

1.) The Privacy Rule (*Part 164, Subpart E*)

- § 164.500 – Applicability
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§ 164.500 – Applicability	The provisions of the Privacy Rule apply to covered entities with respect to protected health information, with some exceptions for health care clearinghouses. ¹	The Proposed Rule added a provision noting that, where provided, the provisions of the Privacy Rule apply to business associates with respect to protected health information of a covered entity. ²	Adopts as proposed. ³
§ 164.501 – Definitions, <i>health care operations</i>	<p><i>Health care operations</i> include six separate groups of activities carried out by a covered entity, to the extent that the activities are related to covered functions.⁴</p> <p>The third activity group includes “underwriting, premium rating, and other activities conducted by a covered entity relating to the creation, renewal or replacement of a contract of health insurance or health benefits...”⁵</p>	<p>The Proposed Rule added “patient safety activities” to the first group of health care operations activities.⁶</p> <p>The Proposed GINA Rule amended the third activity group by removing “underwriting” and adding the term “enrollment.”⁷</p>	<p>The Final Rule adopts the Proposed Rule’s addition.⁸</p> <p>The Final Rule does not remove the term “underwriting,” but adds a reference to the underwriting prohibition at § 164.502(a)(5)(i) to the third activity group; the Final Rule retains the addition of the term “enrollment.”⁹</p>
§ 164.501 – Definitions, <i>marketing</i>	The first paragraph of <i>marketing</i> includes “making a communication about a product or service that encourages recipients to purchase or use the product or service.” Three types of communications are excluded from this definition, and include communications	The Proposed Rule retained the first paragraph of <i>marketing</i> , but modified the excluded communications. The Proposed Rule combined the second and third exceptions into one exception that only applies when a health care provider is making the communication.	The Final Rule retains the proposed changes to <i>marketing</i> , with two modifications. The exception combining the second and third exceptions is moved so that it will also be considered <i>marketing</i> if the covered entity receives financial remuneration in

¹ 45 C.F.R. § 164.500 (2007).

² 75 Fed. Reg. at 40883-84.

³ 78 Fed. Reg. at 5695; 45 C.F.R. § 164.500(c).

⁴ 45 C.F.R. § 164.501, at “Health care operations” (2007).

⁵ 45 C.F.R. § 164.501, at ¶ (3) of “Health care operations” (2007).

⁶ 75 Fed. Reg. at 40884.

⁷ 74 Fed. Reg. at 51703.

⁸ 78 Fed. Reg. at 5592; 45 C.F.R. § 164.501, at ¶ (1) of “Health care operations.”

⁹ 78 Fed. Reg. at 5666; 45 C.F.R. § 164.501, at ¶ (3) of “Health care operations.”

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	<p>made: (i) to describe a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, the covered entity making the communication; (ii) for treatment of the individual; or (iii) for case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual.¹⁰</p> <p>The second paragraph of <i>marketing</i> includes the disclosure of protected health information from a covered entity to a third party, in exchange for direct or indirect remuneration, for use by the third party or its affiliate in marketing its own product or service.¹¹</p>	<p>The Proposed Rule added a qualification to this exclusion, so that if such communication is in writing and the provider receives financial remuneration, it is not <i>marketing</i> only if the requirements of § 164.514(f)(2) are met. The Proposed Rule added an additional exclusion for refill reminders or other communications about a current prescription if the financial remuneration the covered entity receives (if any) is limited to those costs that are reasonably related to the cost of making the communication.</p> <p>The Proposed Rule retained the first exclusion and added an additional exclusion: “contacting individuals with information about treatment alternatives for case management or care coordination and related functions to the extent these activities do not fall within the definition of treatment.” The Proposed Rule added that these two exclusions will be considered <i>marketing</i> if the covered entity receives financial remuneration in exchange for making the communication.¹²</p> <p>The Proposed Rule removed the second</p>	<p>exchange for making the communication. The Final Rule also removes the proposed qualification to this exclusion.¹⁵</p>

¹⁰ 45 C.F.R. § 164.501, at ¶ (1) of “Marketing” (2007).

¹¹ 45 C.F.R. § 164.501, at ¶ (2) of “Marketing” (2007).

¹² 75 Fed. Reg. at 40885-86.

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		<p>paragraph defining <i>marketing</i> as the disclosure of information for use by a third party in its own marketing.¹³</p> <p>The Proposed Rule defined <i>financial remuneration</i> as “direct or indirect payment from or on behalf of a third party whose product or service is being described.” Such payment does not include any payment for treatment.¹⁴</p>	
<p>§ 164.501 – Definitions, <i>underwriting purposes</i></p>	<p>The HIPAA rules do not define <i>underwriting purposes</i>.</p>	<p>The Proposed GINA Rule defined <i>underwriting purposes</i> with respect to a health plan as: (i) rules governing benefit determinations/eligibility for benefits, or the determination of benefits/eligibility for benefits (including enrollment, continued eligibility, and changes in deductibles or other cost-sharing mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program); (ii) premium or contribution calculations (including discounts, rebates, payments in kind, or other premium differential mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program); (iii) the application of any preexisting</p>	<p>The Final Rule adopts the proposed definition of <i>underwriting purposes</i>, but moves it to § 164.502(a)(5)(i), which is referred to as “the underwriting prohibition.”¹⁷</p>

¹⁵ 78 Fed. Reg. at 5595-97; 45 C.F.R. § 164.501, at “Marketing.”

¹³ 75 Fed. Reg. at 40887.

¹⁴ 75 Fed. Reg. at 40885.

¹⁷ 78 Fed. Reg. at 5665; 45 C.F.R. § 164.502(a)(5)(i).

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		<p>condition exclusion; and (iv) other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.</p> <p>The definition excludes determinations of medical appropriateness where an individual seeks a benefit under the plan, coverage, or policy.¹⁶</p>	
<p>§ 164.501 – Definitions, <i>payment</i></p>	<p><i>Payment</i> means the activities undertaken by: (i) a health plan to obtain premiums or to determine or fulfill its responsibility for coverage and provision of benefits; or (ii) a health care provider or health plan to obtain or provide reimbursement for the provision of health care.¹⁸</p>	<p>The Proposed GINA Rule added a reference to the underwriting prohibition to the definition of <i>payment</i>.¹⁹</p>	<p>Adopts as proposed.²⁰</p>
<p>§ 164.502 – Uses and disclosures of protected health information: general rules</p>	<p>This section identifies ten standards governing the general use or disclosure of protected health information, which apply to covered entities.</p> <p>The first standard prohibits a covered entity from using or disclosing protected health information, except as is permitted or required.²¹ The standard includes a provision listing six</p>	<p>The Proposed Rule applied the first standard to business associates, but did not apply the provisions listing the permitted or required disclosures, and changed the titles of those provisions to make clear that they apply only to covered entities.²⁸ The Proposed Rule added two provisions to the first standard. The first identifies the uses or disclosures a business associate is</p>	<p>The Final Rule adopts the Proposed Rule’s modifications to the first standard, with minor technical modifications.³⁵</p> <p>The Final Rule adopts the Proposed GINA Rule’s inclusion of an underwriting prohibition within the first standard, but modifies the language to exclude issuers of long-term care</p>

¹⁶ 74 Fed. Reg. at 51702-03.

¹⁸ 45 C.F.R. § 164.501, at ¶ (1) of “Payment” (2007).

¹⁹ 74 Fed. Reg. at 51703.

²⁰ 78 Fed. Reg. at 5666; 45 C.F.R. § 164.501, at ¶(1)(i) of “Payment.”

²¹ 45 C.F.R. § 164.502(a) (2007).

²⁸ 75 Fed. Reg. at 40887.

³⁵ 78 Fed. Reg. at 5598; 45 C.F.R. § 164.502(a).

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	<p>permitted disclosures, and a provision listing two required disclosures.</p> <p>The second standard requires that, when using or disclosing protected health information (or when requesting such information from another covered entity), a covered entity must make reasonable efforts to limit such information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.²² The minimum necessary standard does not apply to six specific uses and/or disclosures.</p> <p>The fifth standard applies to covered entities that choose to disclose protected health information to a business associate and/or allow a business associate to create or receive protected health information on its behalf, and requires such covered entities to obtain satisfactory assurances that its business associate will appropriately safeguard information.²³ This standard does not apply to three specific uses and/or disclosures.²⁴ A business associate that is itself a covered entity will be held responsible for complying with this</p>	<p>permitted to make (only as permitted or required by its contract or other arrangement or as required by law). A business associate is prohibited from uses or disclosures that would violate the Privacy Rule if done by the covered entity, except for the purposes specified in § 164.504(e)(2)(i)(A) or (B).²⁹ The second added provision identified two disclosures a business associate is required to make (when required by the Secretary under the Enforcement Rule and to the covered entity, individual, or individual’s designee, as necessary to satisfy the covered entity’s obligations under § 164.524(c)(2)(ii) and (3)(ii)).³⁰</p> <p>The Proposed GINA Rule added a provision to the first standard that prohibits health plans from using or disclosing protected health information that is genetic information for underwriting purposes.³¹</p> <p>The Proposed Rule applied the second standard to business associates to the same extent it applies to covered entities.³²</p> <p>The Proposed Rule modified the fifth</p>	<p>policies, and moves the definition of “underwriting purposes” as proposed by the GINA rule at § 164.501 to this standard, which is referred to as “the underwriting prohibition.”³⁶</p> <p>The Final Rule also adds a general prohibition on the sale of protected health information by a covered entity or business associate, except where the covered entity obtains an authorization in accordance with § 164.508(a)(4).³⁷ The Final Rule defines <i>sale of protected health information</i> as a disclosure of protected health information by a covered entity or business associate in exchange for direct or indirect remuneration from or on behalf of the recipient.³⁸ The Final Rule moves exceptions to <i>sale of protected health information</i> from proposed § 164.508(a)(4)(ii) to this provision.³⁹</p> <p>The Final Rule adopts the modifications to the second,⁴⁰ fifth,⁴¹ and sixth standards⁴² as proposed.</p>

²² 45 C.F.R. § 164.502(b)(1) (2007).
²³ 45 C.F.R. § 164.502(e)(1)(i) (2007).
²⁴ 45 C.F.R. § 164.502(e)(1)(ii) (2007).

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	<p>standard, and with § 164.504(e), as a covered entity.²⁵ A covered entity must document the required satisfactory assurances through a written contract or other agreement/arrangement with the business associate that meets the requirements of § 164.504(e).²⁶ The sixth standard requires covered entities to comply with the Privacy Rule with respect to protected health information of a deceased individual.²⁷</p>	<p>standard by specifying that a covered entity is not required to obtain assurances from a subcontractor, and adding a provision requiring a business associate to obtain satisfactory assurances that a subcontractor will appropriately safeguard information. The Proposed Rule removed the provision excluding three specific uses/disclosures (and relocated these exclusions to the revised definition of “business associate” at § 160.103). It also removed the provision holding a business associate responsible for compliance with this standard as a covered entity.³³ The Proposed Rule applied the documentation requirement to business associates in the same manner as it applies to covered entities.</p>	

²⁹ This section governs uses and disclosures for organizational requirements; these provisions permit the use and disclosure of protected health information for the proper management and administration of the business associate, or to provide data aggregation services relating to the health care operations of the covered entity (45 C.F.R. § 164.504(e)(2)(i)(A), (B) (2007)).

³⁰ 75 Fed. Reg. at 40887.

³¹ 74 Fed. Reg. at 51703-04.

³² 75 Fed. Reg. at 40887 – 88.

³⁶ 78 Fed. Reg. at 5666-67; 45 C.F.R. § 164.502(a)(5)(i).

³⁷ 78 Fed. Reg. at 5606; 45 C.F.R. § 164.502(a)(5)(ii)(A).

³⁸ 78 Fed. Reg. at 5606; 45 C.F.R. § 164.502(a)(5)(ii)(B)(1).

³⁹ 78 Fed. Reg. at 5606; 45 C.F.R. § 164.502(a)(5)(ii)(B)(2) (the Proposed Rule describes these exceptions at 75 Fed. Reg. at XX).

⁴⁰ 75 Fed. Reg. at 5599; 45 C.F.R. § 164.502(b)(1).

⁴¹ 75 Fed. Reg. at 5601; 45 C.F.R. § 164.502(e).

⁴² 75 Fed. Reg. at 5614; 45 C.F.R. § 164.502(f).

²⁵ 45 C.F.R. § 164.502(e)(1)(iii) (2007).

²⁶ 45 C.F.R. § 164.502(e)(2) (2007).

²⁷ 45 C.F.R. § 164.502(f) (2007).

³³ 75 Fed. Reg. at 40888.

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		<p>The Proposed Rule modified the sixth standard such that it no longer applies 50 years after the death of the individual.³⁴</p>	
<p>§164.504 – Uses and disclosures: Organizational requirements</p>	<p>This section identifies three organizational requirement standards that covered entities must satisfy.</p> <p>The first standard sets forth the requirements for business associate contracts and other arrangements.⁴³ If a covered entity knows of a material breach or violation of the business associate’s obligation under the contract or other arrangement, it must take certain steps to deal with the violation.⁴⁴ If such steps are unsuccessful, the covered entity must terminate the contract if feasible;⁴⁵ if termination is not feasible, the covered entity must report the problem to the Secretary.⁴⁶</p> <p>A covered entity with a business associate contract satisfies the “business associate contract” standard when the contract includes three specific provisions, including that the business</p>	<p>The Proposed Rule made several modifications to the first standard. It removed the provision requiring a covered entity to report to the Secretary if termination of the contract or arrangement is not feasible.⁵⁵ It added a provision requiring business associates to deal with material breaches or violations by its subcontractors in the same manner as covered entities are required to deal with breaches or violations by their business associates.⁵⁶</p> <p>The Proposed Rule made the following modifications to the requirements a business associate must agree to meet: expanded requirement (B), such that a business associate must comply with the Security Rule where applicable; added to requirement (C), specifying that business associates must report breaches of unsecured protected health information as required; and modified requirement (D) to “ensure that any</p>	<p>Adopts the Proposed Rule’s modifications.⁶⁰</p> <p>The Final Rule adds that a covered entity satisfies the “business associate contract” standard and § 164.314(a)(1) if it discloses only a limited data set for the business associate to carry out a health care operations function and it has a data use agreement that complies with § 164.514(e)(4), and § 164.314(a)(1), if applicable.</p> <p>Adopts the Proposed GINA Rule’s modifications.⁶¹</p>

³⁴ 75 Fed. Reg. at 40894-95.

⁴³ 45 C.F.R. § 164.504(e)(1)(i) (2007).

⁴⁴ 45 C.F.R. § 164.504(e)(1)(ii) (2007).

⁴⁵ 45 C.F.R. § 164.504(e)(1)(ii)(A) (2007).

⁴⁶ 45 C.F.R. § 164.504(e)(1)(ii)(B) (2007).

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	<p>associate agrees to satisfy nine requirements.⁴⁷ Some of these requirements include: (B) use appropriate safeguards to prevent use or disclosure of the information other than as provided for by its contract;⁴⁸ (C) report to the covered entity any use or disclosure of the information not provided for by its contract of which it becomes aware;⁴⁹ and (D) ensure that any agents to whom the business associate provides protected health information it receives from a covered entity or that it creates or receives on behalf of the covered entity, agree to the same restrictions and conditions that apply to the business associate with respect to such information.⁵⁰</p> <p>If a covered entity and its business associate are both governmental entities and have an arrangement other than a business associate contract, the covered entity satisfies the “business associate contract” standard: (A) by entering into</p>	<p>subcontractors that create or receive protected health information on behalf of the business associate agree to the same restrictions and conditions that apply to the business associate with respect to such information.”⁵⁷</p> <p>The Proposed Rule added a tenth requirement that a business associate must agree to satisfy: “to the extent the business associate is to carry out a covered entity’s obligation under the Privacy Rule, [the business associate must] comply with the requirements of the Privacy Rule that apply to the covered entity in the performance of such obligation.”</p> <p>The Proposed Rule modified the “other arrangement” requirement applicable to government entities, such that the covered entity also satisfies § 164.314(a)(1) if the memorandum of understanding or other law accomplishes the objectives of the</p>	

⁵⁵ 75 Fed. Reg. at 40888.

⁵⁶ 75 Fed. Reg. at 40888 – 89.

⁶⁰ 78 Fed. Reg. at 5601; 45 C.F.R. § 164.504(e).

⁶¹ 78 Fed. Reg. at 5667; 45 C.F.R. § 164.504(f)(1)(ii).

⁴⁷ 45 C.F.R. § 164.504(e)(2) (2007).

⁴⁸ 45 C.F.R. § 164.502(e)(2)(ii)(B) (2007).

⁴⁹ 45 C.F.R. § 164.504(e)(2)(ii)(C) (2007).

⁵⁰ 45 C.F.R. § 164.504(e)(2)(ii)(D) (2007).

⁵⁷ 75 Fed. Reg. at 40889.

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	<p>a memorandum of understanding with the business associate that contains terms that accomplish the objectives of the three required contract provisions; or (B) when other law contains requirements applicable to the business associate that accomplish the objectives of the required provisions.⁵¹</p> <p>If a business associate is required by law to perform a function or activity on behalf of a covered entity or to provide a “business associate service” to a covered entity, the covered entity may disclose protected health information to the extent necessary to comply with the legal mandate without meeting the requirements of the “business associate contract” standard, if the covered entity attempts in good faith to obtain satisfactory assurances, and, if such attempt fails, documents the attempt and the reasons that such assurances cannot be obtained.⁵²</p> <p>The second standard sets forth requirements for group health plans and issuers.⁵³ The group health plan may disclose summary health information to the plan sponsor when the plan sponsor</p>	<p>required contract provisions and the objectives of 164.314(a)(2), if applicable.</p> <p>The Proposed Rule modified the provision applicable when a business associate is required by law to perform a function or activity on behalf of a covered entity, such that a covered entity also need not meet the requirements of § 164.314(a)(1) if it attempts in good faith to obtain satisfactory assurances as required by both this section and § 164.314(a)(1), and properly documents the attempt and reasons the assurances cannot be obtained.⁵⁸</p> <p>The Proposed Rule added a provision applying the requirements of § 164.504(e)(2) through (e)(4) to the contract or other arrangement between a business associate and its subcontractor in the same manner as such requirements apply to contracts or other arrangements between a covered entity and business associate.</p> <p>The Proposed GINA Rule added a</p>	

⁵¹ 45 C.F.R. § 164.504(e)(3)(i) (2007).

⁵² 45 C.F.R. § 164.504(e)(3)(ii) (2007).

⁵³ 45 C.F.R. § 164.504(f)(1)(i) (2007).

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	requests such information for one of two specific purposes. ⁵⁴	reference to the underwriting prohibition such that group health plans and issuers may not disclose genetic information that is protected health information for underwriting purposes when disclosing summary health information to a plan sponsor. ⁵⁹	
§ 164.506 – Uses and disclosures to carry out treatment, payment, or health care operations	<p>This section describes the uses and disclosures a covered entity is permitted to make to carry out treatment, payment, or health care operations; this section does not apply to uses or disclosures that require an authorization.⁶²</p> <p>One of the permitted uses and disclosures applies when a covered entity participates in an organized health care arrangement, in which case such covered entity may disclose information to another covered entity that participates in the organized health care arrangement for any of the organized health care arrangement’s health care operations activities.⁶³</p>	<p>The Proposed GINA Rule added a reference to the underwriting prohibition to make clear that covered entities may not use or disclose protected health information that is genetic information for underwriting purposes, even if such a use or disclosure is considered payment or health care operations.⁶⁴</p> <p>The Proposed Rule modified the circumstances in which a covered entity that participates in an organized health care arrangement may disclose protected health information about an individual, such that the covered entity may disclose the information to “other participants” in the arrangement. This change reflects the fact that entities</p>	<p>Adopts the Proposed GINA Rule’s modification.⁶⁶</p> <p>Adopts the Proposed Rule’s modification.⁶⁷</p>

⁵⁸ 75 Fed. Reg. at 40888-89.

⁵⁴ 45 C.F.R. § 164.504(f)(1)(ii) (2007).

⁵⁹ 74 Fed. Reg. at 51704.

⁶² 45 C.F.R. § 164.506(a) (2007).

⁶³ 45 C.F.R. § 164.508(c)(5) (2007).

⁶⁴ 74 Fed. Reg. at 51704.

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<p>§ 164.508 – Uses and disclosures for which authorization is required</p>	<p>This section prohibits uses or disclosures of protected health information without a valid authorization, unless such use or disclosure is otherwise permitted under the Privacy Rule.⁶⁸</p> <p>With limited exceptions, authorizations are required for the use or disclosure of psychotherapy notes⁶⁹ and for the use or disclosure of information for marketing.⁷⁰ The section identifies the elements of a valid authorization,⁷¹ and lists five defects that make an authorization invalid.⁷²</p> <p>An authorization for a research study may be combined with any other type of written permission for the same research study, including another authorization for such research or a consent to participate in such research.⁷³</p>	<p>other than covered entities participate in organized health care arrangements.⁶⁵</p> <p>The Proposed Rule required covered entities to obtain an authorization for the sale of protected health information. The authorization must state that the covered entity will receive remuneration in exchange for disclosing the protected health information.⁷⁵ The Proposed Rule added exceptions to this requirement. Covered entities do not need to obtain an authorization to sell protected health information for: (A) public health purposes; (B) research purposes, where the only remuneration received is a reasonable cost-based fee to cover the cost to prepare and transmit the information; (C) for treatment and payment purposes; (D) for the sale, transfer, merger, or consolidation of all or part of the covered entity and for related due diligence; (E) to or by a business associate for activities that it undertakes on behalf of a covered</p>	<p>The Final Rule notes that the requirement for covered entities to obtain an authorization for the sale of protected health information does not apply as provided by the transition provisions in § 164.532. The Final Rule modifies proposed exception (E) so that it also applies to disclosure of protected health information to or by a subcontractor for activities it undertakes on behalf of a business associate. The Final Rule then moves all eight proposed exceptions (as modified) to § 164.502(a)(5)(ii) as exclusions from the definition of <i>sale of protected health information</i>.⁸²</p> <p>The Final Rule adopts all other proposed modifications.⁸³</p>

⁶⁶ 78 Fed. Reg. at 5667; 45 C.F.R. § 164.506(a).

⁶⁷ 78 Fed. Reg. at 5698; 45 C.F.R. § 164.506(c)(5).

⁶⁵ 75 Fed. Reg. at 40904.

⁶⁸ 45 C.F.R. § 164.508(a)(1) (2007).

⁶⁹ 45 C.F.R. § 164.508(a)(2) (2007).

⁷⁰ 45 C.F.R. § 164.508(a)(3) (2007).

⁷¹ 45 C.F.R. § 164.508(b)(1) (2007).

⁷² 45 C.F.R. § 164.508(b)(2) (2007).

⁷³ 45 C.F.R. § 164.508(b)(3)(i) (2007).

⁷⁵ 75 Fed. Reg. at 40890 – 91.

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	<p>An authorization (other than for the use or disclosure of psychotherapy notes) may be combined with any other authorization under this section, except when a covered entity has conditioned the provision of treatment, payment, enrollment in the health plan, or eligibility for benefits on the provision of one of the authorizations.⁷⁴</p>	<p>entity, if the only remuneration provided is by the covered entity to the business associate for the performance of such activities;⁷⁶ (F) to the individual, when requested;⁷⁷ (G) as required by law; and (H) permitted by and in accordance with the applicable requirements of the Privacy Rule, where the only remuneration received by the covered entity is a reasonable, cost-based fee to cover the cost to prepare and transmit the information for such purpose, or a fee otherwise expressly permitted by law.⁷⁸</p> <p>The Proposed Rule modified the provision permitting covered entities to combine authorizations for the use or disclosure of protected health information for research purposes. The Proposed Rule added that an authorization for a research study may be combined with an authorization for the creation or maintenance of a research database or repository.⁷⁹ It also added that where a covered health care provider conditions the provision of</p>	

⁸² 78 Fed. Reg. at 5606 - 07; 45 C.F.R. § 164.508(a)(4) (see exceptions and general prohibition on the sale of protected health information at 45 C.F.R. § 164.502(a)(5)(ii)(B)).

⁸³ 78 Fed. Reg. at 5610 - 11; 45 C.F.R. § 164.508(b)(3).

⁷⁴ 45 C.F.R. § 164.508(b)(3)(iii) (2007).

⁷⁶ 75 Fed. Reg. at 40891.

⁷⁷ 75 Fed. Reg. at 40891 - 92.

⁷⁸ 75 Fed. Reg. at 40892.

⁷⁹ 75 Fed. Reg. at 40892.

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		<p>research-related treatment on the provision of an authorization, any compound authorization must clearly differentiate between the conditioned and unconditioned components, and allow the individual to opt in to activities described in the unconditioned authorization.⁸⁰</p> <p>The Proposed Rule also modified the provision permitting compound authorizations except where the covered entity has conditioned treatment, payment, enrollment or eligibility on provision of one of the authorizations. The Proposed Rule adds that this prohibition does not apply to a compound authorization created for research purposes as described.⁸¹</p>	
<p>§ 164.510 – Uses and disclosures requiring an opportunity for the individual to agree or to object</p>	<p>This section sets forth uses and disclosures about which an individual must be informed in advance and given an opportunity to agree or to prohibit or restrict the use or disclosure.⁸⁴</p> <p>Except when an objection is expressed, a covered health care provider may disclose certain protected health</p>	<p>The Proposed Rule added that a covered health care provider may also use information for directory purposes.⁸⁹</p> <p>The Proposed Rule adds that when an individual is not present (or an opportunity to agree or object cannot practicably be provided), a covered entity may also disclose information to</p>	<p>Adopts as proposed.⁹²</p>

⁸⁰ 75 Fed. Reg. at 40893.

⁸¹ 75 Fed. Reg. at 40892.

⁸⁴ 45 C.F.R. § 164.510 (2007).

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	<p>information for facility directory purposes.⁸⁵</p> <p>A covered entity may disclose protected health information about an individual to his or her relative, close personal friend, or any other person he or she identifies, to the extent that such information is directly relevant to the person’s involvement with the individual’s health care or payment related to the individual’s health care,⁸⁶ or as is needed to notify such person about the individual’s location, general condition, or death.⁸⁷ Prior to the disclosure, the covered entity must obtain the individual’s agreement to the disclosure, provide the individual an opportunity to object, or reasonably infer that the individual does not object. If the individual is not present (or the opportunity to agree or object cannot practicably be provided), the covered entity may only disclose protected health information to the extent that it is directly relevant to the person’s involvement with the individual’s health care if it determines that such</p>	<p>the extent that it is directly relevant to the person’s involvement with payment related to the individual’s health care or as needed for notification purposes.⁹⁰</p> <p>The Proposed Rule adds a new provision such that if an individual is deceased, a covered entity may disclose information to the individual’s relative, close personal friend, or other person identified by the individual who was involved in the individual’s care or payment for health care prior to the individual’s death. A covered entity may not provide such information if it knows that the individual had expressed that he or she did not want such information disclosed.⁹¹</p>	

⁸⁹ 75 Fed. Reg. at 40904.

⁹² 78 Fed. Reg. at 5615; 45 C.F.R. § 164.510.

⁸⁵ 45 C.F.R. § 164.510(a)(1)(ii) (2007).

⁸⁶ 45 C.F.R. § 164.508(b)(1)(i) (2007).

⁸⁷ 45 C.F.R. § 164.508(b)(1)(ii) (2007).

Provision	HIPAA Requirements	Proposed/Interim Final Rules	Final Rule
	disclosure is in the individual’s best interests. ⁸⁸		
§ 164.512 – Uses and disclosures for which an authorization or opportunity to agree or object is not required	<p>This section sets forth the situations in which a covered entity may use or disclose protected health information without obtaining an authorization or providing an opportunity for the individual to agree or object.⁹³</p> <p>Among other purposes, a covered entity may disclose protected health information to certain entities for public health activities and purposes.⁹⁴</p>	<p>The Proposed Rule added that a covered entity may disclose proof of immunization information to a school about an individual who is a student or prospective student at such school, if a the law requires the school to have such proof prior to admitting the individual. The covered entity must first obtain agreement to the disclosure from the individual (if the individual is an adult or emancipated minor), or from the individual’s parent, guardian, or other person legally acting in place of the individual’s parent..⁹⁵</p>	<p>The Final Rule adopts the Proposed Rule’s modifications, but requires that the covered entity to document the consent to the disclosure.⁹⁶</p>
§ 164.514 – Other requirements relating to uses and disclosures of protected health information	<p>This section sets forth requirements for several uses and disclosures of protected health information not discussed in other sections.</p> <p>A covered entity may, without an authorization and for the purpose of raising funds for its own benefit, use or disclose to a business associate or to an institutionally related foundation the following information: demographic</p>	<p>The Proposed Rule modified the requirements a covered entity must follow to comply with the fundraising authorization provision: (1) include in its notice of privacy practices a statement that it may contact individuals to raise funds for the covered entity as required by § 164.520(b)(1)(iii)(A); (2) in each fundraising communication sent to an individual, provide the individual with “a clear and conspicuous</p>	<p>The Final Rule adopts the proposed fundraising provision and adds that the covered entity may also use or disclose the following information: department of service information, treating physician, outcome information, and health insurance status, and that demographic information relating to an individual may include name, address, other contact information, age, gender, and date of birth.¹⁰⁵ The Final Rule</p>

⁹⁰ 75 Fed. Reg. at 40904.

⁹¹ 75 Fed. Reg. at 40895.

⁸⁸ 45 C.F.R. § 164.510(b)(3) (2007).

⁹³ 45 C.F.R. § 164.512 (2007).

⁹⁴ 45 C.F.R. § 164.512(b)(1) (2007).

⁹⁵ 75 Fed. Reg. at 40895.

⁹⁶ 78 Fed. Reg. at 5617; 45 C.F.R. § 164.512(b)(vi).

Provision	HIPAA Requirements	Proposed/Interim Final Rules	Final Rule
	<p>information relating to an individual, and dates of health care provided to an individual.⁹⁷ There are three requirements a covered entity must follow to comply with the fundraising standard: (1) include a statement as required in §164.520(b)(1)(iii)(B) in its notice;⁹⁸ (2) include in any fundraising materials it sends to an individual a description of how the individual may opt out of receiving any further fundraising communications;⁹⁹ and (3) make reasonable efforts to ensure that individuals who decide to opt out of receiving future fundraising communications are not sent such communications.¹⁰⁰</p> <p>A health plan that receives protected health information about an individual for the purpose of underwriting, premium rating, or other activities relating to the creation, renewal, or replacement of a contract of health insurance or health benefits, but that does not include the insurance or benefits within the plan, may only use</p>	<p>opportunity” to opt out of receiving future fundraising communications. The opt-out method may not cause the individual to incur an undue burden or more than a nominal cost; and (3) where the individual has opted out, the covered entity is prohibited from sending fundraising communications. The Proposed Rule adds a fourth requirement prohibiting covered entities from conditioning provision of treatment or payment on an individual’s decision to opt in or out of fundraising communications.¹⁰²</p> <p>The Proposed Rule also added an exception for uses and disclosures for remunerated treatment communications if certain requirements are met.¹⁰³</p> <p>The Proposed GINA Rule modified the standard for uses and disclosures for underwriting and related purposes by changing the title of the standard to “uses and disclosures for activities relating to the creation, renewal, or replacement of a contract of health</p>	<p>adds a fifth provision allowing a covered entity to provide an individual who has elected not to receive further fundraising communications with a method to opt back in.¹⁰⁶</p> <p>The Final Rule does not adopt the proposed inclusion of an exception for uses and disclosures for remunerated treatment communications.¹⁰⁷</p> <p>The Final Rule does not adopt the Proposed GINA rule’s suggested title change or removal of the term “underwriting,” but does adopt the reference to the underwriting prohibition as proposed.¹⁰⁸</p>

¹⁰⁵ 78 Fed. Reg. at 5622; 45 C.F.R. § 164.514(f).

⁹⁷ 45 C.F.R. § 164.514(f)(1) (2007).

⁹⁸ 45 C.F.R. § 164.514(f)(2)(i) (2007).

⁹⁹ 45 C.F.R. § 164.514(f)(2)(ii) (2007).

¹⁰⁰ 45 C.F.R. § 164.514(f)(2)(iii) (2007).

Provision	HIPAA Requirements	Proposed/Interim Final Rules	Final Rule
	or disclose such information as required by law. ¹⁰¹	insurance or health benefits,” removing the term “underwriting,” and adding that the exception for a use or disclosure as required by law is subject to the underwriting prohibition. ¹⁰⁴	
§ 164.520 – Notice of privacy practices for protected health information	<p>An individual has a right to adequate notice of the uses and disclosures of protected health information that may be made by the covered entity and of the individual’s rights and the covered entity’s legal duties with respect to such information.¹⁰⁹</p> <p>This section identifies the content that must be included in the notice. The notice must describe the uses and disclosures the covered entity is permitted or required to make for treatment, payment, and health care operations,¹¹⁰ and for all other purposes without the individual’s written authorization.¹¹¹ The notice must include the following statements: uses and disclosures [other than those</p>	<p>The Proposed Rule modified some of the provisions describing the required content of the notice. In addition to the required statements that other uses and disclosures require authorization and that individuals may revoke an authorization, covered entities must describe the types of uses and disclosures that require an authorization.</p> <p>The Proposed Rule modified the provision requiring a covered entity to inform individuals if it intends to engage in certain activities. Statement (A) is modified so that it only applies to health care providers, who must inform the individual (as applicable) that they may send communications “concerning</p>	<p>The Final Rule adopts most of the Proposed Rule’s modifications to the content requirements, but omits statement (A) (both the proposed modification and the original).¹¹⁹</p> <p>The Final Rule accepts the Proposed GINA Rule’s addition of a statement about underwriting purposes, but adds that the provision does not apply to issuers of long-term care policies.¹²⁰</p> <p>The Final Rule also modifies the provision requiring a description of the covered entity’s duties, by adding that a covered entity must include in the statement about its legal duties that it is required to notify affected individual’s following a breach of unsecured</p>

¹⁰² 75 Fed. Reg. at 40896-97.

¹⁰³ 75 Fed. Reg. at 40884 – 86.

¹⁰⁶ 78 Fed. Reg. at 5621; 45 C.F.R. § 164.514(f)(2)(v).

¹⁰⁷ 78 Fed. Reg. at 5596.

¹⁰⁸ Final Rule, p. 411.

¹⁰¹ 45 C.F.R. § 164.514(g) (2007).

¹⁰⁴ 74 Fed Reg 51704 (2009).

¹⁰⁹ 45 C.F.R. § 164.520(a)(1) (2007).

¹¹⁰ 45 C.F.R. § 164.520(b)(1)(ii)(A) (2007).

¹¹¹ 45 C.F.R. § 164.520(b)(1)(ii)(B) (2007).

Provision	HIPAA Requirements	Proposed/Interim Final Rules	Final Rule
	<p>specified] require the individual’s written authorization, and the individual may revoke such authorization as provided by § 164.508(b)(5).¹¹²</p> <p>If a covered entity intends to engage in certain activities, it must include a separate statement to that effect (within the description of the types of uses and disclosures the entity is permitted to make for treatment, payment, and health care operations), as applicable. The statements include: (A) the covered entity may contact the individual to provide appointment reminders or information about treatment alternatives or other health-related benefits and services that may be of interest to the individual; (B) the covered entity may contact the individual to raise funds for the covered entity; or (C) a group health plan or issuer may disclose protected health information to the sponsor of the plan.¹¹³</p>	<p>treatment alternatives or other health-related products or services,” for which the provider receives financial remuneration, and that the individual has the right to opt-out of receiving such communications. Statement (B) is modified so that the covered entity must state that the individual has a right to opt out of receiving [fundraising] communications.¹¹⁷</p> <p>The Proposed GINA Rule also modified this provision by adding that if a covered health plan intends to use or disclose protected health information for underwriting purposes, it must include in their notice statement (D): the covered entity is prohibited from using or disclosing protected health information that is genetic information of an individual for underwriting purposes.¹¹⁸</p> <p>Within the provision requiring a statement of the individual’s right to</p>	<p>protected health information.¹²¹</p> <p>The Final Rule adds a new paragraph within the requirements for health plans. When there is a material change to the notice, a health plan that currently post its notice on its web site must prominently post the change or its revised notice on its web site by the effective date of the material change to the notice, and provide the revised notice, or information about the material change and how to obtain the revised notice, in its next annual mailing to individuals then covered by the plan.¹²² A health plan that does not post its notice on a web site must provide the revised notice, or information about the material change and how to obtain the revised notice, to individuals then covered by the plan within 60 days of the material revision to the notice.¹²³</p>

¹¹⁹ 78 Fed. Reg. at 5624 - 25; 45 C.F.R. § 164.520(b)(1).

¹²⁰ 78 Fed. Reg. at 5668; 45 C.F.R. § 164.520(b)(1)(iii)(C).

¹¹² 45 C.F.R. § 164.520(b)(1)(ii)(E) (2007).

¹¹³ 45 C.F.R. § 164.520(b)(1)(iii) (2007).

¹¹⁷ 75 Fed. Reg. at 40897-98.

¹¹⁸ 74 Fed. Reg. at 51704.

¹²¹ 78 Fed. Reg. at 5624 -25; 45 C.F.R. § 164.520(b)(1)(v)(A).

¹²² 78 Fed. Reg. at 5625; 45 C.F.R. § 164.520(c)(1)(v)(A).

¹²³ 78 Fed. Reg. at 5625; 45 C.F.R. § 164.520(c)(1)(v)(B).

Provision	HIPAA Requirements	Proposed/Interim Final Rules	Final Rule
	<p>The notice must describe the individual’s rights with respect to protected health information and how the individual may exercise these rights, including the right to request restrictions on certain uses and disclosures of protected health information as provided by § 164.522(a), including a statement that the covered entity is not required to agree to a requested restriction.¹¹⁴</p> <p>The notice must also describe the covered entity’s duties, including a statement that the covered entity is required by law to maintain the privacy of protected health information and to provide individuals with notice of its legal duties and privacy practices with respect to protected health information.¹¹⁵</p> <p>This section also sets forth requirements governing provision of notice, including specific requirements for health plans.¹¹⁶</p>	<p>request restrictions, the Proposed Rule modified the statement that a covered entity is not required to agree to a requested restriction by adding that it must agree to such request when the is disclosure restricted under §164.522(a)(1).</p>	
<p>§ 164.522 – Rights to request privacy protection for protected</p>	<p>A covered entity must permit an individual to request that the covered entity restrict the use or disclosure of the individual’s protected health information for purposes of treatment,</p>	<p>The Proposed Rule adds a provision to this section requiring covered entities to agree to an individual’s request to restrict disclosure of his or her protected health information to a health plan if:</p>	<p>Adopts as proposed.¹²⁹</p>

¹¹⁴ 45 C.F.R. § 164.520(b)(iv)(A) (2007).

¹¹⁵ 45 C.F.R. § 164.520(b)(1)(v)(A) (2007).

¹¹⁶ 45 C.F.R. § 164.520(c)(1) (2007).

Provision	HIPAA Requirements	Proposed/Interim Final Rules	Final Rule
health information	<p>payment, or health care operations, or for involvement in the individual’s care, payment for care, or notification.¹²⁴ A covered entity is not required to agree to a [requested] restriction.¹²⁵ If a covered entity does choose to agree to a restriction, it must comply with certain requirements.¹²⁶</p> <p>A covered entity may terminate its agreement to a restriction if it meets certain requirements, including informing the individual that it is terminating its agreement to a restriction, and noting that such termination only applies to protected health information created or received after it has so informed the individual.¹²⁷</p>	<p>(A) the disclosure is for the purpose of carrying out payment or health care operations and is not otherwise required by law; and (B) the information pertains solely to a health care service or item paid for in full by either the individual or a third party on behalf of the individual other than the health plan.</p> <p>The Proposed Rule also modified the provision governing termination of a restriction, such that when the covered entity informs the individual that it is terminating its agreement to a restriction, it must also note that such termination does not apply to information it is required to restrict (i.e., to a health plan as described above).¹²⁸</p>	
§ 164.524 – Access of individuals to protected health information	<p>An individual has the right, with limited exceptions, to inspect and obtain a copy of his or her protected health information that is maintained in a designated record set of a covered entity.¹³⁰</p> <p>A covered entity must act on requests</p>	<p>The Proposed Rule makes several modifications to this section, applicable when the requested information is maintained electronically in one or more designated record sets, and the individual requests an electronic copy. In such case, covered entities must provide individuals with access to their</p>	<p>The Final Rule adopts the proposed modifications to this section.¹³⁸</p> <p>The Final Rule modifies the timeliness provisions by removing the provision granting a covered entity 60 days to act when the requested information is not maintained or accessible on-site.</p>

¹²⁹ 78 Fed. Reg. at 5628; 45 C.F.R. § 164.522(a).

¹²⁴ 45 C.F.R. § 164.522(a)(1)(i) (2007).

¹²⁵ 45 C.F.R. § 164.522(a)(1)(ii) (2007).

¹²⁶ 45 C.F.R. § 164.522(a)(1) (2007).

¹²⁷ 45 C.F.R. § 164.522(a)(2)(iii) (2007).

¹²⁸ 75 Fed. Reg. at 40899-901.

¹³⁰ 45 C.F.R. § 164.524(a)(1) (2007).

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	<p>for access within 30 days of receiving the request,¹³¹ but may take up to 60 days to act if the requested information is not maintained or accessible to the covered entity on-site.¹³² If the covered entity is unable to act within either of these time periods (as applicable), it may take a one-time 30 day extension.¹³³</p> <p>Covered entities must provide access to the information in the form or format that the individual requests, if such form or format is readily available. If the requested form or format is not readily available, it must provide a readable hard copy or another form or format agreed to by the covered entity and the individual.¹³⁴</p> <p>The covered entity must mail a copy of the individual’s protected health information at the individual’s request.¹³⁵</p> <p>The covered entity may charge a reasonable, cost-based fee for providing</p>	<p>protected health information in the electronic form and format requested by the individual. If the covered entity cannot produce the information in the requested form or format, it must provide the information in a readable electronic form or format agreed to by the covered entity and the individual. The Proposed Rule expanded the provision requiring covered entities to mail information at the individual’s request. Under the Proposed Rule, a covered entity must transmit a copy of protected health information to another person designated by the individual, at the individual’s request. Such request must be in writing, signed by the individual, and clearly identify the designated person and where to send the copy of protected health information.</p> <p>The Proposed Rule also modified the provision governing fees a covered entity may charge. The reasonable, cost-based fee may only include the cost of:</p> <p>(i) labor for copying the requested information, whether in paper or</p>	<p>Covered entities now have 30 days to act on a request, and may still take a one-time 30 day extension as provided in the original rule.¹³⁹</p>

¹³⁸ 78 Fed. Reg. at 5701; 45 C.F.R. § 164.524(c).

¹³¹ 45 C.F.R. § 164.524(b)(2)(i) (2007).

¹³² 45 C.F.R. § 164.524(b)(2)(ii) (2007).

¹³³ 45 C.F.R. § 164.524(b)(2)(iii) (2007).

¹³⁴ 45 C.F.R. § 164.524(c)(2)(i) (2007).

¹³⁵ 45 C.F.R. § 164.524(c)(3) (2007).

¹³⁹ 78 Fed. Reg. ; 45 C.F.R. § 164.524(b)(2)(ii).

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	<p>copies of information (or a summary or explanation of the information, if the individual agrees), which may only include the cost of: (i) copying, including the cost of supplies and labor; (ii) postage, as applicable; and (iii) preparing an explanation or summary of the protected health information, if agreed to by the individual.¹³⁶</p>	<p>electronic form; (ii) supplies for creating the paper copy or electronic media (if the individual requests that the electronic copy be provided on portable media); (iii) postage; and (iv) preparing an explanation or summary.¹³⁷</p>	
<p>§ 164.530 – Administrative requirements</p>	<p>A covered entity must implement policies and procedures to comply with the Privacy Rule,¹⁴⁰ and must accordingly train its workforce.¹⁴¹ It must change such policies and procedures to comply with changes in the law, including changes to the Privacy Rule,¹⁴² and must re-train each member of its workforce whose functions are affected by a material change.¹⁴³</p> <p>A covered entity must provide a complaint process for individuals concerning its compliance with the Privacy Rule,¹⁴⁴ and apply sanctions</p>	<p>The Interim Final Breach Notification Rule applied the breach notification provisions of subpart D to the administrative requirements. Covered entities must comply with these requirements in addition to the requirements of the Privacy Rule where specified.¹⁴⁸</p> <p>The Interim Final Breach Notification Rule also added that a covered entity is required to maintain documentation sufficient to meets its burden of proof under § 164.414(b).</p>	<p>Retains without modification.¹⁴⁹</p>

¹³⁶ 45 C.F.R. § 164.524(c)(4) (2007).

¹³⁷ 75 Fed. Reg. at 40923-24.

¹⁴⁰ 45 C.F.R. § 164.530(i)(1) (2007).

¹⁴¹ 45 C.F.R. § 164.530(b)(1) (2007).

¹⁴² 45 C.F.R. § 164.530(i)(2)(i) (2007).

¹⁴³ 45 C.F.R. § 164.530(b)(2)(i)(C) (2007).

¹⁴⁴ 45 C.F.R. § 164.530(d)(1) (2007).

Provision	HIPAA Requirements	Proposed/Interim Final Rules	Final Rule
	<p>against its workforce members for noncompliance.¹⁴⁵</p> <p>A covered entity is prohibited from engaging in intimidating or retaliatory acts against an individual for exercising a right, or for participating in any process, provided for by the Privacy Rule,¹⁴⁶ and from requiring an individual to waive his or her rights under the Privacy Rule as a condition of treatment, payment, enrollment, or eligibility.¹⁴⁷</p>		
<p>§ 164.532 – Transition provisions</p>	<p>This section established transition rules for prior authorizations and prior business associate contracts or other arrangements to ensure that covered entities have sufficient time to become compliant with the new HIPAA rules.</p> <p>A covered entity (other than a small health plan) may have a written contract or other arrangement with a business associate that does not comply with §§ 164.502(e) and 164.504(e), if the covered entity is “deemed compliant.”¹⁵⁰ A covered entity is</p>	<p>The Proposed Rule modified the provisions governing prior contracts or other arrangements with business associates. Under the Proposed Rule, a covered entity (including a small health plan), or a business associate with respect to a subcontractor, may have a contract or other arrangement that does not comply with §§ 164.308(b), 164.314(a), 164.502(e) and 164.504(e) if the covered entity or business associate is “deemed compliant.” The Proposed Rule retains the qualifications for “deemed compliance” of a covered</p>	<p>The Final Rule adopts the proposed modifications to the provisions governing prior contracts or other arrangements, inserts specific dates as necessary and makes additional modifications.¹⁵⁵ “Deemed compliance” occurs where the covered entity or business associate enters into the contract or other arrangement prior to January 25, 2013, which then cannot be renewed or modified from March 26, 2013 until September 23, 2013. The deemed compliance period ends on the date the contract or other arrangement is</p>

¹⁴⁸ 74 Fed. Reg. at 42769.

¹⁴⁹ 78 Fed. Reg. at 5566; 45 C.F.R. § 164.530.

¹⁴⁵ 45 C.F.R. § 164.530(e)(1) (2007).

¹⁴⁶ 45 C.F.R. § 164.530(g)(1) (2007).

¹⁴⁷ 45 C.F.R. § 164.530(h) (2007).

¹⁵⁰ 45 C.F.R. § 164.532(d) (2007).

¹⁵⁵ 78 Fed. Reg. at 5603; 45 C.F.R. § 164.532.

Provision	HIPAA Requirements	Proposed/Interim Final Rules	Final Rule
	<p>“deemed compliant” if it meets certain qualifications, including that it entered into the contract or other arrangement prior to the date the Final Rule is published, and that it does not renew or modify the contract or other arrangement during the set transition period.¹⁵¹ A prior contract or other arrangement that meets these requirements will only be “deemed compliant” for a limited time period.¹⁵²</p> <p>Another provision permits a covered entity to use or disclose protected information that it created or received for research, without obtaining an authorization that meets the requirements of §§ 164.508 or 164.512(i). There may not be an agreed-to restriction on the use or disclosure (in accordance with § 164.522(a)), and the covered entity must obtain one of the following items prior to the applicable compliance date: an authorization (or other express legal permission) from the individual, the individual’s informed consent to participate in the research, or a waiver of informed consent by an IRB.¹⁵³</p>	<p>entity and applies them to business associates with respect to subcontractors. The Proposed Rule adds that the contract or other arrangement entered into prior to the publication date of the Final Rule must comply with the applicable provisions of §§ 164.314(a) or 164.504(e) that were in effect on such date.¹⁵⁴</p>	<p>renewed or modified (which may not occur before September 23, 2013), but in no case later than September 22, 2014.</p> <p>The Final Rule modifies the provision permitting a covered entity to use or disclose information for research by adding “a waiver of authorization in accordance with § 164.512(i)(1)(i)” to the list of items sufficient to meet this standard, provided that the covered entity satisfies all other requirements.</p> <p>The Final Rule adds a provision applicable to a covered entity that entered into a data use agreement with a recipient of a limited data set prior to January 25, 2013. If the agreement complies with § 164.514(e), the covered entity may continue to disclose the limited data set in exchange for remuneration until the date the agreement is renewed or modified (which cannot be before September 23, 2013), and in no case later than September 22, 2014.¹⁵⁶</p>

¹⁵¹ 45 C.F.R. § 164.532(e)(1) (2007).

¹⁵² 45 C.F.R. § 164.532(e)(2) (2007).

¹⁵³ 45 C.F.R. § 164.532(c) (2007).

¹⁵⁴ 75 Fed. Reg. at 40889-90.

¹⁵⁶ 78 Fed. Reg. at ; 45 C.F.R. § 164.532(f).