for research that includes treatment) would be eliminated.</li> </ul>

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<p><b>Uses and Disclosures Requiring an Opportunity to Agree or Object: Section 164.510</b></p>	<p>Develop policies and procedures regarding use and disclosure of facility directory information to clergy and others; uses and disclosures regarding family/friends involved in care; uses and disclosures regarding disaster relief and related documentation requirements.</p>	<p><b>No changes</b></p>
<p><b>Uses and Disclosures for Which Consent, Authorization, or Opportunity to Agree or Object Not Required: Section 164.512</b></p>	<p>Develop policies and procedures concerning disclosures and uses regarding the following:</p>	
	<p>Required by law</p>	<p><b>No changes</b></p>
	<p>Public health activities</p>	<p>Under the NPRM, certain additional disclosures to companies or persons subject to the jurisdiction of the FDA would be permitted without an Authorization. Prop. Reg. §164(b)(1)(iii) (67 Fed. Reg. 14814).</p>
	<p>Victims of abuse, neglect or domestic violence</p>	<p><b>No changes</b></p>
	<p>Health oversight</p>	<p><b>No changes</b></p>
	<p>Judicial and Administrative Proceedings Subpoenas, Warrants, Summonses and Discovery Requests</p>	<p><b>No changes</b></p>
	<p>Law Enforcement</p>	<p><b>No changes</b></p>
	<p>Other permissible disclosure Medical examiners and funeral directors</p>	<p><b>No changes</b></p>
	<p>Organ and tissue donation</p>	<p><b>No changes</b></p>
	<p>Research</p>	<p><b>The NPRM would make changes in the process and criteria by which an Institutional Review Board (IRB) or privacy board can waive the authorization requirements.</b></p>
	<p>Serious threats to health or safety</p>	<p><b>No changes</b></p>
	<p>Specialized governmental functions</p>	<p><b>No changes</b></p>
	<p>Workers compensation</p>	<p><b>No changes</b></p>

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<p><b>Other Requirements Relating to Uses and Disclosures of PHI: Section 164.514</b></p>	<p>Develop policy and procedures regarding the de-identification of PHI and when de-identification is required/permissible (<u>see</u> duplicate reference on page 2 regarding requirements under Section 164.502)</p> <p>Develop minimum necessary policy and procedures (<u>see</u> duplicate reference on pages 1-2 regarding requirements under Section 164.502)</p> <p>Develop policy and procedures regarding uses and disclosures for marketing</p> <p>Develop policy and procedures regarding uses and disclosures for fundraising</p>	<p>See discussion on page 2 regarding possible future changes to the de-identification standard.</p> <p>See discussion on pages 1-2 regarding NPRM changes to the minimum necessary standard and its applicability.</p> <p>See discussion on page 6 regarding NPRM changes to the marketing rules.</p> <p><b>No changes</b></p>
<p><b>Notice of Privacy Practices for PHI: Section 164.520</b></p>	<p>Develop Notice of Privacy Practices. If appropriate, develop as joint Notice of Privacy Practices that includes your Medical Staff (and other covered entities in an OHCA, if applicable and desired). (If your organization is designated as an affiliated covered entity, the Notice should apply to the affiliated covered entities as well.)</p>	<p><b>The NPRM would require some changes both the content of the Notice of Privacy Practices and the process for distributing it.</b></p> <ul style="list-style-type: none"> <li>• Under the NPRM, providers with a direct treatment relationship must make a good faith effort to obtain written acknowledgement from patients of receipt of the privacy notice. Prop. Reg. §164.520(c)(2)(ii) (67 Fed. Reg. 14814).</li> <li>• The Notice must be provided at the time of first service delivery, except in emergency treatment situations.</li> <li>• Providers can choose the form of the acknowledgement that is “best suited to the entity’s practices and that will not pose an impediment to delivery of timely, quality health care.” (67 Fed. Reg. 14784).</li> <li>• Electronic notices are permitted. Prop. Reg. §164.520(c)(3). Any system that provides electronic notices as part of the first service delivery should be capable of capturing the individual’s acknowledgement of receipt electronically. (67 Fed. Reg. 14784).</li> <li>• Failure to get a signature acknowledging receipt of the Notice would not be a violation of the rule, assuming that the covered entity documented its good faith efforts and the reason for the failure.</li> </ul>

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		<i><b>New Task:</b> Under the NPRM, covered entities must develop policies and procedures to document their good faith efforts to obtain the written acknowledgement, and the reasons that any acknowledgements were not obtained.</i>
<b>Right to Request Special Privacy Protections for PHI: Section 164.522</b>	Develop policy and procedures regarding requested restrictions and confidential communications of PHI. Include a procedure and decision-making process for addressing such requests.	<b>No substantive changes.</b> The Preamble to the NPRM states that the proposed requirement of obtaining a written acknowledgement of receipt of the Privacy Notice would provide an opportunity for requesting such restrictions. (67 Fed. Reg. 14783).
	Develop appropriate forms for such requests	<b>No changes</b>
<b>Access of Individuals to PHI: Section 164.524</b>	Develop policy and procedures regarding requests for access by an individual to PHI	<b>No changes</b>
	Develop Access Request Form	<b>No changes</b>
<b>Amendment of PHI: Section 164.526</b>	Develop policy and procedures on requests for amendments to PHI Develop Amendment Request Form	<b>No changes</b> <b>No changes</b>
<b>Accounting of Disclosure of PHI: Section 164.528</b>	Develop policy and procedures /mechanisms for tracking and logging uses and disclosures for which an accounting may be requested and regarding an individual's right to an accounting	<b>Under the NPRM, covered entities would not have to account for disclosures made pursuant to an Authorization.</b> Policies and procedures developed would have to reflect this change. Prop. Reg. §164.528(a)(1)(iii) (67 Fed. Reg. 14815).
	Develop form regarding Request for an Accounting	<b>No changes</b>
<b>Administrative Requirements: Section 164.530</b>	Develop a privacy official job description	<b>No changes</b>
	Designate a privacy official	<b>No changes</b>
	Develop an internal complaint policy and procedures for documenting, investigating and resolving complaints.	<b>No changes</b>
	Designate a contact person or office for receiving complaints (can be the privacy official)	<b>No changes</b>
	Develop workforce training programs and educational tools	<b>No changes</b>

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	Develop a workforce training schedule for ongoing training to update knowledge, reinforce policies and practices, and emphasize the organization's commitment to patient privacy	<b>No changes</b>
	Assign personnel responsible for implementing trainings	<b>No changes</b>
	Develop a workforce certification form to be signed by each workforce member following training whereby the workforce member certifies that the member has been trained and understands his or her obligation to maintain the privacy of PHI in accordance with the organization's policies and procedures and the Privacy Rule	<b>No changes</b>
	Review employee handbooks and personnel policies and procedures to address Privacy Rule requirements as necessary	<b>No changes</b>
	Determine the appropriate administrative, technical and physical safeguards necessary to protect PHI and develop a schedule for implementing the safeguards	<b>Safeguards would still be necessary under the NPRM, and may serve to protect against liability for unintentional disclosures.</b>
	Contact and work with software vendors concerning necessary system protections	Under the NPRM, accidental uses and disclosures of PHI that are incident to otherwise permitted uses and disclosures will not violate the Privacy Rule as long as the covered entity has reasonably safeguarded PHI to limit such incidental uses or disclosures, and has implemented the minimum necessary standard. Prop. Reg. §164.502(a)(1)(iii); §164.530(c)(2)(ii) (67 Fed. Reg. 14811, 14815).
		<p><b><i>New Task:</i></b> <i>try to anticipate any disclosures that may be incidental to permitted uses and disclosures as your organization develops policies to implement the minimum necessary standard and safeguard the PHI that you maintain. The NPRM explains that mistaken or erroneous disclosures, or disclosures that result from a failure to reasonably safeguard information, will still violate the Privacy Rule. Thinking through potential "by-products" of the policies you adopt (such as, for example, if you continue to allow providers to discuss patient care issues in the hallway of your facilities where they could be overheard by other patients) can help your organization identify whether these disclosures are truly "incidental," or whether in reality they reasonably can be prevented</i></p>

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	Develop policy and procedures regarding workforce sanctions for violations of privacy policies and procedures	No changes
	Develop policy and procedure for timely investigations of alleged privacy violations, mitigation of the effects of a violation, and remediation of violations	No changes
	Develop policy and procedures (or incorporate into general policy regarding uses and disclosures) that protect an employee's or individual's right to file a complaint or report: <i>(1) internally regarding an alleged violation of the organization's privacy policies and procedures, or</i> <i>(2) with HHS/OCR</i>	No changes
	Develop policy and procedures regarding changes to your Notice of Privacy Practices and changes to your privacy policies and procedures to comply with changes in the law or changes within your organization. (see partial duplicate reference on pages 8-9 regarding requirements under Section 164.520)	No changes
	Draft policy and procedures regarding Privacy Rule documentation and retention requirements	<b>Under the NPRM, the documentation and retention policy would also include documenting efforts to obtain a written acknowledgement of the receipt of the Privacy Notice, and retaining such written acknowledgements.</b> See discussion on pages 8-9 about these proposed requirements. Prop. Reg. §164.520(e) (67 Fed. Reg. 14814).
<b>Transition Provision: Section 164.532</b>	Draft policy and procedures (or incorporate into general policy on uses and disclosures) concerning effect of and reliance on prior consents, authorizations, and similar documents concerning permission to use or disclose PHI.	<b>Transition policy and procedures would still be needed under the NPRM, and must reflect certain changes.</b>  <ul style="list-style-type: none"> <li>• New transition provisions regarding authorizations allow uses and disclosures pursuant to prior authorizations or express legal permission obtained before the compliance date if the permission specifically permits the use or disclosure and there are no agreed-to restrictions. Prop. Reg. §164.532(b) (67 Fed. Reg. 14815).</li> </ul>

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		<ul style="list-style-type: none"> <li>• The research transition provision is broadened to allow use and disclosure of PHI created and received before and after the compliance date in research studies (whether or not treatment is involved) if the individual expressly authorized the research use or disclosure before the compliance date or a waiver of authorization for the study was approved by an IRB. Prop. Reg. §164.532(c) (67 Fed. Reg. 14815).</li> <li>• A Consent would not be needed for uses and disclosures for treatment, payment and health care operations activities, and so the proposed regulation eliminates the transition provisions regarding disclosures for such activities based on preexisting Consent or other legal permission. (67 Fed. Reg. 14781).</li> <li>• The extension for compliance with the business associate agreement requirement (see discussion on page 2) is also contained in the transition provision. Prop. Reg. §164.532(e) (67 Fed. Reg. 14815).</li> </ul>
<b>No Correspondence Privacy Rule Section</b>	Review all existing policies, procedures, forms, medical staff bylaws and other documents that address use or disclosure of protected health information and update based on Privacy Rule.	<b>No changes</b>
<b>No Correspondence Privacy Rule Section</b>	Establish a HIPAA compliance program for the ongoing enforcement of privacy policies and procedure and monitoring of privacy compliance	<b>No changes</b>
<b>No Correspondence Privacy Rule Section</b>	Sponsor ongoing, informal HIPAA education sessions throughout implementation process	<b>No changes</b>
<b>No Correspondence Privacy Rule Section</b>	Meet with your insurer to discuss additional insurance needs, if any, and insurance issues pertaining to Privacy Rule compliance and business associates	<b>No changes</b>