

Privacy Assessment Combined Tool

AMC Checklist	Rule	Questions	Comments
164.502 Uses & disclosures of PHI: general rules (standards)			
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> The covered entity must limit its uses and disclosures to those permitted or required. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Consider managing the consents and authorizations centrally for each covered entity in the AMC. Consider obtaining compliant consents and authorizations prior to the effective date of the regulations. Examine and amend any programs for which patients may not currently give authorization to have their protected health information used or disclosed. Consider adapting existing procedures where only small changes are needed for compliance prior to starting new procedures in programs where no procedure currently exists. 	164.502(a)	<p>(a) may not except per this subpart or 160 subpart C</p> <p>(1) Permitted:</p> <ul style="list-style-type: none"> (i) to individual (ii) per consent § 164.506(a) (iii) W/O consent, § 164.506(a) (iv) per § 164.508 (v) per § 164.510 (vi) per § 164.512, 164.514(e-g) <p>(2) required disclosure</p> <ul style="list-style-type: none"> (i) individual request, § 164.524 (ii) investigation by Sec 	
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Create and implement policies that identify and manage uses and disclosure of protected health information to which the minimum necessary standard does and does not apply. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Routinely monitor procedures and practices related to managing the minimum necessary standard for effectiveness. Use technology, where appropriate, to restrict the flow of protected health information and to manage an accounting of what protected health information is shared with covered entities. Ensure that the right balance is struck between making protected health information needed for care available and ensuring that inappropriate access is inhibited. 	164.502(b)	<p>(b) minimum necessary</p> <ul style="list-style-type: none"> (1) applies when info from another CE, to accomplish intended purpose (2) does not apply: <ul style="list-style-type: none"> (i) to provider for treatment (ii) to individual per other provisions (iii) to Sec (iv) req'd by law 164.512 (v) for compliance w/ reqs of subchapter 	
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Abide by any restrictions the covered entity agrees to. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Consider the practicality of respecting a restriction prior to agreeing to it, and weigh that practicality against the willingness of the patient to participate fully in care without the restriction. Consider the most common causes for requests for special restrictions, and design a small set of restriction protocols to accommodate these common causes where practical (e.g., celebrity, social stigma, physical danger). Establish a systematic way of communicating restrictions to workforce members, some of whom may become workforce members after the restriction comes into being. Avoid making the totality of special restrictions for patients treated by the same workforce members too complex for the staff to respect all of them. When patients ask for restrictions that cannot be agreed to, the covered entity should, when possible, refer them to a facility that can honor the restriction. Examine existing programs for providing aliases for patients for use in complying with this provision. 	164.502(c)	(c) subject to agreed restrictions	

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<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Covered entities must create and manage the contractual requirements as provided in this section. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> To improve efficiency, consider using terms that standardize the operational requirements on the covered entity and on its business associates. Consider encouraging the business associate community to use standard terms so it will have standardized operational requirements with all of the covered entities with which it contracts. Engage in a systematic process of review, amendment (or creation), and negotiation of contracts well before the effective date of the regulations. 	164.502(d)	<p>(d) de-identified</p> <p>(1) CE use to create de-ident info (2) per § 164.514(a-b) is NOT IIHI (i) giving code to re-identify = disclosure of IIHI (ii) if re-identified, subpart rules apply</p>	
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Covered entities must create and manage the contractual requirements as provided in this section. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> To improve efficiency, consider using terms that standardize the operational requirements on the covered entity and on its business associates. Consider encouraging the business associate community to use standard terms so it will have standardized operational requirements with all of the covered entities with which it contracts. Engage in a systematic process of review, amendment (or creation), and negotiation of contracts well before the effective date of the regulations. 	164.502(e)	<p>(e)</p> <p>(1) disclosure to BA</p> <p>(i) may allow if BA assures compliance & safeguard (ii) does NOT apply: (A) by CE to provider for treatment purposes (B) by HP to sponsor & meet 164.504(f) (C) by govt HP admin by other agent (iii) violation = non-compliance (2) implement spec: CE document assurances per (e)(1) via written agreement</p>	
	164.502(f)	(f) deceased: CE protect info	
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Develop policy and procedures for determining who qualifies as a personal representative. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> The designated personal representative should be explicitly documented. The designated personal representative should be educated on his or her rights and responsibilities. 	164.502(g)	<p>(g) other than patient</p> <p>(1) personal reps: = same as individual (2) adults & emancipated minors reps = same (3) un-emancipated minors: if authority, same UNLESS: (i) minor consents & no other consent is needed & minor did not ask for personal rep (ii) minor may obtain legally care w/o consent (iii) rep agrees to confidentiality between CE and minor (4) deceased: if person has legal rep authority, CE must treat as such for deceased (5) for abuse, etc CE may elect not to use personal rep if: (i) CE believes: (A) individual rec'd violence, etc (B) using personal rep endanger individual (ii) CE decides not in best interest of individual</p>	
	164.502(h)	(h) confidential communications: use 164.522(b) to communicate w/ individual	

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<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Ensure that the covered entity's Privacy practices with respect to use and disclosure of protected health information are consistent with its notices of Privacy practices. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Consider developing and implementing measures to determine how well practice conforms to the notice (e.g. surveys, counts of complaints of deviation). 	164.502(i)	(i) must apply notices as req'd				
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Covered entities are not required to do anything to comply with this portion of the regulation other than to be aware that such conditions exist and are defined in the regulation. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Create or bolster internal reporting and compliance programs so as to reduce the need for whistle-blower disclosures. Ensure that it is practical for workforce members who are crime victims to limit their disclosures to law enforcement to the items listed in the regulation. When making disclosures under this section, note that the disclosure is made pursuant to this section. 	164.502(j)	(j) disclosure by whistleblowers & victims (1) whistleblowers: CE not violate if: (i) whistleblower believes CE acted wrongly (ii) disclosure to: (A) health oversight agency etc (B) an attorney to review legal options (2) crime victims: CE not violate if: (i) information is about perpetrator (ii) and information disclosed per § 164.512(f)(2)(i)				
164.504 Use & Disclosure: organizational requirements						
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> If your entity is a hybrid entity, designate which components of your entity are healthcare components. Document this designation. Ensure that all healthcare components of your entity comply with HIPAA privacy requirements. Identify any individuals who work for both healthcare components and non-healthcare components of your entity and ensure that they treat protected health information in accordance with the HIPAA privacy requirements. Make sure this is done on a regular basis, as workforce members change jobs. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Make specialized training available to help workforce members who work for both healthcare and non-healthcare components be aware of their responsibilities. 	164.504(b)	(b) health care component: if CE is hybrid, reqs apply to health care component				

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	164.504(c)	<p>(c) (1) application of other provisions (i) CE refers to health care component (ii) plan, provider, clearinghouse to health care component (iii) protected health information relative to the healthcare component (2) safeguard reqs: ensure HC component complies (i) does not disclose PHI as prohibited (ii) not disclose PHI per (2)(ii) of "health care component" (iii) workforce member not disclose across bounds (3) responsibilities of CE (i) comply w/ subpart c part 160 (ii) comply w/ § 164.530(i) - P&P to ensure compliance (iii) designate components of HC & document per § 164.530(j)</p>		
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> If an affiliated entity is created, make sure to document its creation according to the requirements of §164.530(j). <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Consult your legal staff about whether the creation of an affiliated entity would be advantageous. 	164.504(d)	<p>(d) (1) affiliated covered entities: affiliated but legally separate may = single covered entity (2) reqs for designation of affiliated CE (i) separate CE's may be single CE if common ownership (ii) must be documented (3) affiliated CE must ensure: (i) comply w/ subpart reqs (ii) if combines HP, provider, or clearinghouse, comply w/ (g)</p>		

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<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Develop a Chain of Trust Agreement, which must include: Signatures of contracting parties. The contracts can be free-standing, or can be incorporated into, or as an addendum to, another contract. Contract start date, expiration date, and/or review date. A certification audit must be documented and attached to the agreement. Definition of Terms and Conditions, which must include conditions for disclosure of protected health information, data rights of each party, and minimum levels of security to be maintained. Procedures for reporting breaches within a designated time frame. A method of recording breaches. Each party must be able to provide its incident log for periodic inspection and upon demand. Penalties for non-compliance (intentional versus unintentional). Procedures for the retention and/or destruction of data. Language requiring that subcontractors to the contracting party comply with the requirements of HIPAA privacy, together with a mutually agreed method for monitoring such compliance. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Implement a method to identify all of your entity's contracts. Develop standard contract terms for HIPAA privacy business associate provisions. Incorporate HIPAA business associate terms into existing contracts as part of your contract renewal process. 	<p>164.504(e)(1-2)</p> <p>(e) BA Contracts</p> <p>(1) business associate contracts (i) contract between CE and BA per § 164.502(e)(2) must meet (2) or (3) below (ii) CE out of compliance if knew BA in violation, unless steps to cure (A) terminated contract (B) reported problem to Sec (2) BA contracts must: (i) establish permitted and required uses and disclosures; may not authorize use in violation of this subpart (A) may permit BA use for proper mgmt of BA (B) may permit BA provide data aggregation services to CE (ii) BA will: (A) not use or disclose other than as permitted (B) safeguard to prevent use or disclosure (C) report any use or disclosure not provided for (D) ensure any other agent agrees to same restrictions (E) make info available per § 164.524 (F) and per § 164.526 (G) and per § 164.528 (H) make records and practices available for review by Sec to determine CE compliance (I) at termination, will return or destroy info, or extend protections (iii) allow termination of contract if CE determines violation</p>		

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	164.504(e)(3)	(3) other arrangements (i) if CE and BA are both governmental: (A) CE comply by memorandum w/ BA: terms per (e)(2) (B) CE comply if other law requires BA accomplish objectives of (e)(2) (ii) if BA req'd to function on behalf of CE, CE may disclose to extent necessary to comply w/ legal mandate... (iii) CE may omit termination authorization if it is inconsistent w/ statutory obligations of CE or BA (4) other reqs for contracts (i) contract may permit BA use info if necessary: (A) for proper mgmt of BA (B) for legal responsibilities of BA (ii) contract may permit BA disclose info if: (A) req'd by law (B)(1) BA obtains assurance info will be held confidential (B)(2) recipient notifies BA of any breaches		

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<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> A group health plan must amend its plan documents to: <ul style="list-style-type: none"> Establish permitted and required uses and disclosures of protected health information by the plan sponsor; Describe which workforce members of the plan sponsor will be given access to the group health plan's protected health information; Restrict access to and use by these workforce members to the plan administration functions which the plan sponsor performs for the group health plan; Provide a procedure for resolving issues of noncompliance. The group health plan's sponsor must agree to: Not use or further disclose protected health information provided by the plan other than as permitted or required by the plan documents or required by law; Ensure that its agents adhere to the same rules it adheres to; Not use protected health information for employment-related actions and decisions; Not use protected health information for any other benefit or employee benefit plan; Report any improper uses or disclosures of protected health information to the group health plan. The group health plan's sponsor must make certain information available to the group health plan: make protected health information available to the group health plan for purposes of supporting requests to the plan for access to or amendment of protected health information. make history of disclosures by the plan sponsor available to the group health plan. The group health plan's sponsor must make its internal practices, books, and records relating to the use and disclosure of protected health information received from the group health plan available to the Secretary of HHS for the purpose of determining whether it is in compliance. The group health plan's sponsor must (if feasible) return or destroy protected health information when it is no longer needed. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Pay special attention to the provisions prohibiting a group health plan sponsor from using protected health information obtained from a group health plan for any employment-related action or decision. Consider clearly documenting which protected health information has been obtained under this section. 	<p>164.504(f)(1)</p> <p>(f) Reqs for group health plans (1) reqs for group health plans (i) must ensure plan documents restrict uses per this subpart, except for (f)(1)(ii) and § 164.508 (ii) may disclose for purpose of: (A) obtaining premium bids from HP's (B) modifying or terminating group health plan (2) plan documents req's (i) establish permitted & req'd uses by sponsor consistent w this subpart (ii) provide the group health plan disclose only if certification that plan documents amended: (A) to not use or further disclose info except as permitted by plan or law (B) ensure any agents agree to same restrictions (C) not use for employee related actions (D) report any use that is inconsistent (E) make available per § 164.524 (F) per § 164.526 (G) per § 164.528 (H) make internal records available to Sec (I) return or destroy if feasible when no longer needed (J) ensure separation per (f)(2)(iii) established (iii) provide adequate separation between group health plan and sponsor (A) describe employees to be given access (B) restrict access to and by to plan admin functions (C) provide to resolve noncompliance issues (3) uses & disclosures (i) disclose or admin functions consistent w (f)(2) (ii) not permit issuer or HMO to disclose to plan sponsor except as permitted by this § (iii) not disclose nor permit ... unless statement per § 164.520(b)(1)(iii)(C) included (iv) and not disclose for employment related actions</p>		
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Identify the individuals for whom you provide only health plan services or only healthcare provider services. For individuals for whom you provide only health plan services, limit your uses and disclosures of their protected health information to those permitted to a health plan by the regulation. For individuals for whom you provide only healthcare provider services, limit your uses and disclosures of their protected health information to those permitted to a healthcare provider by the regulation. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> None. 	<p>164.504(g)</p> <p>(g) CE w multiple covered functions (1) CE w multiple covered functions to make any combo of HP, etc must comply (2) CE performing multiple covered functions may use info of those who receive plan OR provider services (not both) only for function being performed</p>		

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164.506 Consent for uses, disclosures for treatment, payment									
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Develop a procedure and a consent form to secure written consent for use or disclosure of protected health information to carry out treatment, payment, and health care operations when an individual first presents himself or herself to the covered entity. If protected health information is used or disclosed for treatment, payment, or health care operations without consent in an emergency, or as required by law, or if consent could not be obtained because of barriers in communication, attempt to get consent as soon as possible. If consent cannot be obtained, document the effort to get consent and state the reason consent was not obtained. Determine what action the covered entity will take if an individual will not consent to use or disclosure of protected health information or treatment, payment, or health care operations. Identify actions to be taken when an individual revokes his or her consent. (The covered entity must comply with the revocation, except to the extent that the covered entity has taken action in reliance upon the original consent.) Develop a procedure to document and retain an individual's signed consent. Adopt a standard form for consent requests that contains all necessary elements cited in §164.506(c), as follows: is written in plain language; informs the individual that protected health information may be used and disclosed for treatment, payment, or health care operations; informs the individual that the covered entity may change its privacy practices as described in its privacy notice and tells the individual how to get a revised notice; states that the individual has a right to request restrictions upon use and disclosure of protected health information for treatment, payment and health care operations; that the covered entity does not have to agree to requested restrictions; and that if the covered entity does agree to restrictions, the restrictions are binding. Prohibit the use or disclosure of protected health information for marketing, sale, fund raising, and health plan enrollment decisions, employment determinations, or disclosure to non-related divisions and employers unless patient authorization is secured under §164.508/PRIV.10. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Consider obtaining consent for use or disclosure of protected health information even when it is not required. Consider using a time and date stamp on consent forms to be sure the handling of patient information was appropriate at the time it was done. Consider having a single point for disclosure of all information from the covered entity, even if decisions to use or disclose are made elsewhere. Instruct the privacy official to work with legal staff to ensure that contracts and business associate agreements reflect appropriate concern for the privacy and security of patient information. Consult with legal counsel about the documentation needed to support use or disclosure of protected health information when the entity was unable to obtain consent. 	164.506(a)	<p>(a) consent req'mt</p> <p>(1) provider must obtain consent prior to using for treatment, payment, or HC operations</p> <p>(2) consent not needed if:</p> <p>(i) provider has indirect treatment relationship w/ individual</p> <p>(ii) or provider has info while providing to an inmate</p> <p>(3)</p> <p>(i) provider may w/o consent use:</p> <p>(A) in emergency situations, if attempts to obtain consent soon as possible</p> <p>(B) if provider is req'd by law to treat & tries but cannot get consent</p> <p>(C) if provider cannot obtain consent due to substantial barriers; and consent is inferred</p> <p>(4) if consent not req'd, may obtain consent as meets req's herein</p> <p>(5) except per (f)(1) below, consent cannot be used for other CE</p>							

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	164.506(b)	<p>(b) general reqs (1) provider may condition treatment on provision of consent (2) health plan may condition enrollment on receipt of such consent (3) consent may NOT be combined with notice per § 164.520 (notice of privacy practices) (4)(i) consent may be combined w other written legal permission from individual (eg informed consent or assign of benefits) if: (A) is visually & organizationally separate from other written legal permission & (B) is separately signed (4)(ii) may be combined w research authorization per § 164.508(f) (5) indiv may revoke at any time, except as CE used already. must be in writing (6) CE must document & retain signed consent</p>				
	164.506(c)	<p>(c) content reqs (1) inform info may be used for treatment, payment, & HC operations (2) reference notice per § 164.520 for more (3) if CE reserves rith to change privacy practice, state terms (4) state: (i) indiv has right to request restrictions (ii) CE not req'd to agree to restrictions (iii) if CE agrees, then binding (5) state indiv has right to revoke consent except as CE has acted on (6) signed by indiv & date (d) defective consents (1) consent lacks an element (2) has been revoked</p>				

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<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Develop a procedure to determine whether more than one consent for use and disclosure of protected health information exists for an individual. If more than one consent exists, determine if any conflicts exist between them, and if conflicts exist adhere to the most restrictive. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Develop a procedure for securing consents that will minimize the number of consents from any one individual and thus reduce the incidence of conflicts. Consider developing a single standard consent form for use in all encounters with an individual, and changing it infrequently. If a consent conflict exists, contact the individual to clarify his or her preference and either: Obtain a new written consent for use and disclosure or other clarification in writing, indicating that this document supercedes all other consents; or Communicate with the individual, obtain verbal clarification, and document the conversation; and Either way, from this point on, only use or disclose protected health information for treatment, payment, or health care operations as clarified by this contact. 	164.506(e)	<p>(e) resolving conflicts</p> <p>(1) disclose only per more restrictive consent</p> <p>(2) CE may attempt to resolve by:</p> <p>(i) new consent</p> <p>(ii) communicate orally/writing for indiv preference. must document preference & honor</p>				
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Determine if the covered entity is eligible to, or wants to, participate in a joint consent with others. If so: Create a joint consent form that meets the requirements of this standard: Include on the joint consent form the individual names of each organization in the joint organization; Include the other requirements of consent forms as specified in § 164.506(a). Establish a process for revocation of consent. Establish a process to notify each covered entity in the joint arrangement of revoked consents. Develop and use a joint notice of privacy practices. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Establish a process to recognize which individuals have no consent or have revoked consent for the use or disclosure of their protected health information for the purpose of treatment, payment, or health care operations. Establish a procedure that protects the protected health information of individuals with a revoked consent from use or disclosure. 	164.506(f)	<p>(f) joint consents</p> <p>(1) CE's w joint notice may comply by joint consent</p> <p>(2) req's</p> <p>(i) joint consent must:</p> <p>(A) include name or ID of other CE's, or classes of CE's</p> <p>(B) meet reqs of this section</p> <p>(ii) if indiv revokes, receiving CE must inform other CE's</p>				

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	164.508(b) <ul style="list-style-type: none"> (b) general (1) valid auths <ul style="list-style-type: none"> (i) contains elements in § (c) & (if applicable) (d), (e), (f) (ii) may contain additional info (2) defective: if: <ul style="list-style-type: none"> (i) expiration date passed (ii) not filled in completely per c, d, e, f (iii) auth known revoked (iv) lacks an element (v) violates (b)(3) (vi) info in auth known to be false (3) compound auths may not be combined except: <ul style="list-style-type: none"> (i) for research & includes treatment (ii) psychotherapy auth only w other psychotherapy auth (iii) combined w any except psychotherapy except when CE has conditioned treat, pay etc on provision of auth (4) may not condition treat, pay etc on provision of auth except: <ul style="list-style-type: none"> (i) CE may condition for research-related (ii) HP may condition enrollment if: <ul style="list-style-type: none"> (A) auth is for HP eligibility or enrollment determinations or underwriting and (B) auth is not for psychotherapy (iii) HP may condition pay on auth if (A) is necessary to determine pay and (B) not for psychotherapy (iv) CE may condition care that is only for purpose of creating info for third party (5) may revoke in writing, except: <ul style="list-style-type: none"> (i) CE has acted on (ii) if auth was condition of obtaining insurance, insurer right to contest claim (6) CE must document & retain 		
	164.508(c) <ul style="list-style-type: none"> (c) core elements (1) auth must contain: <ul style="list-style-type: none"> (i) description of info - specific/meaningful (ii) ID those authorized to use (iii) ID to whom CE makes disclosure (iv) expiration date/event (v) state indiv right to revoke & how (vi) state info may be redisclosed (vii) signature of indiv/date (viii) if by rep, descrip of rep's authority (2) auth must be written in plain language 	<ul style="list-style-type: none"> • 	

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	<p>(d) auths requested by CE for own use (1) req'd elements: (c) & (i) statement that CE will not condition treatment etc on auth (ii) description of each purpose (iii) state the indiv may: (A) inspect or copy the PHI & (B) indiv may refuse to sign & (iv) state if remuneration to CE results (2) provide copy to indiv</p> <p>(e) auths requested by CE for disclosures by others (1) req'd elements: (c) & (i) descrip each purpose (ii) state CE not condition treat etc on auth (iii) state indiv may refuse to sign (2) provide copy to indiv</p> <p>(f) auths created for research & treatment (1) req'd elements: (i) (c) & (d) and: (ii) contain (A) descrip of extent info will be used or disclosed for treat etc. (B) descrip any PHI not used per § 164.510, 164.512 (C) if CE gets consent under 164.506 or 520, auth must refer to that consent (2) auth per this § may be in same document as: (i) consent to participate (ii) consent to use PHI for treat etc (iii) or notice of privacy practices</p>		

164.510 Uses requiring opportunity to agree or object

<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Limit protected health information in patient directories to name, location in facility, general statement of condition, and religious affiliation. Limit disclosure of religious affiliation to members of the clergy only. Limit other disclosures of protected health information in patient directories to persons who ask for individuals by name. Provide individuals with an opportunity to restrict or prohibit the use of some or all of their protected health information in patient directories unless they are unable to communicate their preferences due to emergency circumstances or incapacity. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Establish policies and procedures for authenticating members of the clergy. Establish mechanisms that ensure patients' conditions are appropriately described. Consider the meaning of the term "impracticable" as used here. It is generally taken to be a stronger standard than "impractical." Consider routing some inquiries to personnel who have been specially trained to handle sensitive cases. 	164.510(a)	<p>CE may use PHI w/o consent per § 164.506, 508 if indiv is informed in advance of use & has opportunity to agree or restrict. CE may obtain oral agree or objection.</p> <p>(a) facility directories</p> <p>(1) permitted (except for (2) (3))</p> <p>(i) this PHI for directory of indivs in facility:</p> <p>(A) name</p> <p>(B) location in facility</p> <p>(C) condition in general terms, does not give specific medical information</p> <p>(D) religious affiliation</p> <p>(ii) disclose for directory purposes</p> <p>(A) to members of clergy</p> <p>(B) except for religious affiliation to others who ask for indiv by name</p> <p>(2) must inform about directories; opportunity to restrict</p> <p>(3) emergency</p> <p>(i) if cannot due to incapacity, may use if:</p> <p>(A) consistent w prior preference of indiv</p> <p>(B) is in indiv's best interest</p> <p>(ii) provide must inform when practical to do</p>			
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Develop and implement policies and procedures that help ensure appropriate and correct use and disclosure under this section. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Develop and implement policies and procedures that help ensure that disclosures under this section are not made to inappropriate persons. 	164.510(b)	<p>(b) to those involved in care</p> <p>(1)(i) to family, etc as relevant to such person involvement with care</p> <p>(1)(ii) CE may disclose to notify</p> <p>(2) if indiv can, CE may disclose if:</p> <p>(i) obtains agreement</p> <p>(ii) provides opp to object</p> <p>(iii) in best professional judgment infers no objection</p> <p>(3) if cannot due to circumstances, may use limited & best professional judgment</p> <p>(4) CE may use by law for disaster relief</p>			
164.512 Auth not req'd					
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Establish mechanisms to appropriately limit uses and disclosures required by law. Determine the legal relation of the requirements under this section to stricter state laws. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Establish procedures for authenticating requests for disclosure of protected health information that is required or permitted under this section. Consider checklists in addition to narrative descriptions of reporting requirements to assist staff in avoiding errors in reporting. Involve legal staff and other knowledgeable individuals to ensure appropriate reporting. Maintain records of all disclosures under this section and the statutory rationale for each. 	164.512(a)	<p>(a) req'd by law</p> <p>(1) CE may disclose if req'd by law, & as relevant to law</p> <p>(2) CE meet reqs (c) (e) or (f)</p>			

AMC Checklist	Rule	Questions	Comments
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Develop and implement policies and procedures to ensure that the above reporting requirements are met. Category II Guidelines-Actions should be taken Establish procedures for authenticating requests for disclosure of protected health information that is required or permitted under this section. Consider checklists in addition to narrative descriptions of reporting requirements to assist staff in avoiding errors in reporting. Involve legal staff and other knowledgeable individuals to ensure appropriate reporting. Maintain records of all disclosures under this section and the regulatory rationale for each. 	<p>164.512(b)</p> <p>(b) public health activities</p> <p>(1) permitted:</p> <p>(i) public health authority disease prevent</p> <p>(ii) public health authority child abuse/neglect</p> <p>(iii) FDA:</p> <p>(A) report adverse events</p> <p>(B) track products for FDA</p> <p>(C) enable product recalls etc</p> <p>(D) for post marketing surveillance per compliance reqs for FDA</p> <p>(iv) to person possible exposed to disease for PHA intervention</p> <p>(v) to employer if:</p> <p>(A) CE is provider who is member of that employers workforce or provides care at request of employer</p> <p>(1) for workplace medical evaluation</p> <p>(2) evaluate if indiv has work-related ...</p> <p>(B) PHI consists of work-related problems</p> <p>(C) employer needs findings for legal compliance</p> <p>(D) provider gives written notice to indiv of disclosure</p> <p>(1) copy at time care is given</p> <p>(2) by posting notice if care on-site</p> <p>(2) if CE is PHA, can disclose as allowed</p>		
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Develop and implement detailed policies, procedures, and mechanisms for permitted reporting. Develop a process for informing the individual about public health reports, making the report, and deciding whether or not to inform the individual. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Establish procedures for authenticating requests for disclosure of protected health information that is required or permitted under this section. Consider flow charts in addition to narrative descriptions of reporting requirements to assist staff in avoiding errors in reporting. Involve legal staff and other knowledgeable individuals to ensure appropriate reporting. Document the fact that the report was made or that a decision was made not to report. Determine for your organization who will determine that a reportable event has occurred. 	<p>164.512(c)</p> <p>(c) disclosure about abuse etc</p> <p>(1) permitted to govt agent if CE reasonable believes and as authorized by law</p> <p>(i) to extent req'd by law</p> <p>(ii) if indiv agrees to disclosure or</p> <p>(iii) as authorized by law</p> <p>(A) CE believes necessary to prevent harm</p> <p>(B) indiv incapacity to agree, official says PHI not use against indiv & cannot wait for agreement</p> <p>(2) CE must promptly inform indiv, except</p> <p>(i) believes place indiv at risk</p> <p>(ii) CE would inform rep, & believes rep is responsible for harm</p>		

AMC Checklist	Rule		Questions	Comments
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Develop and document a policy and process compliant with the requirements of this section for the disclosure of protected health information for health oversight activities. Maintain a record of disclosures for health oversight activities; section § 164.528 implies the need to be able to provide a record of these disclosures as part of the disclosure history that entities must provide to individuals on request. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Establish procedures for authenticating requests for disclosure of protected health information that is required or permitted under this section. Document all disclosures and the rationale for health oversight activities. 	164.512(d)	<p>(d) health oversight activities</p> <p>(1) permitted to govt per law; oversight of:</p> <ul style="list-style-type: none"> (i) health care system (ii) govt benefit programs for health information (iii) govt regulatory programs (iv) civil rights laws <p>(4) if CE = oversight agent, may use PHI for oversight activities</p> <p>(3) if health investigation conducted with investigation for public benefits claim not related to health, investigation is considered health oversight activity for (d)</p> <p>(2) exceptions: investigation or activity is not related to:</p> <ul style="list-style-type: none"> (i) receipt of health care (ii) claim for public health benefits (iii) qualification or receipt of public benefits if health integral to claim 		

AMC Checklist	Rule	Questions	Comments
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Develop and document a policy and process compliant with the requirements of this section for the disclosure of protected health information for judicial and administrative proceedings. Maintain a record of disclosures for judicial and administrative proceedings; § 164.528 implies the need to have a record of these disclosures as part of the disclosure history that entities must provide to individuals on request. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Establish procedures for authenticating requests for disclosure of protected health information that is required or permitted under this section. Document all disclosures for judicial and administrative proceedings. Request either return of the disclosed protected health information or assurance that the protected health information has been destroyed. 	<p>164.512(e)</p> <p>(e) disclosure for judicial & administrative proceedings</p> <p>(1) permitted</p> <p>(i) per court order or tribunal, disclose only PHI expressly authorized in the order</p> <p>(ii) for subpoena etc if</p> <p>(A) CE assurance that indiv given notice by party</p> <p>» See also: : (iii) CE is assured if: receives from party written statement & documentation which:</p> <p>(B) CE assurance from party efforts made to receive protective order per (e)(1)(v)</p> <p>» See also: : (iv) CE is assured if: receives from party written statement & documentation which:</p> <p>(iii) CE is assured if: receives from party written statement & documentation which:</p> <p>(A) party made good faith effort to notify indiv</p> <p>(B) notice included info about proceeding in which info is requested so indiv can object to court</p> <p>(C) time for object has elapsed</p> <p>(1) no objections filed</p> <p>(2) objections filed been resolved</p> <p>(iv) CE is assured if: receives from party written statement & documentation which:</p> <p>(A) parties agreed to protective order and</p> <p>(B) party seeking PHI requested protective order</p> <p>(v) protective order means: court order that</p> <p>(A) prohibits PHI disclosure any other purpose</p> <p>(B) requires return to CE or destroy PHI</p> <p>(vi) CE may give PHI w/o above assurances if CE makes effort to notify indiv...</p> <p>(2) this paragraph does not supersede other provisions of section</p>		

AMC Checklist	Rule	Questions	Comments
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Develop policies and processes compliant with the requirements of this section for releasing protected health information to law enforcement agencies. Maintain a record of disclosures for law enforcement purposes; § 164.528 implies the need to have a record of these disclosures as part of the disclosure history that entities must provide to individuals on request. Determine if de-identified information would be adequate prior to making any disclosure. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Establish procedures for authenticating requests for disclosure of protected health information that is required or permitted under this section. Request law enforcement agencies to return disclosed protected health information or report that the protected health information has been destroyed. Require law enforcement agencies to sign an agreement that they will follow standards to safeguard the disclosed protected health information. 	<p>164.512(f)</p> <p>(f) law enforcement purposes</p> <p>(1) may disclose:</p> <p>(i) as req'd by law (wounds, injuries) except subject to (b)(1)(ii)</p> <p>(ii) to comply w/:</p> <p>(A) court order, warrant, subpoena</p> <p>(B) grand jury subpoena</p> <p>(C) civil administrative request</p> <p>(1) info is relevant</p> <p>(2) request is specific & limited</p> <p>(3) de-identified info cannot be used</p> <p>(3) about victim, if:</p> <p>(i) indiv agrees</p> <p>(iii) indiv incapacitated</p> <p>(A) law represents the info is needed, not be used against victim</p> <p>(B) law represents immediate action adversely affected by waiting</p> <p>(6) crime in emergency</p> <p>(i) if necessary to alert to:</p> <p>(A) commission & nature of crime</p> <p>(B) location of crime or victim</p> <p>(C) identity, descrip, location of perpetrator</p> <p>(ii) if CE believes abuse etc (f)(6)(i) does not apply, (c) applies</p> <p>(5) crime on premises</p> <p>(4) about indiv if died & probable cause was criminal</p> <p>(2) limited for identification & location purposes</p> <p>(i) only:</p> <p>(A) name, address</p> <p>(B) date, place of birth</p> <p>(C) SSN</p> <p>(D) ABO blood type, rh factor</p> <p>(E) type of injury</p> <p>(F) date, time of treatment</p> <p>(G) date, time of death</p> <p>(H) distinguishing physical characteristics</p> <p>(ii) no DNA, dental, typing, samples or fluids/tissue analysis (except per (f)(2)(i))</p>		
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Develop policies and procedures for determining what information should be released to whom it should be released, as well as how such releases should be documented. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Establish procedures for authenticating requests for disclosure of protected health information that is required or permitted under this section. Develop a list of the minimum necessary protected health information to disclose to funeral directors. 	<p>164.512(g)</p> <p>(g) decedents</p> <p>(1) to coroner or medical examiner for identifying, cause of death, etc</p> <p>(2) to funeral directors to carry out their duties</p>		

AMC Checklist	Rule		Questions		Comments	
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Develop policies and procedures on how protected health information will be disclosed for the purpose of cadaveric tissue donation. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Determine if minimum necessary disclosure is appropriate for procurement, banking, and transport resources purposes since the scope of their involvement may be limited. The actual transport team should be considered as the treatment team for whom the complete disclosure of protected health information is appropriate. 	164.512(h)	(h) for organ procurement purposes				
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Ensure that the IRB or privacy Board reviews relevant research proposals before researchers can obtain any protected health information. Provide training and funding to the IRB or privacy Board so it can perform these duties. <p>Category II Guidelines – Areas where policies should be considered</p> <ul style="list-style-type: none"> Update the IRB processes and documentation to reflect these new requirements. For research planning, consider using de-identified protected health information at the earliest opportunity in the data gathering cycle. 	164.512(i)	(i) research purposes (1) permitted if: (i) waiver approved by: (A) IRB, established per various CFR's, or (B) privacy board that: (1) members varied backgrounds, competency needed (2) at least one member not affiliated (3) no member conflict of interest (ii) CE represents: (A) solely for research purposes (B) no PHI leaves CE (C) PHI sought is necessary (iii) on decedents; CE obtains from researcher: (A) solely for research on decedents (B) documentation of death on request (C) PHI is necessary				
	164.512(i) cont'd	(2) waiver approval documentation: (i) identify IRB/privacy board (ii) that IRB/ privacy board states: (A) no more than minimal risk to indiv (B) will not adversely affect privacy rights (C) research can't be done w/o waiver (D) research can't be done w/o PHI (E) privacy risks reasonable to benefits of research (F) plan to protect identifiers from improper use (G) plan to destroy identifiers, unless retention is necessary (H) adequate written assurance PHI not used or disclosed elsewhere (iii) descrip of PHI needed (iv) statement waiver/alteration reviewed & approved (A) IRB must follow Common Rule (see CFR's) (B) privacy board must review by majority at meetings, waiver/alt approved by majority (C) expedited process OK if only minimal risk to privacy (v) waiver signed by IRB/privacy board chair				

AMC Checklist	Rule		Questions		Comments
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Develop policies and procedures on how protected health information can be disclosed to avert a serious threat to health and safety. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> None. 	164.512(j)	<p>(j) avert threat to health or safety (1) permitted, consistent w/ law, ethical, if: (i) (A) necessary to prevent threat (B) to person(s) reasonably able to prevent (ii) is needed for law to identify or apprehend (A) due to statement by individual (B) appears indiv is escaped (2) not permitted if learned by CE: (i) in course of treatment to affect propensity to commit criminal conduct (ii) through request by indiv for treatment etc. (3) limit on info that can be disclosed: only statement per (j)(1)(ii)(A) and PHI in (f)(2)(i) (4) presumption of good faith: CE presumed to act in good faith if based on CE's actual knowledge or credible representation</p>			

AMC Checklist	Rule	Questions	Comments
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Develop policies and procedures for the use and disclosure of protected health information for specialized government functions. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Establish procedures for authenticating requests for disclosure of protected health information that is required or permitted under this section. Ensure that written and approved procedures are in place and available to all personnel associated with these agencies. Collaborate with specialized government agencies for effective transmission, use, and disclosure of protected health information. 	<p>164.512(k)</p> <p>(k) special govt functions</p> <p>(1) military & veterans (i) armed forces as deemed necessary by authority, and if published notice in Federal Register (A) app. command authority (B) purposes (ii) separation or discharge to DVA for entitlement (iii) CE is part of DVA may disclose to Dept for eligibility (iv) to foreign military authority PHI of foreign military personnel; notice in Federal Register, same uses (2) national security, intelligence per National Security Act (3) protective services (president etc) (4) medical suitability: CE part of DOS for (i) security clearance (ii) availability for worldwide service (iii) for family to accompany Foreign Service member (5) correctional & law enforcement (i) if necessary for: (A) provision of health care (B) health & safety of indiv or others (C) health & safety of officers, employees (D) health & safety of transport personnel (E) law enforce on premises (F) maintain security of institution (ii) permitted: if CE is correctional inst may use PHI of inmates for any purpose for which it may be used (iii) no application after release (6) govt programs (i) may disclose for eligibility in govt plan within govt agents, as req'd by law (ii) govt agent re: public benefits if necessary to administer</p>		
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Develop a process and procedure for disclosure of the minimum necessary protected health information when it is requested by an authorized compensation agency. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Establish procedures for authenticating requests for disclosure of protected health information that is required or permitted under this section. Confirm the existence of written policies and procedures that delineate responsibility and that identify that consent or authorization are not required when protected health information is disclosed to a lawful compensation agency. Communicate the covered entity's understanding of the standard to associated workers' compensation agencies. 	<p>164.512(l)</p> <p>(l) workers comp: per laws regulating</p>		

164.514 Other reqs for uses & disclosures

<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Develop and implement policies, procedures, organizational structures, and processes for determining when and how to de-identify protected health information. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Develop methods for monitoring the efficacy of de-identification strategies and for remedying failures to adequately de-identify. Be aware of and make use of “more advanced statistical techniques.” Consider how to qualify people to do disclosure analysis. 	<p>164.514 (a)</p>	<p>(a) de-identified info is not IIHI (b) reqs for de-identifying PHI</p> <p>(1) general accepted methods for rendering unidentifiable</p> <p>(i) are applied and risk is very small</p> <p>(ii) documents methods and results of analysis to justify</p> <p>(2)</p> <p>(i) identifiers are removed:</p> <p>(A) names</p> <p>(B) all geographic codes less than State</p> <p>(1) first 3 digits zip is > 20,000 people</p> <p>(2) if < 20K people, first 3 digits removed</p> <p>(C) all dates (except year) direct to indiv; & all ages over 89 (may be aggregate category)</p> <p>(D) phone #'s; (E) Fax #'s; (F) e-mail</p> <p>(G) SSN;</p> <p>(H) MRN</p> <p>health plan #'s;</p> <p>(J) acct #'s</p> <p>(K) certificate/license #'s</p> <p>(L) vehicle identifiers;</p> <p>(M) device identifiers</p> <p>(N) URL's;</p> <p>(O) IP addresses</p> <p>(P) biometrics; (Q) photographs (facial etc)</p> <p>(R) any other unique, and</p> <p>(ii) CE no knowledge that info could be used to identify</p> <p>(c) re-identification: may assign code to re-identify if:</p> <p>(1) code not derived from or related to info</p> <p>(2) CE keeps code secure</p>		<p>P E</p>
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AMC Checklist	Rule	Questions	Comments
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Identify appropriate persons to determine what protected health information should be used, disclosed, and requested consistent with the minimum necessary standard. Ensure that the persons identified under paragraph (b)(2)(i) of this section make the minimum necessary determinations, when required. Within the limits of the covered entity's technological capabilities, provide for the making of such determinations individually. Define and implement only reasonable policies; the regulations don't require entities to accept unreasonable cost or disruption in pursuit of this objective. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Develop and implement policies and procedures for uses and disclosures that are covered in the various other subsections on uses and disclosures. Key articles are: § 164.508(a)(1) deals with authorizations for use or disclosure initiated by the affected individual. § 164.514 deals with access of individuals to their own protected health information, but only mentions copying costs for records. § 164.522 is a section entitled "Rights to request privacy protection for protected health information." § 164.510 describes uses and disclosures permitted without individual authorization. Subsections are devoted to: public health; health oversight; judicial proceedings; coroners and medical examiners; law enforcement; government health data systems; directories; payment; research; emergencies; next-of-kin; other disclosures required by law; application to specialized classes (DOD, VA, other government workers). 	<p>164.514(d)(1)</p> <p>(d) minimum necessary requirements</p> <p>(1) CE ensure § 164.502(b) & minimum necessary</p> <p>(2) minimum necessary uses</p> <p>(i) CE must identify:</p> <p>(A) those in workforce who need access for duties</p> <p>(B) for each person or class, the category of info and conditions</p> <p>(ii) CE reasonable efforts to limit access per above</p> <p>(3) min necessary disclosures</p> <p>(i) CE policies routine disclosures limit PHI to min necessary for purpose</p> <p>(ii) all other disclosures CE must:</p> <p>(A) develop criteria limit PHI disclosure to necessary</p> <p>(B) review requests on individual basis per criteria</p> <p>(iii) request = min necessary if:</p> <p>(A) to public officials per § 164.512, if so stated</p> <p>(B) info requested by other CE</p> <p>(C) by professional member workforce or BA for purpose of service to CE, and so stated</p> <p>(D) documentation per § 164.512(i) provided</p> <p>(4) min necessary requests</p> <p>(i) CE limit to that necessary for purpose when requesting from other CE's</p> <p>(ii) for routine requests CE P&P to limit</p> <p>(iii) other requests review individually to ensure request = min necessary</p> <p>(5) may not request entire medical record unless clearly justified</p>		

<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> For health related products: Identify the covered entity in the marketing communication. If the covered entity receives direct or indirect remuneration, state that fact prominently in the communication. Except for newsletters and the like, offer individuals the opportunity to opt out of future such communications. Maintain a record of the disclosures. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Have a central method to manage opt-outs. 	164.514(e)(1)	<p>(e) for marketing</p> <p>(1) marketing uses reqs per § 164.508 or below</p> <p>(2) reqs</p> <p>(i) no auth req'd if:</p> <p>(A) face to face marketing</p> <p>(B) products or services of nominal value</p> <p>(C) communication meets (e)(3)</p> <p>(ii) disclose only to BA which assists CE with such communications</p> <p>(3) marketing comm qualify:</p> <p>(i) it must:</p> <p>(A) identify CE as party</p> <p>(B) state remuneration to be received</p> <p>(C) except for general distribution (newsletter ad etc), instruct how to opt out of future comms</p> <p>(ii) if CE uses PHI to target:</p> <p>(A) product/service must be beneficial to target</p> <p>(B) must explain why indiv is targeted & how relates</p> <p>(iii) ensure those who opt out do not receive</p>	♦		
<p>Category I Guidelines-Actions must be taken if fundraising is pursued</p> <ul style="list-style-type: none"> Include an opt-out method. Make reasonable efforts to ensure that opt-outs are honored across the covered entity. Maintain a record of disclosures. Include a statement in privacy notice if patient information will be used to target patients for receipt of fundraising materials. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Review the notice of privacy policy to determine whether it permits the use of other protected health information for fundraising. 	164.514(f)(1)	<p>(f) fundraising</p> <p>(1) fundraising: OK to use/disclose this info: (to BA or related foundation)</p> <p>(i) demographic info</p> <p>(ii) dates of health care to individ</p> <p>(2) fundraising reqs:</p> <p>(i) must include statement per § 164.520(b)(1)(iii)(B) in CE notice</p> <p>(ii) include notice how to opt out</p> <p>(iii) ensure those who opt out do not receive</p>			
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Develop policies and procedures to limit the use or disclosure of protected health information received as part of an unsuccessful application process for health insurance or other health benefits to only that required by law. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> None. 	164.514(g)	<p>(g) underwriting: if rec'd for bidding etc, & insurance not placed w health plan, may not use PHI for other purposes</p>			

AMC Checklist	Rule		Questions	Comments
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Develop policies and procedures for verifying identity and authority of requestors: Obtain representation or documentation of purpose from any person requesting protected health information under this regulation; Verify the identity of persons requesting protected health information before giving them access; Confirm that persons acting on behalf of a public official have appropriate statements on official letterhead before providing them with protected health information; Establish a policy that legal authority is presumed when a request is made relative to a legal proceeding, warrant, subpoena, or order; Develop a formal process to authorize disclosure in the absence of a written verification; Make good faith efforts to identify the people requesting disclosure and the circumstances of disclosure as provided in this section. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Develop policies that clearly define what sources of identification and what documents of authority can be used to verify permission for disclosure. Provide comprehensive guidelines and back-up resources to assist with questions of verification. When protected health information is released to a legal authority without valid consent, send a cover letter with the material containing a reminder to the recipients that the information is of a sensitive nature and must be handled as such. Retain a copy of the letter for the record. Consider existing processes for disclosure under this section in concert with verifications for parties to whom protected health information is disclosed. Brief frequent requesters of information on the procedural changes required under this standard. 	164.514(h)(1)	<p>(h) verification</p> <p>(1) CE must prior to disclosure:</p> <p>(i) verify identity & authority of requester</p> <p>(ii) obtain documentation, statements from requester when req'd</p> <p>(2) verification</p> <p>(i) if disclosure conditioned on this subpart, CE may rely on if reasonable</p> <p>(A) conditions in § 164.512(f)(1)(ii)(C) may satisfy</p> <p>(B) documentation per § 164.512(i)(2) satisfied by written, dated, signed</p> <p>(ii) if public official may rely on:</p> <p>(A) agency identification or credentials</p> <p>(B) request on govt letterhead</p> <p>(C) if person on behalf, statement on govt letterhead or similar</p> <p>(iii) may rely to verify</p> <p>(A) written statement of legal authority (oral if written not pract)</p> <p>(B) request pursuant to legal process</p> <p>(iv) CE rely on professional judgment & good faith & § 164.510, 164.512(j)</p>		

AMC Checklist	Rule	Questions	Comments
	<p>164.520(b)</p> <p>(b) content of notice</p> <p>(1) req'd elements & plain language req'd elements & plain language (i) header: "THIS NOTICE..." (ii) uses & disclosures (A) descrip & one example of types for each: treat, pay, HC ops (B) descrip of each of other purposes w/o consent (C) if other law is more stringent, descrip must reflect (D) descrip sufficient detail (E) state other uses only w/ written authorization (iii) if any of following, include separate statement: (A) CE can contact for appt reminders, treatment alternatives, or other benefits of interest to indiv (B) CE may contact to raise funds (C) group HP issuer, HMO may disclose to sponsor of plan (iv) statement of indiv rights (A) right to request restrictions... (B) to receive confidential comms of PHI (C) to inspect & copy (D) to amend per 164.526 (E) receive accounting of disclosures per 164.528 (F) right to paper copy of the notice (v) CE duties: must include: (A) CE req'd by law maintain privacy, & notice of legal duties (B) state CE req'd abide by notice (C) state reserve right to change & how CE will notify indivs (vi) statement indiv may complain, how & no retaliation (vii) contact name, title & phone (viii) effective date (2) optional (i) may describe other uses/disclosures (ii) to apply change in limited uses/disclosures, include (b)(1)(v)(C) (3) revisions: whenever change o uses, rights, etc</p>		

AMC Checklist	Rule	Questions	Comments
	<p>164.520(c-e)</p> <p>(c) provide upon request</p> <p>(1) health plans (i) must provide: (A) no later than compliance date, to those covered at that time (B) then at enrollment to new (C) within 60 days of revision to all covered (ii) at least once each 3 years reminders (iii) to named insured (iv) if multiple notices, the one relevant to named insured (2) direct provider must: (i) no later than first service date (including electronic delivery) (ii) if physical delivery site: (A) notice available at site + copies (B) post clearly (iii) make available on revision (3) for electronic notice (i) post on web site + copy available (ii) provide by e-mail if indiv agrees (replace w paper if e-mail fails) (iii) if first service electronic, notice automatic & with response to service (iv) indiv right to paper on request</p> <p>(d) joint notice by separate CE's</p> <p>(1) CE's agree to terms of notice (2) joint notice meets (b) specs (i) describes CE's to which notice applies (ii) describes service delivery sites (iii) states CE's will share PHI as needed (3) CE's provide notice per (c)</p> <p>(e) CE must document compliance</p>		<p>details</p>

164.522 Individ access to PHI

<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Establish a policy to allow or deny restrictions. Establish procedures for patients to request restrictions. Document any agreed-to restrictions. Establish a process to ensure communication of and compliance with any agreed-to restrictions. Notify others to whom restricted information is released of such restrictions. Establish a process to notify providers to whom protected health information has been disclosed for emergency care of any restrictions on use or disclosure that apply. Establish procedures for documenting and terminating a restriction for each of the following circumstances: When an individual requests a termination in writing; When an individual orally agrees to the termination; When the covered entity informs the individual that it is terminating its agreement to a restriction. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Develop an integrated audit function to track protected health information covered by restriction requests. Develop consistent policies regarding the application of restrictions for any provider agreeing to restrictions. Maintain a comprehensive record of any agreed-to restrictions. Identify any agreed to restrictions within each affected patient's record. 	<p>164.522(a)(1)</p>	<p>(a) Right to request privacy for PHI (1) right to request restrictions (i) CE allow indiv restrict: (A) uses or disclosures for treat, pay, or HC ops (B) disclosures permitted under 164.510(b) (ii) CE not req'd to agree (iii) CE may not disclose except for emergency treatment (iv) if disclosed, CE must request no further disclosure (v) restriction does not apply to 164.502(a)(2)(i), 164.510(a) or 164.512 (2) CE may terminate if: (i) indiv agrees in writing (ii) oral agreement is documented (iii) CE informs, & affects only PHI after termination (3) CE must document restriction</p>			<p align="center">P E</p>
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Provide a way for patients or plan members to request alternative means of communication, and accommodate such requests if there is a reasonable way to do so. Establish a procedure so all workforce members who are engaging in communications with a patient who has requested and received an agreement to use alternate means of communication are aware of the need to use those channels. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Consider creating a limited set of alternative communications models and offering these models to patients or plan members requesting alternative means. Consider establishing a referral program for patients whose communications needs the covered entity cannot reasonably accommodate. Create a method of review to determine the effectiveness of alternative means of communication. Consult legal staff about what constitutes a reasonable request. 	<p>164.522(b)(1)</p>	<p>(b) (1) confidentiality reqs (i) CE (provider) permit communications to indiv to alternative means or locations (ii) HP permit communications to indiv to alternative means or locations (2) conditions for confidential communications (i) CE may require indiv make request for confidential comms (ii) CE may condition on: (A) inf as to how payment handled (B) specification of alternative address or method (iii) CE may not require explanation (iv) HP may require such request contain statement that disclosure could harm indiv</p>			

AMC Checklist	Rule	Questions	Comments
164.524 Access of Individual to PHI			
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Develop and document policies and processes to receive and act upon an individual's request to access, inspect, and receive a copy of his or her protected health information, including the denial of such requests. Respond to requests within the timeframe specified in the regulation. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Develop processes to release required protected health information to requestors. Develop legally defensible grounds for denials. Develop processes to review denial of requests. Develop processes to allow for access and appeal of decisions made by the AMC. Identify the authority to release protected health information and process denials and appeals. Consider including a temporary suspension of the patient's right of access to research records in research consent forms. Have the privacy official develop and maintain an inventory of the kinds of data the institution keeps about individuals. 	<p>164.524(a)</p> <p>(a) access to PHI</p> <p>(1) indiv right to access & copy own PHI, except for (2) and (3) and</p> <p>(i) psychotherapy notes</p> <p>(ii) info compiled for use legal proceeding</p> <p>(iii) PHI is:</p> <p>(A) subject to Clinical Lab Improvements Amendment 1988 42 USC 263a</p> <p>(B) exempt from above 42 CFR 493.3(a)(2)</p> <p>(2) CE may deny access w/o review if:</p> <p>(i) PHI is excepted by (a)(1)</p> <p>(ii) If CE is correctional or acting per correctional and request might jeopardize health, safety, etc of others</p> <p>(iii) during research including treatment if indiv agreed & informed access reinstated at completion</p> <p>(iv) PHI subject to Privacy Act 5 USC 552a (if legal)</p> <p>(v) if PHI obtained under promise of confidentiality...</p> <p>(3) CE may deny access w/ review by indiv if:</p> <p>(i) in professional judgment access may endanger safety of another</p> <p>(ii) PHI references another and access may cause harm</p> <p>(iii) request by representative and access may cause harm</p> <p>(4) right of review: indiv request, CE name non-involved party to review</p>		

AMC Checklist	Rule	Questions	Comments
	<p>164.524(b-e)</p> <p>(b) request for access & timely access (1) CE must permit access requests (2) timely (i) within 30 days, except (b)(2)(ii) (A) If CE grants, must inform & provide access (B) if CE denies, provide written denial per (d) (ii) if PHI not on-site, w/in 60 days (iii) may extend by 30 days if: (A) provide indiv written statement of delay (B) only one extension</p> <p>(c) provision of access (1) CE must provide inspection, copy, or both (2) form of access (i) provide in form requested (if possible) or hard (ii) CE may provide summary in lieu if: (A) indiv agrees in advance (B) indiv agrees to fees if any (3) CE and indiv agree on time, format, scope, manner of delivery (4) CE reasonable fees, only: (i) copying supplies & labor (ii) postage if requested mailed (iii) prep summary of PHI</p> <p>(d) if denies access, must: (1) give access to other PHI requested & exclude only PHI which CE has grounds (2) CE provide timely written denial, plain +: (i) basis (ii) state indiv review rights (iii) complaint procedures, w name, title, phone of contact per 164.530(a)(1)(ii) (3) if CE not have PHI, & knows where, must inform indiv (4) if review requested, CE appoint professional not involved, promptly</p> <p>(e) documentation specs (1) designated record sets subject to access (2) titles of those responsible for processing requests</p>		

164.526 Amendment of PHI

<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> • Develop and document policies and processes to receive and act upon an individual's request to amend their protected health information, including the denial of such requests. • Respond to requests within the timeframe specified in the regulation. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> • Consider the provision of resources to assist patients with record reviews. • Have the privacy official identify processes for retrieving protected health information about individuals pursuant to their request to revise that information. • Have the privacy official define a process for evaluating, and accepting or rejecting, requests for correction and implementing corrections. • Consider how to deal with the amendment process for paper and electronic records (including requests for removal of a record). • Should have a procedure well documented so that it can be executed by workforce members who are unfamiliar with it who do not do it very often. • Consider date-stamping requests. 	<p>164.526(a)</p>	<p>(a) right to amend (1) may request CE amend PHI for as long as PHI is maintained (2) CE may deny if: (i) was not created by CE (unless originator not available) (ii) is not part of designated record set (iii) not available for inspection per 164.524 (iv) is accurate & complete (b) request for amendment & timely action (1) CE must permit request, may be in writing (2) timely action (i) CE act w/in 60 days (A) if approves (B) if denies written denial (ii) if unable may extend 30 days (A) written statement of reasons (B) only one extension (c) if accepts amendment (1) identify records affected & appending or linking amendment (2) CE inform, obtain from indiv ID and agreement to share per (c)(3) (3) CE effort inform: (i) persons ID'd by indiv as having PHI & needing amendment (ii) persons or BA's that CE knows have and rely on the PHI being amended (d) denial of amendment (1) CE provide written, plain &: (i) basis (ii) right to written disagreement & how to file (iii) state indiv may request CE provide the request & denial with any future disclosures (iv) how to file complaint, w name, title, phone (2) CE must permit written disagreement (3) CE written rebuttal, copy to indiv (4) CE link request, denial, rebuttal to record (5) future disclosures (i) must include w future disclosure (ii) if no disagreement, include request & denial (iii) if standard transaction (162) does not permit, send separately (e) second CE informed about amendment must amend also CE must document titles or offices who receive and process requests & retain</p>		<p>P</p>

164.528 Accounting of disclosures

<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Establish policies and procedures to ensure that disclosure records are retained. Maintain a record of all individuals requesting reports of disclosure and the disposition of those requests. On a case-by-case basis, determine whether disclosures must, may, or must not be reported. Establish a process to ensure that all covered disclosures are reported in a timely period. <p>If an extension of the time limit is needed, ensure that the individual is notified of the delay as required by the regulation, and that the extension does not exceed permissible limits.</p> <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Provide a system to audit access control with the ability to report all accesses of a patients record. Publish the covered entity's fair information policy. Establish incident procedures that include reporting and response procedures. Maintain a list of those who access a record. Respond to requests within the timeframe specified in the regulation. Determine if the covered entity will charge for these reports and, if so, establish a basis for all such charges. 	<p>164.528(a)</p>	<p>(a) right to accounting (1) right to accounting 6 years prior, except: (i) for treat, pay, HC ops (ii) to indiv's about them (iii) facility directories or to those involved in care, other notification (iv) national security purposes (v) to correctional/law (vi) prior to compliance date (2) (i) CE must suspend right re: health oversight or law enforce for time specified (ii) if statement per above is oral; (A) document statement & identity of official (B) temp suspend right to accounting (C) limit temp suspension to 30 days of oral statement (3) may request for < 6 years (b) content of accounting (1) include disclosures during time requested (2) include: (i) date of disclosure (ii) name entity/person rec'd; address (iii) brief description of PHI (iv) brief statement of purpose of disclosure, or: (A) copy of indiv written authorization per 164.508 (B) copy of written request for disclosure per 164.502(a)(2)(ii), 164.512 (3) if multiple disclosures; (i) info for first disclosure (ii) frequency, periods, or number of disclosures (iii) date of last disclosure (c) providing accounting (1) act on < 60 days (i) provide accounting requested (ii) extend for 30 days if needed (A) provide written statement (B) only one extension (2) first accounting any 12 month period w/o charge; fees for subsequent in 12 month period</p>			<p>P</p>
	<p>164.528(d)</p>	<p>(d) documentation & retention (1) information req'd for accounting per (b) (2) written accounting to indiv (3) titles or offices for receiving & processing of accounting</p>			
	<p>164.528(d)</p>			<p align="center">•</p>	

AMC Checklist	Rule		Questions		Comments	
164.530 Administrative Requirements						
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Select a single individual to serve as the privacy official for each covered entity. Designate one privacy official for covered entities that consist of several subsidiaries pursuant to § 164.504(b). Maintain a written or electronic record of privacy official designation(s). <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Create a job description for the privacy official defining the position's role, responsibilities, and reporting relationship(s). The privacy official: Should work with a committee representing several different components of the covered entity to develop and implement the privacy policy; and should have a position on the institution's HIPAA Oversight Board. 	164.530(a)(1)(i)	<p>(a) personnel</p> <p>(1) (i) CE must designate privacy officer, responsible for development & implementation of P&P's</p>				
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Designate an individual or an office to receive complaints and provide information about matters covered by the covered entity's Notice of privacy Practices (§ 164.520). Add the contact information to the covered entity's Notice of Privacy Practices. Maintain a written or electronic record of this personnel designation. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Establish a reporting structure and process to involve persons with appropriate authority to investigate and track complaints. Ensure that the process of responding to complaints is done in a way that is consistent with good public relations practices as well as good privacy policy. Consider adding the reporting responsibility to an existing function or office. 	164.530(a)(1)(ii)	<p>(ii) CE must designate contact person to receive complaints & provide information</p> <p>(2) CE must document personnel designations</p>				
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Train workforce members on privacy policy and procedure prior to the effective date of the privacy regulations. Thereafter, train new workforce members reasonably soon after they join the covered entity. When significant changes in policy and/or procedure occur, train the affected workforce members as soon as possible after such changes. Document the training in written or electronic form and retain the records for at least six years. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Consider providing forms of training that help the trainee relate the policy to how they are to behave in their working environment. Consider including training on how to report a privacy problem. Consider "refresher" courses and periodic reminders for workforce members about privacy policy. Consider competency tests to evaluate training effectiveness. 	164.530(b)(1)	<p>(b) training</p> <p>(1) training: must train all members workforce on P&P's to carry out functions</p> <p>(2) (i) CE must train per (b)(1): (A) all staff by compliance date (B) to each new member (C) to each member whose functions affected by changes</p> <p>(ii) CE must document training</p>				
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AMC Checklist	Rule		Questions		Comments
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> A covered entity must establish administrative, technical, and physical safeguards to protect the privacy of protected health information from unauthorized use or disclosure. These safeguards must be appropriate and reasonable. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Engage in a risk analysis (as the proposed Security regulations require) and create and implement a risk management plan for both electronic and non-electronic information assets. Have the privacy official consult on safeguard requirements with the security officer and others responsible for information practices. Ensure that security and privacy officials have the authority necessary to implement effective safeguards. Have the privacy official create a list of reasonably anticipated threats and hazards to privacy of protected health information and unauthorized uses or disclosures. Be aware that many areas of section (g) address specific parts of the safeguards (training, complaints, sanctions, etc.) and consult those sections for details. 	164.530(c)(1)	<p>(c) safeguards</p> <ul style="list-style-type: none"> (1) CE safeguards of PHI (2) protect from any use in violation 			

<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Identify a contact person or office to receive complaints about policies and procedures and compliance with them. Maintain a record of complaints and brief explanations of their resolution. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Determine whether the person or office identified to receive complaints will handle them personally or triage them for handling by others. Determine timeframes and protocols for handling and reporting complaints. Use complaints as evaluative and improvement tools where appropriate. Determine who will access complaint information and for what purposes. Specify a method to track complaints. Report periodically on resolutions of complaints. Coordinate this requirement with the covered entity's Patient Rights policy. 	164.530(d)(1)	<p>(d) complaints:</p> <ul style="list-style-type: none"> (1) provide process for (2) document all complaints & disposition 			
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Develop sanctions against workforce members who fail to comply with the covered entity's privacy policy. Charge an individual or group to review policy and procedural violations and specify corrective and/or disciplinary action. Apply disciplinary action as necessary and appropriate. Document corrective and disciplinary action taken. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Make sanctions progressive and commensurate with the severity, frequency, and intent of violations. Apply sanctions equitably without regard to an offender's role or position within the covered entity. Include termination of employment or contract relationship and/or criminal prosecution as possible sanctions. Include provision for sanctions in contract and labor agreements. Coordinate sanctions with the covered entity's human resources department. Consider establishing progressive sanctions, such as verbal warning, written warning, up to termination, and determine when progressive sanctions are appropriate. Make workforce members aware of the sanction procedures. 	164.530(e)(1)	<p>(e) sanctions:</p> <ul style="list-style-type: none"> (1) have & apply sanctions to workforce in violation (2) must document sanctions applied 			

AMC Checklist	Rule	Questions	Comments
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Minimize harmful effects resulting from unauthorized use or disclosure of protected health information by: Containing the damage and stopping further compromise; and Informing those responsible for the policy or procedural breach to prevent future actions that would have harmful effects. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Consider whether inappropriate use or disclosure may in itself constitute a harmful effect. (This is a legal issue. See Comments.) Consider notifying individuals if misuse or inappropriate disclosure of their protected health information will likely lead to a harmful effect. Include contract language to transfer the potential financial burden of harm to business associates. 	164.530(f)		
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Establish policies and procedures that prohibit intimidation, threats, coercion, discrimination, or retaliatory action against individuals who exercise their rights under this act. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Communicate the non-retaliation policy through related policies and programs (e.g. Standards of Conduct, Mutual Respect, and/or the Integrity Program). Consider reporting mechanisms that protect complainers against retaliation (e.g., removing complainants' identifying information from complaint reports). Coordinate with human resources and labor relations representatives. 	164.530(g)		
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Do not require individuals to waive their rights to file a complaint or their other rights under the privacy standards as a condition of treatment, payment, and enrollment in a health plan or eligibility for benefits. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Consider not putting waivers of rights on consent forms. Covered entities should not ask patients to waive their privacy rights. 	164.530(h)		
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Implement a reasonable policy/procedure set given the covered entity's size and type of operations. (Group health plans that operate as described in §164.530(k) need not conform to this requirement.) <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Formally determine how the covered entity's size and type affect its required policy/procedure creation and implementation process. 	164.530(i)(1)		

AMC Checklist	Rule	Questions	Comments
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Change policies and procedures when changes to law or regulations require it. If the privacy notice provides for changes, change it when policies that affect it change. The new notice will either cover all protected health information, or only new information, depending on whether the prior notice reserved the right to change. Document the policy and procedure change process, either in writing or electronically. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Consider reserving the right to change privacy policy in the privacy notice. Consider the logistics and communications issues of changes when crafting privacy policies and notices—to employees as well as patients. Determine how covered entity size, complexity, and type affect the policy/procedure creation and implementation process. 	<p>164.530(i)(2)</p> <p>(2) P&P changes (i) CE must change P&P's to comply w changes in law & rules (ii) when changes per Notice, may effect info prior to effective date if statement in Notice includes this right (iii) P&P changes documented per (i)(5) (3) CE changes to P&P's w changes in law (4) changes to privacy practices per Notice (i) to implement: (A) ensure P&P complies (B) document revised P&P pre (j) (C) revise Notice & make available (ii) if CE does not reserve right to change privacy practice, is bound by Notice re: PHI created or received while Notice in effect (A) changes meet implement reqs (i)(4)(i)(A)-(C) (B) change effective re: info after effective date (5) may change other P&P's not affect content of Notice if: (i) P&P complies (ii) revised P&P documented prior to change per (j)</p>		
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Document privacy policies and procedures in written or electronic form. Document required communications, designations, actions, and activities. Record date of creation and last date of effectiveness of documents. Maintain required documentation for six years from date of creation or the date when the policy or procedure was last in effect, whichever is later. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Promulgate the policy on documentation from the highest organizational level. Clearly delineate responsibility for documentation of policies and procedures. Specify the rescission and review dates for documentation. Centralize retention of policy and procedure documentation. Communicate to managers that a lack of documentation may be interpreted as failure of compliance. Organize documentation in such a way that it can be identified when necessary. Centralize and standardize documentation across the organization so that it is easily accessible. 	<p>164.530(j)</p> <p>(j) (1) documentation, must: (i) maintain P&P's for (i) in written or electronic (ii) if communication req'd in writing, maintain such as documentation (iii) if action etc is req'd t/b documented, maintain copy (2) CE must retain documentation 6 years</p>		

AMC Checklist	Rule		Questions		Comments	
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Determine whether your entity is exempt under this section. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> None. 	164.530(k)	<p>(k) group health plans (1) group HP not subject to (a) through (f) and (i) to the extent: (i) group HP benefits solely through insurance contract w insurer or HMO (ii) group HP does not create or receive PHI except: (A) summary health info per 164.504(a) (B) info on indiv participation in group HP & enrollment (2) group HP subject to (j) only for plan documents amended per 164.504(f)</p>				
164.532 Transition provisions						
<p>Category I Guidelines-Actions must be taken</p> <ul style="list-style-type: none"> Decide whether or not to treat protected health information created or received before the HIPAA compliance date with a different set of privacy consents and authorizations from protected health information created or received after the HIPAA compliance date. If protected health information will be handled in different ways depending on the date it was created or received, clearly identify the protected health information that existed before the HIPAA compliance date. Verify that uses and disclosures of protected health information are in accordance with the consent, authorization, or other documented wishes of the individual that were effective at the time the protected health information was created or received. <p>Category II Guidelines-Actions should be taken</p> <ul style="list-style-type: none"> Consider using HIPAA standards for all uses and disclosures of protected health information, whether it was created before or after the HIPAA compliance date, once the HIPAA regulations are in effect. 	164.532(a)	<p>(a) prior consents continue per (b) (b) consent etc prior to compliance date & does not comply w 164.506 or 164.508 (1) if consent permits use for treat, pay, hc ops, CE may use (i) CE does not make use expressly excluded (ii) CE complies w limitations (2) if consent permits other than treat, pay, hc ops, may use if: (i) CE does not use excluded (ii) CE complies w limitations (3) if consent for research & includes treat: (i) CE may use for that project (ii) if general consent, may use for project w limitations (4) if agrees to restriction after compliance date, CE must comply</p>				
<ul style="list-style-type: none"> 						

Types of Actions:

- P P&P's written and/or revised
- E Education (managers and/or staff)
- R Revision of processes
- A Assignment of responsibility (individual or committee)
- I Implement SW or HW
- F New or revised forms
- D Documentation created