

HIPAA Privacy Requirements Checklist

Section	HIPAA Requirement	Existing Policies & Practices	To Do List
Subpart A--General Provisions § 164.102 Statutory basis	The provisions of this part are adopted pursuant to the Secretary's authority to prescribe standards, requirements, and implementation standards under part C of title XI of the Act and section 264 of Public Law 104-191.		
§ 164.104 Applicability	Except as otherwise provided, the provisions of this part apply to covered entities: health plans, health care clearinghouses, and health care providers who transmit health information in electronic form in connection with any transaction referred to in section 1173(a)(1) of the Act.	PA applies only to Federal Records, which may include medical records Covered entity, health plan & clearinghouse defined at 160.103	
§ 164.106 Relationship to other parts	In complying with the requirements of this part, covered entities are required to comply with the applicable provisions of parts 160 and 162 of this subchapter.	5 USC 552a; 45 CFR 5b; IHS SOR 09-17-0001.	Update SOR and/or policy.
Subpart E - Privacy of Individually Identifiable Health Information § 164.500 Applicability	(a) Except as otherwise provided herein, the standards, requirements, and implementation specifications of this subpart apply to covered entities with respect to protected health information. (b) Health care clearinghouses must comply with the standards, requirements, and implementation specifications as follows: (1) When a health care clearinghouse creates or receives protected health information as a business associate of another covered entity, the clearinghouse must comply with: (i) Section 164.500 relating to applicability; (ii) Section 164.501 relating to definitions; (iii) Section 164.502 relating to uses and disclosures of	5 USC 552a; 45 CFR 5b; IHS SOR 09-17-0001. Refer to 160.103 for meaning and examples of clearinghouse	Update SOR and/or policy. Update SOR and/or policy.

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	<p>protected health information, except that a clearinghouse is prohibited from using or disclosing protected health information other than as permitted in the business associate contract under which it created or received the protected health information;</p> <p>(iv) Section 164.504 relating to the organizational requirements for covered entities, including the designation of health care components of a covered entity;</p> <p>(v) Section 164.512 relating to uses and disclosures for which consent, individual authorization or an opportunity to agree or object is not required, except that a clearinghouse is prohibited from using or disclosing protected health information other than as permitted in the business associate contract under which it created or received the protected health information;</p> <p>(vi) Section 164.532 relating to transition requirements; and</p> <p>(vii) Section 164.534 relating to compliance dates for initial implementation of the privacy standards.</p> <p>(2) When a health care clearinghouse creates or receives protected health information other than as a business associate of a covered entity, the clearinghouse must comply with all of the standards, requirements, and implementation specifications of this subpart.</p> <p>(c) The standards, requirements, and implementation specifications of this subpart do not apply to the Department of Defense or to any other federal agency, or non- governmental organization acting on its behalf, when providing health care to overseas foreign national beneficiaries.</p>	<p>Not covered in PA, HHS, or IHS.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p>	<p>Update SOR and/or policy.</p> <p>Same as above.</p> <p>Same as above. Requires business associate contract</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Not applicable to IHS.</p>

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§ 164.501 Definitions	<p>As used in this subpart, the following terms have the following meanings:</p> <p>Correctional institution means any penal or correctional facility, jail, reformatory, detention center, work farm, halfway house, or residential community program center operated by, or under contract to, the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, for the confinement or rehabilitation of persons charged with or convicted of a criminal offense or other persons held in lawful custody. <i>Other persons held in lawful custody</i> includes juvenile offenders adjudicated delinquent, aliens detained awaiting deportation, persons committed to mental institutions through the criminal justice system, witnesses, or others awaiting charges or trial.</p> <p>Covered functions means those functions of a covered entity the performance of which makes the entity a health plan, health care provider, or health care clearinghouse.</p> <p>Data aggregation means, with respect to protected health information created or received by a business associate in its capacity as the business associate of a covered entity, the combining of such protected health information by the business associate with the protected health information received by the business associate in its capacity as a business associate of another covered entity, to permit data analyses that relate to the health care operations of the respective covered entities.</p> <p>Designated record set means:</p> <p>(1) A group of records maintained by or for a covered entity</p>	<p>Some terms are covered in PA, HHS, and IHS.</p> <p>Not in PA</p> <p>Not in PA</p> <p>IHS PA SOR 09-17-0001 is for medical & billing</p>	<p>Update SOR and/or policy.</p> <p>Legal review of some definitions for IHS.</p> <p>Need to explain how this will impact IHS facility interaction with tribes and tribal organizations</p> <p>Need to provide the functions in the definition</p> <p>Send to research, statistics for input regarding policy & procedure implementation</p> <p>Need to expand definition of medical record to include</p>

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	<p>that is:</p> <p>(i) The medical records and billing records about individuals maintained by or for a covered health care provider;</p> <p>(ii) The enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or</p> <p>(iii) Used, in whole or in part, by or for the covered entity to make decisions about individuals.</p> <p>(2) For purposes of this paragraph, the term <i>record</i> means any item, collection, or grouping of information that includes protected health information and is maintained, collected, used, or disseminated by or for a covered entity</p>	<p>records</p> <p>Reference Page 3 top of this report.</p> <p>In PA record means any item, collection, or grouping of info about an individual that is maintained by the Dept, incl'g but not limited to the individuals education, financial transactions, medical history, and criminal or employment history and that contains his name, or an identifying number, symbol, or other identifying particular assigned to the individual, such as a finger or voice print, or a photograph,. When used in this part, record means only a record that is in a system of records.</p>	<p>billing records</p> <p>Reference Page 3 top of this report.</p> <p>HIPAA rule does not include 'system of records' concept</p>

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	<p><i>Direct treatment relationship</i> means a treatment relationship between an individual and a health care provider that is not an indirect treatment relationship.</p> <p><i>Disclosure</i> means the release, transfer, provision of access to, or divulging in any other manner of information outside the entity holding the information.</p> <p><i>Health care operations</i> means any of the following activities of the covered entity to the extent that the activities are related to covered functions, and any of the following activities of an organized health care arrangement in which the covered entity participates:</p> <p>(1) Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment;</p> <p>(2) Reviewing the competence or qualifications of health care</p>	<p>Not in PA or IHS SOR</p> <p>45 CFR 5b(1)(d) Disclosure means the availability or release of a record to anyone other than the subject individual</p> <p>All IHS activities that relate to health care</p> <p>Would this include risk assessments?</p> <p>Apparently, does not include Research activities</p> <p>IHS PA SOR 09-17-0003, Medical staff credentials and privileges records</p>	<p>Add to definitions</p> <p>HIPAA expands definition of disclosure</p> <p>Explain what is meant by and provide examples of quality assessments, improvement activities, outcomes evaluation and development of clinical guidelines</p> <p>Send to OPH medical and research staff for input regarding policy and procedure implementation</p> <p>Send to OPH medical staff for input regarding policy and procedure implement-</p>

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	<p>professionals, evaluating practitioner and provider performance, health plan performance, conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers, training of non-health care professionals, accreditation, certification, licensing, or credentialing activities;</p> <p>(3) Underwriting, premium rating, and other activities relating to the creation, renewal or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care (including stop-loss insurance and excess of loss insurance), provided that the requirements of § 164.514(g) are met, if applicable;</p> <p>(4) Conducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs;</p> <p>(5) Business planning and development, such as conducting cost-management and planning-related analyses related to managing and operating the entity, including formulary development and administration, development or improvement of methods of payment or coverage policies; and</p> <p>(6) Business management and general administrative activities of the entity, including, but not limited to:</p> <p>(i) Management activities relating to implementation of and compliance with the requirements of this subchapter;</p> <p>(ii) Customer service, including the provision of data analyses</p>	<p>includes peer reviews</p> <p>Does CHS program perform any of these functions?</p> <p>IHS business office, finance office, pharmacy and other program offices</p> <p>IHS HQs, Area, SU management</p> <p>IHS privacy advocate</p> <p>What office does customer</p>	<p>ation</p> <p>Consider combining 0003 into 0001</p> <p>Send to 3rd Party & CHS staff for input regarding implementation</p> <p>Identify appropriate office and send for input regarding implementation</p> <p>Send to business office, finance, pharmacy for input regarding implementation</p> <p>Send to Statistics staff for input regarding implementation</p>

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	<p>for policy holders, plan sponsors, or other customers, provided that protected health information is not disclosed to such policy holder, plan sponsor, or customer.</p> <p>(iii) Resolution of internal grievances;</p> <p>(iv) Due diligence in connection with the sale or transfer of assets to a potential successor in interest, if the potential successor in interest is a covered entity or, following completion of the sale or transfer, will become a covered entity; and</p> <p>(v) Consistent with the applicable requirements of § 164.514, creating de-identified health information, fundraising for the benefit of the covered entity, and marketing for which an individual authorization is not required as described in § 164.514(e)(2).</p> <p>Health oversight agency means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant.</p> <p>Indirect treatment relationship means a relationship between</p>	<p>service?</p> <p>Data analysis</p> <p>Would this include a 638 contract or compact transfer</p> <p>Would IHS be considered a health oversight agency?</p> <p>How about the Alaska consortium?</p> <p>What IHS offices would this apply to?</p>	<p>Need written policy and procedure for handling internal grievances</p> <p>Send to OTA & SG office for input regarding implementation</p> <p>Send to research and statistics staff for input regarding implementation</p> <p>Legal Review by OGC.</p> <p>Send to OPH staff for input regarding implementation</p>

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	<p>(1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and</p> <p>(2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and</p> <p>(i) That identifies the individual; or</p> <p>(ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.</p> <p>Inmate means a person incarcerated in or otherwise confined to a correctional institution.</p> <p>Law enforcement official means an officer or employee of any agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, who is empowered by law to:</p> <p>(1) Investigate or conduct an official inquiry into a potential violation of law; or</p> <p>(2) Prosecute or otherwise conduct a criminal, civil, or administrative proceeding arising from an alleged violation of law.</p> <p>Marketing means to make a communication about a product or service a purpose of which is to encourage recipients of the communication to purchase or use the product or service.</p>	<p>Not in PA</p> <p>Not in PA</p> <p>I/T/U facilities may market their services</p>	<p>Send to OPH for input re: implementation</p> <p>Will impact IHS facility/tribal activities</p> <p>Send to OPH, OTA & SG offices for input for implementation.</p> <p>Not applicable to IHS operated facilities</p> <p>Tribal/Urban facilities may market their services and</p>

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	<p>(1) A clinically integrated care setting in which individuals typically receive health care from more than one health care provider;</p> <p>(2) An organized system of health care in which more than one covered entity participates, and in which the participating covered entities:</p> <p>(i) Hold themselves out to the public as participating in a joint arrangement; and</p> <p>(ii) Participate in joint activities that include at least one of the following:</p> <p>(A) Utilization review, in which health care decisions by participating covered entities are reviewed by other participating covered entities or by a third party on their behalf;</p> <p>(B) Quality assessment and improvement activities, in which treatment provided by participating covered entities is assessed by other participating covered entities or by a third party on their behalf; or</p> <p>(C) Payment activities, if the financial risk for delivering health care is shared, in part or in whole, by participating covered entities through the joint arrangement and if protected health information created or received by a covered entity is reviewed by other participating covered entities or by a third party on their behalf for the purpose of administering the sharing of financial risk.</p> <p>(3) A group health plan and a health insurance issuer or HMO with respect to such group health plan, but only with respect to</p>	<p>definition of an organized health care arrangement</p> <p>Tribes maybe?</p> <p>Urbans ?</p> <p>See Page 10 on “Organized health care arrangements”</p>	<p>Send to OPH, OTA & SG offices for input re: implementation</p> <p>See Page 10 on “Organized health care arrangements”</p>

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	<p>protected health information created or received by such health insurance issuer or HMO that relates to individuals who are or who have been participants or beneficiaries in such group health plan;</p> <p>(4) A group health plan and one or more other group health plans each of which are maintained by the same plan sponsor; or</p> <p>(5) The group health plans described in paragraph (4) of this definition and health insurance issuers or HMOs with respect to such group health plans, but only with respect to protected health information created or received by such health insurance issuers or HMOs that relates to individuals who are or have been participants or beneficiaries in any of such group health plans.</p> <p>Payment means:</p> <p>(1) The activities undertaken by:</p> <p>(i) A health plan to obtain premiums or to determine or fulfill its responsibility for coverage and provision of benefits under the health plan; or</p> <p>(ii) A covered health care provider or health plan to obtain or provide reimbursement for the provision of health care; and</p> <p>(2) The activities in paragraph (1) of this definition relate to the individual to whom health care is provided and include, but are not limited to:</p>	<p style="text-align: center;">I/T/U each perform this activity</p>	<p>Send to OPH, OTA & SG, Urban, 3rd Party and CHS offices for input re: implementation</p>

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	<p>(i) Determinations of eligibility or coverage (including coordination of benefits or the determination of cost sharing amounts), and adjudication or subrogation of health benefit claims;</p> <p>(ii) Risk adjusting amounts due based on enrollee health status and demographic characteristics;</p> <p>(iii) Billing, claims management, collection activities, obtaining payment under a contract for reinsurance (including stop-loss insurance and excess of loss insurance), and related health care data processing;</p> <p>(iv) Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges;</p> <p>(v) Utilization review activities, including pre-certification and preauthorization of services, concurrent and retrospective review of services; and</p> <p>(vi) Disclosure to consumer reporting agencies of any of the following protected health information relating to collection of premiums or reimbursement:</p> <p>(A) Name and address;</p> <p>(B) Date of birth;</p> <p>(C) Social security number;</p> <p>(D) Payment history;</p>	<p>5 USC, Section 552a.(b)(12) to a consumer reporting agency in accordance with section 37119e) of title 31.</p>	

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	<p>(E) Account number; and</p> <p>(F) Name and address of the health care provider and/or health plan.</p> <p>Plan sponsor is defined as defined at section 3(16)(B) of ERISA, 29 U.S.C. 1002(16)(B).</p> <p>Protected health information means individually identifiable health information:</p> <p>(1) Except as provided in paragraph (2) of this definition, that is:</p> <p>(i) Transmitted by electronic media;</p> <p>(ii) Maintained in any medium described in the definition of <i>electronic media</i> at § 162.103 of this subchapter; or</p> <p>(iii) Transmitted or maintained in any other form or medium.</p> <p>(2) Protected health information excludes individually identifiable health information in:</p> <p>(i) Education records covered by the Family Educational Right and Privacy Act, as amended, 20 U.S.C. 1232g; and</p> <p>(ii) Records described at 20 U.S.C. 1232g(a)(4)(B)(iv).</p> <p>Psychotherapy notes means notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the</p>	<p>Not in PA</p> <p>Get the definition!</p> <p>Not in PA</p> <p>Incl's paper records</p> <p>??</p> <p>??</p> <p>Not in PA or SOR</p>	<p>Send OPH mental health office for input regarding implementation</p>

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	<p>individual's medical record. <i>Psychotherapy notes</i> excludes medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date.</p> <p>Public health authority means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.</p> <p>Required by law means a mandate contained in law that compels a covered entity to make a use or disclosure of protected health information and that is enforceable in a court of law. <i>Required by law</i> includes, but is not limited to, court orders and court-ordered warrants; subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.</p> <p>Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or</p>	<p>May include I/T/U & their employees</p> <p>PA, b-11 exemption :court of competent jurisdiction does not include tribal court orders</p> <p>PA more restrictive than HIPAA rule on the subject of court orders</p> <p>Definition not in PA</p>	<p>Send to OGC for legal review to find out if this definition includes I/T/U and their employees Send to OPH, OTA & SG for input regarding implementation</p> <p>Send to OGC for legal clarification</p> <p>Provide examples, clarify, effects I/T/U,</p> <p>Send to OTA & SG for input regarding implementation</p> <p>Send to research office staff for input regarding</p>

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	<p>contribute to generalizable knowledge.</p> <p><i>Treatment</i> means the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another.</p> <p><i>Use</i> means, with respect to individually identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information.</p>	<p>Definition not in PA</p> <p>Definition not in PA</p>	<p>implementation</p> <p>Send to OPH for input re: implementation</p> <p>Uses made within the covered entity... send to OPH for input regarding implementation</p>
<p>§ 164.502 Uses and disclosures of protected health information: general rules</p>	<p>(a) <u>Standard</u>. A covered entity may not use or disclose protected health information, except as permitted or required by this subpart or by subpart C of part 160 of this subchapter.</p> <p>(1) <u>Permitted uses and disclosures</u>. A covered entity is permitted to use or disclose protected health information as follows:</p> <p>(i) To the individual;</p> <p>(ii) Pursuant to and in compliance with a consent that complies with § 164.506, to carry out treatment, payment, or health care operations;</p> <p>(iii) Without consent, if consent is not required under §</p>	<p>5 USC 552a; 45 CFR 5b.; IHS SOR 09-17-0001.</p> <p>5 USC 552a; 45 CFR 5b.; IHS SOR 09-17-0001</p>	<p>Update SOR and/or policy. Have work group consisting of appropriate staff develop the policy and procedure (OPH, medical staff, med records, privacy, etc)</p> <p>Update SOR and/or policy. Have work group consisting of appropriate staff develop the policy and procedure</p> <p>(OPH, medical staff, med records, privacy, etc)</p>

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	<p>164.506(a) and has not been sought under § 164.506(a)(4), to carry out treatment, payment, or health care operations, except with respect to psychotherapy notes;</p> <p>(iv) Pursuant to and in compliance with an authorization that complies with § 164.508;</p> <p>(v) Pursuant to an agreement under, or as otherwise permitted by, § 164.510; and</p> <p>(vi) As permitted by and in compliance with this section, § 164.512, or § 164.514(e), (f), and (g).</p> <p>(2) <u>Required disclosures</u>. A covered entity is required to disclose protected health information:</p> <p>(i) To an individual, when requested under, and as required by §§ 164.524 or 164.528; and</p> <p>(ii) When required by the Secretary under subpart C of part 160 of this subchapter to investigate or determine the covered entity's compliance with this subpart.</p> <p>(b) Standard: minimum necessary.</p> <p>(1) <u>Minimum necessary applies</u>. When using or disclosing protected health information or when requesting protected health information from another covered entity, a covered entity must make reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.</p> <p>(2) <u>Minimum necessary does not apply</u>. This requirement does</p>	<p>5 USC 552a(d); 45 CFR 5b.; IHS SOR 09-17-0001.</p> <p>Not covered in PA.</p> <p>PA language similar to “need to know” provision.</p>	<p>Update SOR and/or policy.</p> <p>Have workgroup consisting of appropriate staff developing the policy and procedure for implementation. (OPH, medical staff, medical records, privacy, etc.)</p>

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	<p>information that is not individually identifiable health information or disclose protected health information only to a business associate for such purpose, whether or not the de-identified information is to be used by the covered entity.</p> <p>(2) <u>Uses and disclosures of de-identified information.</u> Health information that meets the standard and implementation specifications for de-identification under § 164.514(a) and (b) is considered not to be individually identifiable health information, i.e., de-identified. The requirements of this subpart do not apply to information that has been de-identified in accordance with the applicable requirements of § 164.514, provided that:</p> <p>(i) Disclosure of a code or other means of record identification designed to enable coded or otherwise de-identified information to be re-identified constitutes disclosure of protected health information; and</p> <p>(ii) If de-identified information is re-identified, a covered entity may use or disclose such re-identified information only as permitted or required by this subpart.</p> <p>(e)(1) Standard: disclosures to business associates.</p> <p>(i) A covered entity may disclose protected health information to a business associate and may allow a business associate to create or receive protected health information on its behalf, if the covered entity obtains satisfactory assurance that the business associate will appropriately safeguard the information.</p>	<p>Not covered in PA.</p> <p>HIPAA 160.103 for definition.</p> <p>Written assurance?</p>	<p>Have workgroup consisting of appropriate staff develop the policy and procedure. (OPH, business office, contract, medical records, privacy staff, etc.)</p>

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	<p>(ii) This standard does not apply:</p> <p>(A) With respect to disclosures by a covered entity to a health care provider concerning the treatment of the individual;</p> <p>(B) With respect to disclosures by a group health plan or a health insurance issuer or HMO with respect to a group health plan to the plan sponsor, to the extent that the requirements of § 164.504(f) apply and are met; or</p> <p>(C) With respect to uses or disclosures by a health plan that is a government program providing public benefits, if eligibility for, or enrollment in, the health plan is determined by an agency other than the agency administering the health plan, or if the protected health information used to determine enrollment or eligibility in the health plan is collected by an agency other than the agency administering the health plan, and such activity is authorized by law, with respect to the collection and sharing of individually identifiable health information for the performance of such functions by the health plan and the agency other than the agency administering the health plan.</p> <p>(iii) A covered entity that violates the satisfactory assurances it provided as a business associate of another covered entity will be in noncompliance with the standards, implementation specifications, and requirements of this paragraph and § 164.504(e).</p> <p>(2) <u>Implementation specification: documentation.</u> A covered entity must document the satisfactory assurances required by paragraph (e)(1) of this section through a written contract or</p>	<p>IHS is a health plan 160.103.</p> <p>Assurance must be written</p>	<p>Have workgroup consisting of appropriate staff develop the policy and procedure to implement.</p> <p>(OPH, medical, business office, CHS, medical records, privacy staff, etc.)</p>

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	<p>other written agreement or arrangement with the business associate that meets the applicable requirements of §164.504(e).</p> <p>(f) <u>Standard: deceased individuals.</u> A covered entity must comply with the requirements of this subpart with respect to the protected health information of a deceased individual.</p> <p>(g)(1) <u>Standard: personal representatives.</u> As specified in this paragraph, a covered entity must, except as provided in paragraphs (g)(3) and (g)(5) of this section, treat a personal representative as the individual for purposes of this subchapter.</p> <p>(2) <u>Implementation specification: adults and emancipated minors.</u> If under applicable law a person has authority to act on behalf of an individual who is an adult or an emancipated minor in making decisions related to health care, a covered entity must treat such person as a personal representative under this subchapter, with respect to protected health information relevant to such personal representation.</p> <p>(3) <u>Implementation specification: unemancipated minors.</u> If under applicable law a parent, guardian, or other person acting <i>in loco parentis</i> has authority to act on behalf of an individual who is an unemancipated minor in making decisions related to health care, a covered entity must treat such person as a personal representative under this subchapter, with respect to protected health information relevant to such personal representation, except that such person may not be a personal representative of an unemancipated minor, and the minor has the authority to act as an individual, with respect to protected health information pertaining to a health care service, if:</p>	<p>Not covered in PA, HHS, or IHS.</p> <p>5 USC 552a; 45 CFR 5b.5(b)(iii); 5b.6(ii); and 5b.10; IHS SOR 09-17-0001.</p> <p>IHS SOR 09-17-0001 under routine uses</p>	<p>Have workgroup consisting of appropriate staff develop the policy and procedure to implement</p> <p>Have workgroup consisting of appropriate staff develop the policy and procedure to implement</p>

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	<p>(i) The minor consents to such health care service; no other consent to such health care service is required by law, regardless of whether the consent of another person has also been obtained; and the minor has not requested that such person be treated as the personal representative;</p> <p>(ii) The minor may lawfully obtain such health care service without the consent of a parent, guardian, or other person acting <i>in loco parentis</i>, and the minor, a court, or another person authorized by law consents to such health care service; or</p> <p>(iii) A parent, guardian, or other person acting <i>in loco parentis</i> assents to an agreement of confidentiality between a covered health care provider and the minor with respect to such health care service.</p> <p>(4) <u>Implementation specification: deceased individuals.</u> If under applicable law an executor, administrator, or other person has authority to act on behalf of a deceased individual or of the individual's estate, a covered entity must treat such person as a personal representative under this subchapter, with respect to protected health information relevant to such personal representation.</p> <p>(5) <u>Implementation specification: abuse, neglect, endangerment situations.</u> Notwithstanding a State law or any requirement of this paragraph to the contrary, a covered entity may elect not to treat a person as the personal representative of an individual if:</p> <p>(i) The covered entity has a reasonable belief that:</p> <p>(A) The individual has been or may be subjected to domestic</p>	<p>Not covered in PA, HHS, or IHS.</p> <p>Not covered in PA, HHS, or IHS.</p>	

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	<p>violence, abuse, or neglect by such person; or</p> <p>(B) Treating such person as the personal representative could endanger the individual; and</p> <p>(ii) The covered entity, in the exercise of professional judgment, decides that it is not in the best interest of the individual to treat the person as the individual's personal representative.</p> <p>(h) <u>Standard: confidential communications.</u> A covered health care provider or health plan must comply with the applicable requirements of § 164.522(b) in communicating protected health information.</p> <p>(i) <u>Standard: uses and disclosures consistent with notice.</u> A covered entity that is required by § 164.520 to have a notice may not use or disclose protected health information in a manner inconsistent with such notice. A covered entity that is required by § 164.520(b)(1)(iii) to include a specific statement in its notice if it intends to engage in an activity listed in § 164.520(b)(1)(iii)(A)-(C), may not use or disclose protected health information for such activities, unless the required statement is included in the notice.</p>	<p>HIPAA rule applies to all forms of communication including oral.</p> <p>Rule eliminates nexus to electronic information; all individually identifiable health info of the covered entity is covered by the Rule.</p> <p>Not covered in PA, HHS, or</p>	

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	<p>(j) Standard: disclosures by whistleblowers and workforce member crime victims.</p> <p>(1) <u>Disclosures by whistleblowers.</u> A covered entity is not considered to have violated the requirements of this subpart if a member of its workforce or a business associate discloses protected health information, provided that:</p> <p>(i) The workforce member or business associate believes in good faith that the covered entity has engaged in conduct that is unlawful or otherwise violates professional or clinical standards, or that the care, services, or conditions provided by the covered entity potentially endangers one or more patients, workers, or the public; and</p> <p>(ii) The disclosure is to:</p> <p>(A) A health oversight agency or public health authority authorized by law to investigate or otherwise oversee the relevant conduct or conditions of the covered entity or to an appropriate health care accreditation organization for the purpose of reporting the allegation of failure to meet professional standards or misconduct by the covered entity; or</p> <p>(B) An attorney retained by or on behalf of the workforce member or business associate for the purpose of determining the legal options of the workforce member or business associate with regard to the conduct described in paragraph (j)(1)(i) of this section.</p> <p>(2) <u>Disclosures by workforce members who are victims of a crime.</u> A covered entity is not considered to have violated the requirements of this subpart if a member of its workforce who is</p>	<p>IHS.</p>	

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	<p>the victim of a criminal act discloses protected health information to a law enforcement official, provided that:</p> <p>(i) The protected health information disclosed is about the suspected perpetrator of the criminal act; and</p> <p>(ii) The protected health information disclosed is limited to the information listed in § 164.512(f)(2)(i).</p>		
<p><u>§ 164.504 Uses and disclosures: organizational requirements</u></p>	<p>(a) <u>Definitions</u>. As used in this section:</p> <p><i>Common control</i> exists if an entity has the power, directly or indirectly, significantly to influence or direct the actions or policies of another entity.</p> <p><i>Common ownership</i> exists if an entity or entities possess an ownership or equity interest of 5 percent or more in another entity.</p> <p><i>Health care component</i> has the following meaning:</p> <p>(1) Components of a covered entity that perform covered functions are part of the health care component.</p> <p>(2) Another component of the covered entity is part of the entity's health care component to the extent that:</p> <p>(i) It performs, with respect to a component that performs covered functions, activities that would make such other component a business associate of the component that performs covered functions if the two components were separate legal entities; and</p> <p>(ii) The activities involve the use or disclosure of protected</p>	<p>This section applies to IHS.</p>	<p>May require legal review from OGC to determine if this applies. Also IHS and 638 facilities may be construed as common control.</p> <p>Have workgroup consisting of appropriate staff to develop the policy and procedure to implement.</p>

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	<p>health information that such other component creates or receives from or on behalf of the component that performs covered functions.</p> <p><i>Hybrid entity</i> means a single legal entity that is a covered entity and whose covered functions are not its primary functions.</p> <p><i>Plan administration functions</i> means administration functions performed by the plan sponsor of a group health plan on behalf of the group health plan and excludes functions performed by the plan sponsor in connection with any other benefit or benefit plan of the plan sponsor.</p> <p><i>Summary health information</i> means information, that may be individually identifiable health information, and:</p> <p>(1) That summarizes the claims history, claims expenses, or type of claims experienced by individuals for whom a plan sponsor has provided health benefits under a group health plan; and</p> <p>(2) From which the information described at § 164.514(b)(2)(i) has been deleted, except that the geographic information described in § 164.514(b)(2)(i)(B) need only be aggregated to the level of a five digit zip code.</p> <p>(b) <u>Standard: health care component.</u> If a covered entity is a hybrid entity, the requirements of this subpart, other than the requirements of this section, apply only to the health care component(s) of the entity, as specified in this section.</p> <p>(c)(1) <u>Implementation specification: application of other provisions.</u> In applying a provision of this subpart, other than</p>		

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	<p>this section, to a hybrid entity:</p> <p>(i) A reference in such provision to a “covered entity” refers to a health care component of the covered entity;</p> <p>(ii) A reference in such provision to a “health plan,” “covered health care provider,” or “health care clearinghouse” refers to a health care component of the covered entity if such health care component performs the functions of a health plan, covered health care provider, or health care clearinghouse, as applicable; and</p> <p>(iii) A reference in such provision to “protected health information” refers to protected health information that is created or received by or on behalf of the health care component of the covered entity.</p> <p>(2) <u>Implementation specifications: safeguard requirements.</u> The covered entity that is a hybrid entity must ensure that a health care component of the entity complies with the applicable requirements of this subpart. In particular, and without limiting this requirement, such covered entity must ensure that:</p> <p>(i) Its health care component does not disclose protected health information to another component of the covered entity in circumstances in which this subpart would prohibit such disclosure if the health care component and the other component were separate and distinct legal entities;</p> <p>(ii) A component that is described by paragraph (2)(i) of the definition of <i>health care component</i> in this section does not use or disclose protected health information that is within paragraph (2)(ii) of such definition for purposes of its activities other than</p>		

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	<p>those described by paragraph (2)(i) of such definition in a way prohibited by this subpart; and</p> <p>(iii) If a person performs duties for both the health care component in the capacity of a member of the workforce of such component and for another component of the entity in the same capacity with respect to that component, such workforce member must not use or disclose protected health information created or received in the course of or incident to the member's work for the health care component in a way prohibited by this subpart.</p> <p>(3) <u>Implementation specifications: responsibilities of the covered entity.</u> A covered entity that is a hybrid entity has the following responsibilities:</p> <p>(i) For purposes of subpart C of part 160 of this subchapter, pertaining to compliance and enforcement, the covered entity has the responsibility to comply with this subpart.</p> <p>(ii) The covered entity has the responsibility for complying with § 164.530(i), pertaining to the implementation of policies and procedures to ensure compliance with this subpart, including the safeguard requirements in paragraph (c)(2) of this section.</p> <p>(iii) The covered entity is responsible for designating the components that are part of one or more health care components of the covered entity and documenting the designation as required by § 164.530(j).</p> <p>(d)(1) Standard: affiliated covered entities. Legally separate covered entities that are affiliated may designate themselves as a single covered entity for purposes of this subpart.</p>	<p>IHS may want to consider being designated as a single affiliated covered entity.</p>	<p>Determine whether this</p>

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	<p>(2) Implementation specifications: requirements for designation of an affiliated covered entity.</p> <p>(i) Legally separate covered entities may designate themselves (including any health care component of such covered entity) as a single affiliated covered entity, for purposes of this subpart, if all of the covered entities designated are under common ownership or control.</p> <p>(ii) The designation of an affiliated covered entity must be documented and the documentation maintained as required by § 164.530(j).</p> <p>(3) Implementation specifications: safeguard requirements. An affiliated covered entity must ensure that:</p> <p>(i) The affiliated covered entity's use and disclosure of protected health information comply with the applicable requirements of this subpart; and</p> <p>(ii) If the affiliated covered entity combines the functions of a health plan, health care provider, or health care clearinghouse, the affiliated covered entity complies with paragraph (g) of this section.</p> <p>(e)(1) Standard: business associate contracts.</p> <p>(i) The contract or other arrangement between the covered entity and the business associate required by § 164.502(e)(2) must meet the requirements of paragraph (e)(2) or (e)(3) of this section, as applicable.</p> <p>(ii) A covered entity is not in compliance with the standards in §</p>	<p>All affiliated covered entities must comply.</p> <p>Not covered in PA, HHS, or IHS.</p>	<p>applies to IHS, require OGC legal review.</p> <p>Have workgroup consisting of appropriate staff develop the policy and procedure to implement.</p> <p>Have workgroup consisting of appropriate staff develop the written business associate contracts and the policy and procedure to implement. (OPH, business office, CHS, contract, privacy staff, etc.)</p>

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	<p>164.502(e) and paragraph (e) of this section, if the covered entity knew of a pattern of activity or practice of the business associate that constituted a material breach or violation of the business associate’s obligation under the contract or other arrangement, unless the covered entity took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful:</p> <p>(A) Terminated the contract or arrangement, if feasible; or</p> <p>(B) If termination is not feasible, reported the problem to the Secretary.</p> <p>(2) <u>Implementation specifications: business associate contracts.</u> A contract between the covered entity and a business associate must:</p> <p>(i) Establish the permitted and required uses and disclosures of such information by the business associate. The contract may not authorize the business associate to use or further disclose the information in a manner that would violate the requirements of this subpart, if done by the covered entity, except that:</p> <p>(A) The contract may permit the business associate to use and disclose protected health information for the proper management and administration of the business associate, as provided in paragraph (e)(4) of this section; and</p> <p>(B) The contract may permit the business associate to provide data aggregation services relating to the health care operations of the covered entity.</p> <p>(ii) Provide that the business associate will:</p>	<p>Business associate contract establishes the permitted and required uses and disclosures.</p> <p>Data aggregation must be in the contract.</p>	

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	<p>entity and the business associate may permit the business associate to disclose the information received by the business associate in its capacity as a business associate for the purposes described in paragraph (e)(4)(i) of this section, if:</p> <p>(A) The disclosure is required by law; or</p> <p>(B)(1) The business associate obtains reasonable assurances from the person to whom the information is disclosed that it will be held confidentially and used or further disclosed only as required by law or for the purpose for which it was disclosed to the person; and (2) The person notifies the business associate of any instances of which it is aware in which the confidentiality of the information has been breached.</p> <p>(f)(1)Standard: requirements for group health plans.</p> <p>(i) Except as provided under paragraph (f)(1)(ii) of this section or as otherwise authorized under § 164.508, a group health plan, in order to disclose protected health information to the plan sponsor or to provide for or permit the disclosure of protected health information to the plan sponsor by a health insurance issuer or HMO with respect to the group health plan, must ensure that the plan documents restrict uses and discloses of such information by the plan sponsor consistent with the requirements of this subpart.</p> <p>(ii) The group health plan, or a health insurance issuer or HMO with respect to the group health plan, may disclose summary health information to the plan sponsor, if the plan sponsor requests the summary health information for the purpose of :</p> <p>(A) Obtaining premium bids from health plans for providing</p>	<p>See definition at 160.103; define plan sponsor; and this section may not apply to IHS.</p> <p>May not be applicable to IHS.</p>	<p>Legal review by OGC to determine if this applies to IHS.</p>

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	<p>health insurance coverage under the group health plan; or</p> <p>(B) Modifying, amending, or terminating the group health plan.</p> <p>(2) <u>Implementation specifications: requirements for plan documents.</u> The plan documents of the group health plan must be amended to incorporate provisions to:</p> <p>(i) Establish the permitted and required uses and disclosures of such information by the plan sponsor, provided that such permitted and required uses and disclosures may not be inconsistent with this subpart.</p> <p>(ii) Provide that the group health plan will disclose protected health information to the plan sponsor only upon receipt of a certification by the plan sponsor that the plan documents have been amended to incorporate the following provisions and that the plan sponsor agrees to:</p> <p>(A) Not use or further disclose the information other than as permitted or required by the plan documents or as required by law;</p> <p>(B) Ensure that any agents, including a subcontractor, to whom it provides protected health information received from the group health plan agree to the same restrictions and conditions that apply to the plan sponsor with respect to such information;</p> <p>(C) Not use or disclose the information for employment-related actions and decisions or in connection with any other benefit or employee benefit plan of the plan sponsor;</p> <p>(D) Report to the group health plan any use or disclosure of the information that is inconsistent with the uses or disclosures</p>		

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	<p>provided for of which it becomes aware;</p> <p>(E) Make available protected health information in accordance with § 164.524;</p> <p>(F) Make available protected health information for amendment and incorporate any amendments to protected health information in accordance with §164.526;</p> <p>(G) Make available the information required to provide an accounting of disclosures in accordance with § 164.528;</p> <p>(H) 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 for purposes of determining compliance by the group health plan with this subpart;</p> <p>(I) If feasible, return or destroy all protected health information received from the group health plan that the sponsor still maintains in any form and retain no copies of such information when no longer needed for the purpose for which disclosure was made, except that, if such return or destruction is not feasible, limit further uses and disclosures to those purposes that make the return or destruction of the information infeasible; and</p> <p>(J) Ensure that the adequate separation required in paragraph (f)(2)(iii) of this section is established.</p> <p>(iii) Provide for adequate separation between the group health plan and the plan sponsor. The plan documents must:</p> <p>(A) Describe those employees or classes of employees or other persons under the control of the plan sponsor to be given access</p>		

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	<p>to the protected health information to be disclosed, provided that any employee or person who receives protected health information relating to payment under, health care operations of, or other matters pertaining to the group health plan in the ordinary course of business must be included in such description;</p> <p>(B) Restrict the access to and use by such employees and other persons described in paragraph (f)(2)(iii)(A) of this section to the plan administration functions that the plan sponsor performs for the group health plan; and</p> <p>(C) Provide an effective mechanism for resolving any issues of noncompliance by persons described in paragraph (f)(2)(iii)(A) of this section with the plan document provisions required by this paragraph.</p> <p>(3) Implementation specifications: uses and disclosures. A group health plan may:</p> <p>(i) Disclose protected health information to a plan sponsor to carry out plan administration functions that the plan sponsor performs only consistent with the provisions of paragraph (f)(2) of this section;</p> <p>(ii) Not permit a health insurance issuer or HMO with respect to the group health plan to disclose protected health information to the plan sponsor except as permitted by this paragraph;</p> <p>(iii) Not disclose and may not permit a health insurance issuer or HMO to disclose protected health information to a plan sponsor as otherwise permitted by this paragraph unless a statement required by § 164.520(b)(1)(iii)(C) is included in the</p>		

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	<p>appropriate notice; and</p> <p>(iv) Not disclose protected health information to the plan sponsor for the purpose of employment-related actions or decisions or in connection with any other benefit or employee benefit plan of the plan sponsor.</p> <p>(g) Standard: requirements for a covered entity with multiple covered functions.</p> <p>(1) A covered entity that performs multiple covered functions that would make the entity any combination of a health plan, a covered health care provider, and a health care clearinghouse, must comply with the standards, requirements, and implementation specifications of this subpart, as applicable to the health plan, health care provider, or health care clearinghouse covered functions performed.</p> <p>(2) A covered entity that performs multiple covered functions may use or disclose the protected health information of individuals who receive the covered entity's health plan or health care provider services, but not both, only for purposes related to the appropriate function being performed.</p>		
<p>§ 164.506 Consent for uses or disclosures to carry out treatment, payment, or health care operations</p>	<p>(a) Standard: consent requirement.</p> <p>(1) Except as provided in paragraph (a)(2) or (a)(3) of this section, a covered health care provider must obtain the individual's consent, in accordance with this section, prior to using or disclosing protected health information to carry out treatment, payment, or health care operations.</p> <p>(2) A covered health care provider may, without consent, use or disclose protected health information to carry out treatment,</p>	<p>5 USC 552a; 45 CFR 5b.; IHS SOR 09-17-0001. Note: As a health plan, IHS may but is not required to obtain a consent but would individual IHS direct health care providers and facilities</p>	<p>Refer to OGC for legal review.</p> <p>Have workgroup consisting of appropriate staff develop the written consent and the</p>

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	<p>payment, or health care operations, if:</p> <p>(i) The covered health care provider has an indirect treatment relationship with the individual; or</p> <p>(ii) The covered health care provider created or received the protected health information in the course of providing health care to an individual who is an inmate.</p> <p>(3)(i) A covered health care provider may, without prior consent, use or disclose protected health information created or received under paragraph (a)(3)(i)(A)-(C) of this section to carry out treatment, payment, or health care operations:</p> <p>(A) In emergency treatment situations, if the covered health care provider attempts to obtain such consent as soon as reasonably practicable after the delivery of such treatment;</p> <p>(B) If the covered health care provider is required by law to treat the individual, and the covered health care provider attempts to obtain such consent but is unable to obtain such consent; or</p> <p>(C) If a covered health care provider attempts to obtain such consent from the individual but is unable to obtain such consent due to substantial barriers to communicating with the individual, and the covered health care provider determines, in the exercise of professional judgment, that the individual's consent to receive treatment is clearly inferred from the circumstances.</p> <p>(ii) A covered health care provider that fails to obtain such consent in accordance with paragraph (a)(3)(i) of this section must document its attempt to obtain consent and the reason why</p>	<p>would need to obtain a written consent?</p>	<p>policy and procedure to implement.</p> <p>(OPH, medical, business office, CHS, privacy staff, OGC, etc.)</p>

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	<p>consent was not obtained.</p> <p>(4) If a covered entity is not required to obtain consent by paragraph (a)(1) of this section, it may obtain an individual's consent for the covered entity's own use or disclosure of protected health information to carry out treatment, payment, or health care operations, provided that such consent meets the requirements of this section.</p> <p>(5) Except as provided in paragraph (f)(1) of this section, a consent obtained by a covered entity under this section is not effective to permit another covered entity to use or disclose protected health information.</p> <p>(b) Implementation specifications: general requirements.</p> <p>(1) A covered health care provider may condition treatment on the provision by the individual of a consent under this section.</p> <p>(2) A health plan may condition enrollment in the health plan on the provision by the individual of a consent under this section sought in conjunction with such enrollment.</p> <p>(3) A consent under this section may not be combined in a single document with the notice required by § 164.520.</p> <p>(4)(i) A consent for use or disclosure may be combined with other types of written legal permission from the individual (e.g., an informed consent for treatment or a consent to assignment of benefits), if the consent under this section:</p> <p>(A) Is visually and organizationally separate from such other written legal permission; and</p>	<p>Can not combine a consent with the notice.</p> <p>Exception</p>	

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	<p>(B) Is separately signed by the individual and dated.</p> <p>(ii) A consent for use or disclosure may be combined with a research authorization under § 164.508(f).</p> <p>(5) An individual may revoke a consent under this section at any time, except to the extent that the covered entity has taken action in reliance thereon. Such revocation must be in writing.</p> <p>(6) A covered entity must document and retain any signed consent under this section as required by § 164.530(j).</p> <p>(c) <u>Implementation specifications: content requirements.</u> A consent under this section must be in plain language and:</p> <p>(1) Inform the individual that protected health information may be used and disclosed to carry out treatment, payment, or health care operations;</p> <p>(2) Refer the individual to the notice required by § 164.520 for a more complete description of such uses and disclosures and state that the individual has the right to review the notice prior to signing the consent;</p> <p>(3) If the covered entity has reserved the right to change its privacy practices that are described in the notice in accordance with § 164.520(b)(1)(v)(C), state that the terms of its notice may change and describe how the individual may obtain a revised notice;</p> <p>(4) State that: (i) The individual has the right to request that the covered entity restrict how protected health information is used or disclosed to carry out treatment, payment, or health care</p>	<p>Right to revoke consent.</p> <p>Retain consent for 6 years.</p> <p>Written in plain English language.</p> <p>Right to change notice</p> <p>Required</p>	<p>Refer to research staff for input regarding implementation.</p> <p>Initial draft being developed.</p>

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	<p>operations;</p> <p>(ii) The covered entity is not required to agree to requested restrictions; and</p> <p>(iii) If the covered entity agrees to a requested restriction, the restriction is binding on the covered entity;</p> <p>(5) State that the individual has the right to revoke the consent in writing, except to the extent that the covered entity has taken action in reliance thereon; and</p> <p>(6) Be signed by the individual and dated.</p> <p>(d) <u>Implementation specifications: defective consents.</u> There is no consent under this section, if the document submitted has any of the following defects:</p> <p>(1) The consent lacks an element required by paragraph (c) of this section, as applicable; or</p> <p>(2) The consent has been revoked in accordance with paragraph (b)(5) of this section.</p> <p>(e) Standard: resolving conflicting consents and authorizations.</p> <p>(1) If a covered entity has obtained a consent under this section and receives any other authorization or written legal permission from the individual for a disclosure of protected health information to carry out treatment, payment, or health care operations, the covered entity may disclose such protected health information only in accordance with the more restrictive consent, authorization, or other written legal permission from the individual.</p>	<p>Required</p> <p>Required</p> <p>OCR “draft” guidance discusses this issue (page 9 of 45).</p> <p>Use the more restrictive</p> <p>Consent gives direct treatment providers permission to use and disclose all phi for TPO</p>	

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	<p>(2) A covered entity may attempt to resolve a conflict between a consent and an authorization or other written legal permission from the individual described in paragraph (e)(1) of this section by:</p> <p>(i) Obtaining a new consent from the individual under this section for the disclosure to carry out treatment, payment, or health care operations; or</p> <p>(ii) Communicating orally or in writing with the individual in order to determine the individual's preference in resolving the conflict. The covered entity must document the individual's preference and may only disclose protected health information in accordance with the individual's preference.</p> <p>(f)(1) Standard: joint consents. Covered entities that participate in an organized health care arrangement and that have a joint notice under § 164.520(d) may comply with this section by a joint consent.</p> <p>(2) Implementation specifications: requirements for joint consents.</p> <p>(i) A joint consent must:</p>	<p>Authorization gives covered entities permission to use and disclose specified TPO for specified purposes other than TPO.</p> <p>Get a new consent</p> <p>Put oral agreement in writing.</p> <p>IHS may want to consider using the joint consent.</p>	

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	<p>(A) Include the name or other specific identification of the covered entities, or classes of covered entities, to which the joint consent applies; and</p> <p>(B) Meet the requirements of this section, except that the statements required by this section may be altered to reflect the fact that the consent covers more than one covered entity.</p> <p>(ii) If an individual revokes a joint consent, the covered entity that receives the revocation must inform the other entities covered by the joint consent of the revocation as soon as practicable.</p>		
§164.508 Uses and disclosures for which an authorization is required	<p>(a) Standard: authorizations for uses and disclosures.</p> <p>(1) <u>Authorization required: general rule.</u> Except as otherwise permitted or required by this subchapter, a covered entity may not use or disclose protected health information without an authorization that is valid under this section. When a covered entity obtains or receives a valid authorization for its use or disclosure of protected health information, such use or disclosure must be consistent with such authorization.</p> <p>(2) <u>Authorization required: psychotherapy notes.</u> Notwithstanding any other provision of this subpart, other than transition provisions provided for in § 164.532, a covered entity must obtain an authorization for any use or disclosure of psychotherapy notes, except:</p> <p>(i) To carry out the following treatment, payment, or health care operations, consistent with consent requirements in § 164.506:</p> <p>(A) Use by originator of the psychotherapy notes for treatment;</p>	<p>5 USC 552a(b); 45 CFR 5b.9; IHS SOR 09-17-0001</p> <p>Not covered in PA, HHS, or IHS.</p>	<p>Update SOR and/or policy.</p> <p>Send to OPH mental health office for input regarding implementation.</p>

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	<p>(B) Use or disclosure by the covered entity in training programs in which students, trainees, or practitioners in mental health learn under supervision to practice or improve their skills in group, joint, family, or individual counseling; or</p> <p>(C) Use or disclosure by the covered entity to defend a legal action or other proceeding brought by the individual; and</p> <p>(ii) A use or disclosure that is required by § 164.502(a)(2)(ii) or permitted by § 164.512(a); § 164.512(d) with respect to the oversight of the originator of the psychotherapy notes; § 164.512(g)(1); or § 164.512(j)(1)(i).</p> <p>(b) Implementation specifications: general requirements.</p> <p>(1) Valid authorizations.</p> <p>(i) A valid authorization is a document that contains the elements listed in paragraph (c) and, as applicable, paragraph (d), (e), or (f) of this section.</p> <p>(ii) A valid authorization may contain elements or information in addition to the elements required by this section, provided that such additional elements or information are not be inconsistent with the elements required by this section.</p> <p>(2) <u>Defective authorizations.</u> An authorization is not valid, if the document submitted has any of the following defects:</p> <p>(i) The expiration date has passed or the expiration event is known by the covered entity to have occurred;</p> <p>(ii) The authorization has not been filled out completely, with respect to an element described by paragraph (c), (d), (e), or (f)</p>		<p>Have workgroup consisting of appropriate staff develop the written authorization and the policy and procedure to implement.</p> <p>(OPH, medical, business office, chs, privacy staff, OGC, etc.)</p>

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	<p>of this section, if applicable;</p> <p>(iii) The authorization is known by the covered entity to have been revoked;</p> <p>(iv) The authorization lacks an element required by paragraph (c), (d), (e), or (f) of this section, if applicable;</p> <p>(v) The authorization violates paragraph (b)(3) of this section, if applicable;</p> <p>(vi) Any material information in the authorization is known by the covered entity to be false.</p> <p>(3) <u>Compound authorizations.</u> An authorization for use or disclosure of protected health information may not be combined with any other document to create a compound authorization, except as follows:</p> <p>(i) An authorization for the use or disclosure of protected health information created for research that includes treatment of the individual may be combined as permitted by § 164.506(b)(4)(ii) or paragraph (f) of this section;</p> <p>(ii) An authorization for a use or disclosure of psychotherapy notes may only be combined with another authorization for a use or disclosure of psychotherapy notes;</p> <p>(iii) An authorization under this section, other than an authorization for a use or disclosure of psychotherapy notes may be combined with any other such authorization under this section, except when a covered entity has conditioned the</p>		<p>Send to research staff for input re: implementation</p>

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	<p>provision of treatment, payment, enrollment in the health plan, or eligibility for benefits under paragraph (b)(4) of this section on the provision of one of the authorizations.</p> <p>(4) Prohibition on conditioning of authorizations. A covered entity may not condition the provision to an individual of treatment, payment, enrollment in the health plan, or eligibility for benefits on the provision of an authorization, except:</p> <p>(i) A covered health care provider may condition the provision of research-related treatment on provision of an authorization under paragraph (f) of this section;</p> <p>(ii) A health plan may condition enrollment in the health plan or eligibility for benefits on provision of an authorization requested by the health plan prior to an individual's enrollment in the health plan, if:</p> <p>(A) The authorization sought is for the health plan's eligibility or enrollment determinations relating to the individual or for its underwriting or risk rating determinations; and</p> <p>(B) The authorization is not for a use or disclosure of psychotherapy notes under paragraph (a)(2) of this section;</p> <p>(iii) A health plan may condition payment of a claim for specified benefits on provision of an authorization under paragraph (e) of this section, if:</p> <p>(A) The disclosure is necessary to determine payment of such claim; and</p> <p>(B) The authorization is not for a use or disclosure of</p>		<p>Send to research staff for input re: implementation</p>

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	<p>psychotherapy notes under paragraph (a)(2) of this section; and</p> <p>(iv) A covered entity may condition the provision of health care that is solely for the purpose of creating protected health information for disclosure to a third party on provision of an authorization for the disclosure of the protected health information to such third party.</p> <p>(5) <u>Revocation of authorizations.</u> An individual may revoke an authorization provided under this section at any time, provided that the revocation is in writing, except to the extent that:</p> <p>(i) The covered entity has taken action in reliance thereon; or</p> <p>(ii) If the authorization was obtained as a condition of obtaining insurance coverage, other law provides the insurer with the right to contest a claim under the policy.</p> <p>(6) <u>Documentation.</u> A covered entity must document and retain any signed authorization under this section as required by § 164.530(j).</p> <p>(c) Implementation specifications: core elements and requirements.</p> <p>(1) <u>Core elements.</u> A valid authorization under this section must contain at least the following elements:</p> <p>(i) A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion;</p> <p>(ii) The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure;</p>	<p>6 year retention.</p> <p>Required.</p> <p>Required.</p>	

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	<p>(iii) The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure;</p> <p>(iv) An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure;</p> <p>(v) A statement of the individual’s right to revoke the authorization in writing and the exceptions to the right to revoke, together with a description of how the individual may revoke the authorization;</p> <p>(vi) A statement that information used or disclosed pursuant to the authorization may be subject to redisclosure by the recipient and no longer be protected by this rule;</p> <p>(vii) Signature of the individual and date; and</p> <p>(viii) If the authorization is signed by a personal representative of the individual, a description of such representative’s authority to act for the individual.</p> <p>(2) <u>Plain language requirement.</u> The authorization must be written in plain language.</p> <p>(d) <u>Implementation specifications: authorizations requested by a covered entity for its own uses and disclosures.</u> If an authorization is requested by a covered entity for its own use or disclosure of protected health information that it maintains, the covered entity must comply with the following requirements.</p> <p>(1) <u>Required elements.</u> The authorization for the uses or disclosures described in this paragraph must, in addition to</p>	<p>Required.</p> <p>Required.</p> <p>Required.</p> <p>Required.</p> <p>Required.</p> <p>Required.</p> <p>Required.</p>	<p>Have workgroup consisting of appropriate staff develop the written authorization and the policy and procedure to implement.</p> <p>(OPH, medical, business office, chs, privacy staff, OGC, etc.)</p>

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	<p>meeting the requirements of paragraph (c) of this section, contain the following elements:</p> <p>(i) For any authorization to which the prohibition on conditioning in paragraph (b)(4) of this section applies, a statement that the covered entity will not condition treatment, payment, enrollment in the health plan, or eligibility for benefits on the individual's providing authorization for the requested use or disclosure;</p> <p>(ii) A description of each purpose of the requested use or disclosure;</p> <p>(iii) A statement that the individual may:</p> <p>(A) Inspect or copy the protected health information to be used or disclosed as provided in § 164.524; and</p> <p>(B) Refuse to sign the authorization; and</p> <p>(iv) If use or disclosure of the requested information will result in direct or indirect remuneration to the covered entity from a third party, a statement that such remuneration will result.</p> <p>(2) <u>Copy to the individual.</u> A covered entity must provide the individual with a copy of the signed authorization.</p> <p>(e) <u>Implementation specifications: authorizations requested by a covered entity for disclosures by others.</u> If an authorization is requested by a covered entity for another covered entity to disclose protected health information to the covered entity requesting the authorization to carry out treatment, payment, or health care operations, the covered entity requesting the</p>	<p>Required.</p> <p>Required.</p> <p>Required.</p> <p>Required.</p> <p>Required.</p>	

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	<p>authorization must comply with the following requirements.</p> <p>(1) <u>Required elements</u>. The authorization for the disclosures described in this paragraph must, in addition to meeting the requirements of paragraph (c) of this section, contain the following elements:</p> <p>(i) A description of each purpose of the requested disclosure;</p> <p>(ii) Except for an authorization on which payment may be conditioned under paragraph (b)(4)(iii) of this section, a statement that the covered entity will not condition treatment, payment, enrollment in the health plan, or eligibility for benefits on the individual's providing authorization for the requested use or disclosure; and</p> <p>(iii) A statement that the individual may refuse to sign the authorization.</p> <p>(2) <u>Copy to the individual</u>. A covered entity must provide the individual with a copy of the signed authorization.</p> <p>(f) Implementation specifications: authorizations for uses and disclosures of protected health information created for research that includes treatment of the individual.</p> <p>(1) <u>Required elements</u>. Except as otherwise permitted by § 164.512(i), a covered entity that creates protected health information for the purpose, in whole or in part, of research that includes treatment of individuals must obtain an authorization for the use or disclosure of such information. Such authorization must:</p> <p>(i) For uses and disclosures not otherwise permitted or required</p>	<p>Required.</p> <p>Required.</p> <p>Required.</p> <p>Required.</p>	

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	<p>under this subpart, meet the requirements of paragraphs (c) and (d) of this section; and</p> <p>(ii) Contain:</p> <p>(A) A description of the extent to which such protected health information will be used or disclosed to carry out treatment, payment, or health care operations;</p> <p>(B) A description of any protected health information that will not be used or disclosed for purposes permitted in accordance with §§ 164.510 and 164.512, provided that the covered entity may not include a limitation affecting its right to make a use or disclosure that is required by law or permitted by § 164.512(j)(1)(i); and</p> <p>(C) If the covered entity has obtained or intends to obtain the individual’s consent under § 164.506, or has provided or intends to provide the individual with a notice under § 164.520, the authorization must refer to that consent or notice, as applicable, and state that the statements made pursuant to this section are binding.</p> <p>(2) <u>Optional procedure.</u> An authorization under this paragraph may be in the same document as: (i) A consent to participate in the research;</p> <p>(ii) A consent to use or disclose protected health information to carry out treatment, payment, or health care operations under § 164.506; or</p> <p>(iii) A notice of privacy practices under § 164.520.</p>		<p>Send to research staff for input re: implementation</p>
§ 164.510 Uses and	A covered entity may use or disclose protected health	Advance notice with	

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disclosures requiring an opportunity for the individual to agree or to object	<p>information without the written consent or authorization of the individual as described by §§ 164.506 and 164.508, respectively, provided that the individual is informed in advance of the use or disclosure and has the opportunity to agree to or prohibit or restrict the disclosure in accordance with the applicable requirements of this section. The covered entity may orally inform the individual of and obtain the individual's oral agreement or objection to a use or disclosure permitted by this section.</p> <p>(a) Standard: use and disclosure for facility directories.</p> <p>(1) <u>Permitted uses and disclosure.</u> Except when an objection is expressed in accordance with paragraphs (a)(2) or (3) of this section, a covered health care provider may:</p> <p>(i) Use the following protected health information to maintain a directory of individuals in its facility:</p> <p>(A) The individual's name;</p> <p>(B) The individual's location in the covered health care provider's facility;</p> <p>(C) The individual's condition described in general terms that does not communicate specific medical information about the individual; and</p> <p>(D) The individual's religious affiliation; and</p> <p>(ii) Disclose for directory purposes such information:</p> <p>(A) To members of the clergy; or</p>	<p>opportunity to agree or disagree.</p> <p>Does the oral notice and agreement have to be recorded in writing by the covered entity?</p>	<p>Have workgroup consisting of appropriate staff develop the policy and procedure to implement.</p> <p>(OPH, medical, business office, chs, privacy staff, OGC, etc.)</p>

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	<p>(B) Except for religious affiliation, to other persons who ask for the individual by name.</p> <p>(2) <u>Opportunity to object.</u> A covered health care provider must inform an individual of the protected health information that it may include in a directory and the persons to whom it may disclose such information (including disclosures to clergy of information regarding religious affiliation) and provide the individual with the opportunity to restrict or prohibit some or all of the uses or disclosures permitted by paragraph (a)(1) of this section.</p> <p>(3) Emergency circumstances.</p> <p>(i) If the opportunity to object to uses or disclosures required by paragraph (a)(2) of this section cannot practicably be provided because of the individual’s incapacity or an emergency treatment circumstance, a covered health care provider may use or disclose some or all of the protected health information permitted by paragraph (a)(1) of this section for the facility’s directory, if such disclosure is:</p> <p>(A) Consistent with a prior expressed preference of the individual, if any, that is known to the covered health care provider; and</p> <p>(B) In the individual’s best interest as determined by the covered health care provider, in the exercise of professional judgment.</p> <p>(ii) The covered health care provider must inform the individual and provide an opportunity to object to uses or disclosures for directory purposes as required by paragraph (a)(2) of this</p>	<p>Required</p>	<p>Have workgroup consisting of appropriate staff develop the policy and procedure to implement.</p> <p>(OPH, medical, business office, chs, privacy staff, OGC, etc.)</p>

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	<p>section when it becomes practicable to do so.</p> <p>(b) Standard: uses and disclosures for involvement in the individual's care and notification purposes.</p> <p>(1) Permitted uses and disclosures.</p> <p>(i) A covered entity may, in accordance with paragraphs (b)(2) or (3) of this section, disclose to a family member, other relative, or a close personal friend of the individual, or any other person identified by the individual, the protected health information directly relevant to such person's involvement with the individual's care or payment related to the individual's health care.</p> <p>(ii) A covered entity may use or disclose protected health information to notify, or assist in the notification of (including identifying or locating), a family member, a personal representative of the individual, or another person responsible for the care of the individual of the individual's location, general condition, or death. Any such use or disclosure of protected health information for such notification purposes must be in accordance with paragraphs (b)(2), (3), or (4) of this section, as applicable.</p> <p>(2) <u>Uses and disclosures with the individual present.</u> If the individual is present for, or otherwise available prior to, a use or disclosure permitted by paragraph (b)(1) of this section and has the capacity to make health care decisions, the covered entity may use or disclose the protected health information if it:</p> <p>(i) Obtains the individual's agreement;</p> <p>(ii) Provides the individual with the opportunity to object to the</p>	<p>Verbally or in writing. Can this be a gesture or must it be in writing.</p>	<p>Have workgroup consisting of appropriate staff develop the policy and procedure to implement.</p> <p>(OPH, medical, business office, chs, privacy staff, OGC, etc.)</p>

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	<p>disclosure, and the individual does not express an objection; or</p> <p>(iii) Reasonably infers from the circumstances, based the exercise of professional judgment, that the individual does not object to the disclosure.</p> <p>(3) <u>Limited uses and disclosures when the individual is not present.</u> If the individual is not present for, or the opportunity to agree or object to the use or disclosure cannot practicably be provided because of the individual’s incapacity or an emergency circumstance, the covered entity may, in the exercise of professional judgment, determine whether the disclosure is in the best interests of the individual and, if so, disclose only the protected health information that is directly relevant to the person’s involvement with the individual’s health care. A covered entity may use professional judgment and its experience with common practice to make reasonable inferences of the individual’s best interest in allowing a person to act on behalf of the individual to pick up filled prescriptions, medical supplies, X-rays, or other similar forms of protected health information.</p> <p>(4) <u>Use and disclosures for disaster relief purposes.</u> A covered entity may use or disclose protected health information to a public or private entity authorized by law or by its charter to assist in disaster relief efforts, for the purpose of coordinating with such entities the uses or disclosures permitted by paragraph (b)(1)(ii) of this section. The requirements in paragraphs (b)(2) and (3) of this section apply to such uses and disclosure to the extent that the covered entity, in the exercise of professional judgment, determines that the requirements do not interfere with</p>	<p>Professional judgment</p> <p>Professional judgment</p> <p>Professional judgment</p>	

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	<p>birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions; or, at the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public health authority;</p> <p>(ii) A public health authority or other appropriate government authority authorized by law to receive reports of child abuse or neglect;</p> <p>(iii) A person subject to the jurisdiction of the Food and Drug Administration:</p> <p>(A) To report adverse events (or similar reports with respect to food or dietary supplements), product defects or problems (including problems with the use or labeling of a product), or biological product deviations if the disclosure is made to the person required or directed to report such information to the Food and Drug Administration;</p> <p>(B) To track products if the disclosure is made to a person required or directed by the Food and Drug Administration to track the product;</p> <p>(C) To enable product recalls, repairs, or replacement (including locating and notifying individuals who have received products of product recalls, withdrawals, or other problems); or</p> <p>(D) To conduct post marketing surveillance to comply with requirements or at the direction of the Food and Drug Administration;</p> <p>(iv) A person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading a</p>	<p>Routine Uses 7 & 8.</p> <p>IHS SOR 09-17-0001, Routine Uses 7 & 8.</p> <p>5 USC 552a(b)(1); 45 CFR 5b.</p>	

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	<p>disease or condition, if the covered entity or public health authority is authorized by law to notify such person as necessary in the conduct of a public health intervention or investigation; or</p> <p>(v) An employer, about an individual who is a member of the workforce of the employer, if:</p> <p>(A) The covered entity is a covered health care provider who is a member of the workforce of such employer or who provides a health care to the individual at the request of the employer:</p> <p>(1) To conduct an evaluation relating to medical surveillance of the workplace; or</p> <p>(2) To evaluate whether the individual has a work-related illness or injury;</p> <p>(B) The protected health information that is disclosed consists of findings concerning a work-related illness or injury or a workplace-related medical surveillance;</p> <p>(C) The employer needs such findings in order to comply with its obligations, under 29 CFR parts 1904 through 1928, 30 CFR parts 50 through 90, or under state law having a similar purpose, to record such illness or injury or to carry out responsibilities for workplace medical surveillance;</p> <p>(D) The covered health care provider provides written notice to the individual that protected health information relating to the medical surveillance of the workplace and work-related illnesses and injuries is disclosed to the employer:</p> <p>(1) By giving a copy of the notice to the individual at the time</p>		

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	<p>the health care is provided; or</p> <p>(2) If the health care is provided on the work site of the employer, by posting the notice in a prominent place at the location where the health care is provided.</p> <p>(2) <u>Permitted uses</u>. If the covered entity also is a public health authority, the covered entity is permitted to use protected health information in all cases in which it is permitted to disclose such information for public health activities under paragraph (b)(1) of this section.</p> <p>(c) Standard: disclosures about victims of abuse, neglect or domestic violence.</p> <p>(1) <u>Permitted disclosures</u>. Except for reports of child abuse or neglect permitted by paragraph (b)(1)(ii) of this section, a covered entity may disclose protected health information about an individual whom the covered entity reasonably believes to be a victim of abuse, neglect, or domestic violence to a government authority, including a social service or protective services agency, authorized by law to receive reports of such abuse, neglect, or domestic violence:</p> <p>(i) To the extent the disclosure is required by law and the disclosure complies with and is limited to the relevant requirements of such law;</p> <p>(ii) If the individual agrees to the disclosure; or</p> <p>(iii) To the extent the disclosure is expressly authorized by statute or regulation and:</p> <p>(A) The covered entity, in the exercise of professional</p>		<p>Have workgroup consisting of appropriate staff develop the policy and procedure to implement.</p> <p>(OPH, medical, business office, chs, privacy staff, OGC, etc.)</p>

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	<p>judgment, believes the disclosure is necessary to prevent serious harm to the individual or other potential victims; or</p> <p>(B) If the individual is unable to agree because of incapacity, a law enforcement or other public official authorized to receive the report represents that the protected health information for which disclosure is sought is not intended to be used against the individual and that an immediate enforcement activity that depends upon the disclosure would be materially and adversely affected by waiting until the individual is able to agree to the disclosure.</p> <p>(2) <u>Informing the individual.</u> A covered entity that makes a disclosure permitted by paragraph (c)(1) of this section must promptly inform the individual that such a report has been or will be made, except if:</p> <p>(i) The covered entity, in the exercise of professional judgment, believes informing the individual would place the individual at risk of serious harm; or</p> <p>(ii) The covered entity would be informing a personal representative, and the covered entity reasonably believes the personal representative is responsible for the abuse, neglect, or other injury, and that informing such person would not be in the best interests of the individual as determined by the covered entity, in the exercise of professional judgment.</p> <p>(d) Standard: uses and disclosures for health oversight activities.</p> <p>(1) <u>Permitted disclosures.</u> A covered entity may disclose protected health information to a health oversight agency for</p>		<p>Have workgroup consisting of appropriate staff develop the policy and procedure to implement.</p>

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	<p>oversight activities authorized by law, including audits; civil, administrative, or criminal investigations; inspections; licensure or disciplinary actions; civil, administrative, or criminal proceedings or actions; or other activities necessary for appropriate oversight of:</p> <p>(i) The health care system;</p> <p>(ii) Government benefit programs for which health information is relevant to beneficiary eligibility;</p> <p>(iii) Entities subject to government regulatory programs for which health information is necessary for determining compliance with program standards; or</p> <p>(iv) Entities subject to civil rights laws for which health information is necessary for determining compliance.</p> <p>(2) <u>Exception to health oversight activities.</u> For the purpose of the disclosures permitted by paragraph (d)(1) of this section, a health oversight activity does not include an investigation or other activity in which the individual is the subject of the investigation or activity and such investigation or other activity does not arise out of and is not directly related to:</p> <p>(i) The receipt of health care;</p> <p>(ii) A claim for public benefits related to health; or</p> <p>(iii) Qualification for, or receipt of, public benefits or services when a patient's health is integral to the claim for public benefits or services.</p> <p>(3) <u>Joint activities or investigations.</u> Notwithstanding paragraph</p>		<p>(OPH, medical, business office, chs, privacy staff, OGC, etc.)</p>

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	<p>(d)(2) of this section, if a health oversight activity or investigation is conducted in conjunction with an oversight activity or investigation relating to a claim for public benefits not related to health, the joint activity or investigation is considered a health oversight activity for purposes of paragraph (d) of this section.</p> <p>(4) <u>Permitted uses</u>. If a covered entity also is a health oversight agency, the covered entity may use protected health information for health oversight activities as permitted by paragraph (d) of this section.</p> <p>(e) Standard: disclosures for judicial and administrative proceedings.</p> <p>(1) <u>Permitted disclosures</u>. A covered entity may disclose protected health information in the course of any judicial or administrative proceeding:</p> <p>(i) In response to an order of a court or administrative tribunal, provided that the covered entity discloses only the protected health information expressly authorized by such order; or</p> <p>(ii) In response to a subpoena, discovery request, or other lawful process, that is not accompanied by an order of a court or administrative tribunal, if:</p> <p>(A) The covered entity receives satisfactory assurance, as described in paragraph (e)(1)(iii) of this section, from the party seeking the information that reasonable efforts have been made by such party to ensure that the individual who is the subject of the protected health information that has been requested has been given notice of the request; or</p>		<p>Have workgroup consisting of appropriate staff develop the policy and procedure to implement.</p> <p>(OPH, medical, business office, chs, privacy staff, OGC, etc.)</p>

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	<p>(B) The covered entity receives satisfactory assurance, as described in paragraph (e)(1)(iv) of this section, from the party seeking the information that reasonable efforts have been made by such party to secure a qualified protective order that meets the requirements of paragraph (e)(1)(v) of this section.</p> <p>(iii) For the purposes of paragraph (e)(1)(ii)(A) of this section, a covered entity receives satisfactory assurances from a party seeking protecting health information if the covered entity receives from such party a written statement and accompanying documentation demonstrating that:</p> <p>(A) The party requesting such information has made a good faith attempt to provide written notice to the individual (or, if the individual's location is unknown, to mail a notice to the individual's last known address);</p> <p>(B) The notice included sufficient information about the litigation or proceeding in which the protected health information is requested to permit the individual to raise an objection to the court or administrative tribunal; and</p> <p>(C) The time for the individual to raise objections to the court or administrative tribunal has elapsed, and:</p> <p>(1) No objections were filed; or</p> <p>(2) All objections filed by the individual have been resolved by the court or the administrative tribunal and the disclosures being sought are consistent with such resolution.</p> <p>(iv) For the purposes of paragraph (e)(1)(ii)(B) of this section, a covered entity receives satisfactory assurances from a party</p>		

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	<p>seeking protected health information, if the covered entity receives from such party a written statement and accompanying documentation demonstrating that:</p> <p>(A) The parties to the dispute giving rise to the request for information have agreed to a qualified protective order and have presented it to the court or administrative tribunal with jurisdiction over the dispute; or</p> <p>(B) The party seeking the protected health information has requested a qualified protective order from such court or administrative tribunal.</p> <p>(v) For purposes of paragraph (e)(1) of this section, a <i>qualified protective order</i> means, with respect to protected health information requested under paragraph (e)(1)(ii) of this section, an order of a court or of an administrative tribunal or a stipulation by the parties to the litigation or administrative proceeding that:</p> <p>(A) Prohibits the parties from using or disclosing the protected health information for any purpose other than the litigation or proceeding for which such information was requested; and</p> <p>(B) Requires the return to the covered entity or destruction of the protected health information (including all copies made) at the end of the litigation or proceeding.</p> <p>(vi) Notwithstanding paragraph (e)(1)(ii) of this section, a covered entity may disclose protected health information in response to lawful process described in paragraph (e)(1)(ii) of this section without receiving satisfactory assurance under paragraph (e)(1)(ii)(A) or (B) of this section, if the covered</p>		

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	<p>entity makes reasonable efforts to provide notice to the individual sufficient to meet the requirements of paragraph (e)(1)(iii) of this section or to seek a qualified protective order sufficient to meet the requirements of paragraph (e)(1)(iv) of this section.</p> <p>(2) <u>Other uses and disclosures under this section.</u> The provisions of this paragraph do not supersede other provisions of this section that otherwise permit or restrict uses or disclosures of protected health information.</p> <p>(f) Standard: disclosures for law enforcement purposes. A covered entity may disclose protected health information for a law enforcement purpose to a law enforcement official if the conditions in paragraphs (f)(1) through (f)(6) of this section are met, as applicable.</p> <p>(1) Permitted disclosures: pursuant to process and as otherwise required by law. A covered entity may disclose protected health information:</p> <p>(i) As required by law including laws that require the reporting of certain types of wounds or other physical injuries, except for laws subject to paragraph (b)(1)(ii) or (c)(1)(i) of this section; or</p> <p>(ii) In compliance with and as limited by the relevant requirements of:</p> <p>(A) A court order or court-ordered warrant, or a subpoena or summons issued by a judicial officer;</p> <p>(B) A grand jury subpoena; or</p> <p>(C) An administrative request, including an administrative</p>	<p>5 USC 552a(b); 45 CFR 5b.9; IHS SOR 09-17-0001</p>	<p>Have workgroup consisting of appropriate staff develop the policy and procedure to implement.</p> <p>(OPH, medical, business office, chs, privacy staff, OGC, etc.)</p>

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	<p>subpoena or summons, a civil or an authorized investigative demand, or similar process authorized under law, provided that:</p> <p>(1) The information sought is relevant and material to a legitimate law enforcement inquiry;</p> <p>(2) The request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought; and</p> <p>(3) De-identified information could not reasonably be used.</p> <p>(2) Permitted disclosures: limited information for identification and location purposes. Except for disclosures required by law as permitted by paragraph (f)(1) of this section, a covered entity may disclose protected health information in response to a law enforcement official's request for such information for the purpose of identifying or locating a suspect, fugitive, material witness, or missing person, provided that:</p> <p>(i) The covered entity may disclose only the following information:</p> <p>(A) Name and address;</p> <p>(B) Date and place of birth;</p> <p>(C) Social security number;</p> <p>(D) ABO blood type and rh factor;</p> <p>(E) Type of injury;</p> <p>(F) Date and time of treatment;</p>	<p>5 USC 552a(b); 45 CFR 5b.9; IHS SOR 09-17-0001</p>	<p>Update SOR and/or policy.</p>

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	<p>(G) Date and time of death, if applicable; and</p> <p>(H) A description of distinguishing physical characteristics, including height, weight, gender, race, hair and eye color, presence or absence of facial hair (beard or moustache), scars, and tattoos.</p> <p>(ii) Except as permitted by paragraph (f)(2)(i) of this section, the covered entity may not disclose for the purposes of identification or location under paragraph (f)(2) of this section any protected health information related to the individual's DNA or DNA analysis, dental records, or typing, samples or analysis of body fluids or tissue.</p> <p>(3) Permitted disclosure: victims of a crime. Except for disclosures required by law as permitted by paragraph (f)(1) of this section, a covered entity may disclose protected health information in response to a law enforcement official's request for such information about an individual who is or is suspected to be a victim of a crime, other than disclosures that are subject to paragraph (b) or (c) of this section, if:</p> <p>(ii) The individual agrees to the disclosure; or</p> <p>(iii) The covered entity is unable to obtain the individual's agreement because of incapacity or other emergency circumstance, provided that:</p> <p>(A) The law enforcement official represents that such information is needed to determine whether a violation of law by a person other than the victim has occurred, and such information is not intended to be used against the victim;</p>	<p>5 USC 552a(b); 45 CFR 5b.9; IHS SOR 09-17-0001</p>	<p>Update SOR and/or policy.</p>

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	<p>(B) The law enforcement official represents that immediate law enforcement activity that depends upon the disclosure would be materially and adversely affected by waiting until the individual is able to agree to the disclosure; and</p> <p>(C) The disclosure is in the best interests of the individual as determined by the covered entity, in the exercise of professional judgment.</p> <p>(4) Permitted disclosure: decedents. A covered entity may disclose protected health information about an individual who has died to a law enforcement official for the purpose of alerting law enforcement of the death of the individual if the covered entity has a suspicion that such death may have resulted from criminal conduct.</p> <p>(5) Permitted disclosure: crime on premises. A covered entity may disclose to a law enforcement official protected health information that the covered entity believes in good faith constitutes evidence of criminal conduct that occurred on the premises of the covered entity.</p> <p>(6) Permitted disclosure: reporting crime in emergencies.</p> <p>(i) A covered health care provider providing emergency health care in response to a medical emergency, other than such emergency on the premises of the covered health care provider, may disclose protected health information to a law enforcement official if such disclosure appears necessary to alert law enforcement to:</p>	<p>5 USC 552a(b)(j)(k); 45 CFR 5b.9; IHS SOR 09-17-0001</p> <p>Same as above.</p> <p>5 USC 552a(b)(j)(k); 45 CFR 5b.9; IHS SOR 09-17-0001</p>	<p>Update SOR and/or policy.</p> <p>Update SOR and/or policy.</p>

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	<p>(A) The commission and nature of a crime;</p> <p>(B) The location of such crime or of the victim(s) of such crime; and</p> <p>(C) The identity, description, and location of the perpetrator of such crime.</p> <p>(ii) If a covered health care provider believes that the medical emergency described in paragraph (f)(6)(i) of this section is the result of abuse, neglect, or domestic violence of the individual in need of emergency health care, paragraph (f)(6)(i) of this section does not apply and any disclosure to a law enforcement official for law enforcement purposes is subject to paragraph (c) of this section.</p> <p>(g) Standard: uses and disclosures about decedents.</p> <p>(1) <u>Coroners and medical examiners.</u> A covered entity may disclose protected health information to a coroner or medical examiner for the purpose of identifying a deceased person, determining a cause of death, or other duties as authorized by law. A covered entity that also performs the duties of a coroner or medical examiner may use protected health information for the purposes described in this paragraph.</p> <p>(2) <u>Funeral directors.</u> A covered entity may disclose protected health information to funeral directors, consistent with applicable law, as necessary to carry out their duties with respect to the decedent. If necessary for funeral directors carry out their duties, the covered entity may disclose the protected health information prior to, and in reasonable anticipation of, the individual's death.</p>	<p>5 USC 552a(b)(j)(k); 45 CFR 5b.9; IHS SOR 09-17-0001</p> <p>Not covered in PA, HHS, or IHS.</p> <p>Not covered in PA, HHS, or IHS.</p>	<p>Update SOR and/or policy.</p> <p>Same as above.</p> <p>Same as above.</p>

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	<p>(h) <u>Standard: uses and disclosures for cadaveric organ, eye or tissue donation purposes.</u> A covered entity may use or disclose protected health information to organ procurement organizations or other entities engaged in the procurement, banking, or transplantation of cadaveric organs, eyes, or tissue for the purpose of facilitating organ, eye or tissue donation and transplantation.</p> <p>(i) Standard: uses and disclosures for research purposes.</p> <p>(1) <u>Permitted uses and disclosures.</u> A covered entity may use or disclose protected health information for research, regardless of the source of funding of the research, provided that:</p> <p>(i) <u>Board approval of a waiver of authorization.</u> The covered entity obtains documentation that an alteration to or waiver, in whole or in part, of the individual authorization required by §164.508 for use or disclosure of protected health information has been approved by either:</p> <p>(A) An Institutional Review Board (IRB), established in accordance with 7 CFR 1c.107, 10 CFR 745.107, 14 CFR 1230.107, 15 CFR 27.107, 16 CFR 1028.107, 21 CFR 56.107, 22 CFR 225.107, 24 CFR 60.107, 28 CFR 46.107, 32 CFR 219.107, 34 CFR 97.107, 38 CFR 16.107, 40 CFR 26.107, 45 CFR 46.107, 45 CFR 690.107, or 49 CFR 11.107; or</p> <p>(B) A privacy board that:</p> <p>(I) Has members with varying backgrounds and appropriate professional competency as necessary to review the effect of the research protocol on the individual's privacy rights and related interests;</p>	<p>5 USC 552a(b); 45 CFR 5b.9; IHS SOR 09-17-0001</p>	<p>Refer to Research for input re: implementation</p>

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	<p>(2) Includes at least one member who is not affiliated with the covered entity, not affiliated with any entity conducting or sponsoring the research, and not related to any person who is affiliated with any of such entities; and</p> <p>(3) Does not have any member participating in a review of any project in which the member has a conflict of interest.</p> <p>(ii) <u>Reviews preparatory to research.</u> The covered entity obtains from the researcher representations that:</p> <p>(A) Use or disclosure is sought solely to review protected health information as necessary to prepare a research protocol or for similar purposes preparatory to research;</p> <p>(B) No protected health information is to be removed from the covered entity by the researcher in the course of the review; and</p> <p>(C) The protected health information for which use or access is sought is necessary for the research purposes.</p> <p>(iii) <u>Research on decedent's information.</u> The covered entity obtains from the researcher:</p> <p>(A) Representation that the use or disclosure is sought is solely for research on the protected health information of decedents;</p> <p>(B) Documentation, at the request of the covered entity, of the death of such individuals; and</p> <p>(C) Representation that the protected health information for which use or disclosure is sought is necessary for the research</p>		<p>Refer to Research for input re: implementation.</p>

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	<p>purposes.</p> <p>(2) <u>Documentation of waiver approval.</u> For a use or disclosure to be permitted based on documentation of approval of an alteration or waiver, under paragraph (i)(1)(i) of this section, the documentation must include all of the following:</p> <p>(i) <u>Identification and date of action.</u> A statement identifying the IRB or privacy board and the date on which the alteration or waiver of authorization was approved;</p> <p>(ii) <u>Waiver criteria.</u> A statement that the IRB or privacy board has determined that the alteration or waiver, in whole or in part, of authorization satisfies the following criteria:</p> <p>(A) The use or disclosure of protected health information involves no more than minimal risk to the individuals;</p> <p>(B) The alteration or waiver will not adversely affect the privacy rights and the welfare of the individuals;</p> <p>(C) The research could not practicably be conducted without the alteration or waiver;</p> <p>(D) The research could not practicably be conducted without access to and use of the protected health information;</p> <p>(E) The privacy risks to individuals whose protected health information is to be used or disclosed are reasonable in relation to the anticipated benefits if any to the individuals, and the importance of the knowledge that may reasonably be expected to result from the research;</p> <p>(F) There is an adequate plan to protect the identifiers from</p>		

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	<p>improper use and disclosure;</p> <p>(G) There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law; and</p> <p>(H) There are adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart.</p> <p>(iii) <u>Protected health information needed.</u> A brief description of the protected health information for which use or access has been determined to be necessary by the IRB or privacy board has determined, pursuant to paragraph (i)(2)(ii)(D) of this section;</p> <p>(iv) <u>Review and approval procedures.</u> A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures, as follows:</p> <p>(A) An IRB must follow the requirements of the Common Rule, including the normal review procedures (7 CFR 1c.108(b), 10 CFR 745.108(b), 14 CFR 1230.108(b), 15 CFR 27.108(b), 16 CFR 1028.108(b), 21 CFR 56.108(b), 22 CFR 225.108(b), 24 CFR 60.108(b), 28 CFR 46.108(b), 32 CFR 219.108(b), 34 CFR 97.108(b), 38 CFR 16.108(b), 40 CFR 26.108(b), 45 CFR 46.108(b), 45 CFR 690.108(b), or 49 CFR 11.108(b)) or the expedited review procedures (7 CFR 1c.110, 10 CFR 745.110,</p>		<p>Refer to Research for input re: implementation.</p> <p>Refer to Research for input re: implementation.</p>

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	<p>14 CFR 1230.110, 15 CFR 27.110, 16 CFR 1028.110, 21 CFR 56.110, 22 CFR 225.110, 24 CFR 60.110, 28 CFR 46.110, 32 CFR 219.110, 34 CFR 97.110, 38 CFR 16.110, 40 CFR 26.110, 45 CFR 46.110, 45 CFR 690.110, or 49 CFR 11.110);</p> <p>(B) A privacy board must review the proposed research at convened meetings at which a majority of the privacy board members are present, including at least one member who satisfies the criterion stated in paragraph (i)(1)(i)(B)(2) of this section, and the alteration or waiver of authorization must be approved by the majority of the privacy board members present at the meeting, unless the privacy board elects to use an expedited review procedure in accordance with paragraph (i)(2)(iv)(C) of this section;</p> <p>(C) A privacy board may use an expedited review procedure if the research involves no more than minimal risk to the privacy of the individuals who are the subject of the protected health information for which use or disclosure is being sought. If the privacy board elects to use an expedited review procedure, the review and approval of the alteration or waiver of authorization may be carried out by the chair of the privacy board, or by one or more members of the privacy board as designated by the chair; and</p> <p>(v) <u>Required signature.</u> The documentation of the alteration or waiver of authorization must be signed by the chair or other member, as designated by the chair, of the IRB or the privacy board, as applicable.</p> <p>(j) Standard: uses and disclosures to avert a serious threat to health or safety.</p>	<p>IHS SOR 09-17-0001; 45 CFR 5b; 5 USC 552a</p> <p>5 USC 552a(b)(8); 45 CFR 5b(b8); IHS SOR</p> <p>5 USC 552a(b)(7); 45 CFR 5b(b7); IHS SOR RU #7</p>	<p>Privacy Act more stringent; legal review of “serious & imminent threat.”</p> <p>Privacy Act more stringent</p>

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	<p>(1) Permitted disclosures. A covered entity may, consistent with applicable law and standards of ethical conduct, use or disclose protected health information, if the covered entity, in good faith, believes the use or disclosure:</p> <p>(i)(A) Is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public; and (B) Is to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat; or</p> <p>(ii) Is necessary for law enforcement authorities to identify or apprehend an individual:</p> <p>(A) Because of a statement by an individual admitting participation in a violent crime that the covered entity reasonably believes may have caused serious physical harm to the victim; or</p> <p>(B) Where it appears from all the circumstances that the individual has escaped from a correctional institution or from lawful custody, as those terms are defined in § 164.501.</p> <p>(2) Use or disclosure not permitted. A use or disclosure pursuant to paragraph (j)(1)(ii)(A) of this section may not be made if the information described in paragraph (j)(1)(ii)(A) of this section is learned by the covered entity:</p> <p>(i) In the course of treatment to affect the propensity to commit the criminal conduct that is the basis for the disclosure under paragraph (j)(1)(ii)(A) of this section, or counseling or therapy; or</p> <p>(ii) Through a request by the individual to initiate or to be</p>	<p>Not covered in PA, HHS, or IHS.</p> <p>Not covered in PA, HHS, or IHS.</p> <p>Not cited in PA, HHS or IHS</p> <p>Not cited in PA, HHS or IHS</p> <p>Not cited in PA, HHS or IHS</p> <p>Not cited in PA, HHS, or IHS</p>	<p>Privacy Act more stringent</p>

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	<p>referred for the treatment, counseling, or therapy described in paragraph (j)(2)(i) of this section.</p> <p>(3) <u>Limit on information that may be disclosed.</u> A disclosure made pursuant to paragraph (j)(1)(ii)(A) of this section shall contain only the statement described in paragraph (j)(1)(ii)(A) of this section and the protected health information described in paragraph (f)(2)(i) of this section.</p> <p>(4) <u>Presumption of good faith belief.</u> A covered entity that uses or discloses protected health information pursuant to paragraph (j)(1) of this section is presumed to have acted in good faith with regard to a belief described in paragraph (j)(1)(i) or (ii) of this section, if the belief is based upon the covered entity's actual knowledge or in reliance on a credible representation by a person with apparent knowledge or authority.</p> <p>(k) Standard: uses and disclosures for specialized government functions.</p> <p>(1) Military and veterans activities.</p> <p>(i) <u>Armed Forces personnel.</u> A covered entity may use and disclose the protected health information of individuals who are Armed Forces personnel for activities deemed necessary by appropriate military command authorities to assure the proper execution of the military mission, if the appropriate military authority has published by notice in the Federal Register the following information:</p> <p>(A) Appropriate military command authorities; and</p> <p>(B) The purposes for which the protected health information</p>	<p>5 USC 552a(f); Not cited in HHS or IHS.</p> <p>Not cited in HHS or IHS.</p> <p>Not cited in HHS or IHS</p> <p>Not cited in HHS or IHS</p> <p>Not cited in HHS or IHS</p>	<p>Not applicable to IHS.</p>

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	<p>may be used or disclosed.</p> <p>(ii) <u>Separation or discharge from military service.</u> A covered entity that is a component of the Departments of Defense or Transportation may disclose to the Department of Veterans Affairs (DVA) the protected health information of an individual who is a member of the Armed Forces upon the separation or discharge of the individual from military service for the purpose of a determination by DVA of the individual's eligibility for or entitlement to benefits under laws administered by the Secretary of Veterans Affairs.</p> <p>(iii) <u>Veterans.</u> A covered entity that is a component of the Department of Veterans Affairs may use and disclose protected health information to components of the Department that determine eligibility for or entitlement to, or that provide, benefits under the laws administered by the Secretary of Veterans Affairs.</p> <p>(iv) <u>Foreign military personnel.</u> A covered entity may use and disclose the protected health information of individuals who are foreign military personnel to their appropriate foreign military authority for the same purposes for which uses and disclosures are permitted for Armed Forces personnel under the notice published in the Federal Register pursuant to paragraph (k)(1)(i) of this section.</p> <p>(2) <u>National security and intelligence activities.</u> A covered entity may disclose protected health information to authorized federal officials for the conduct of lawful intelligence, counter-intelligence, and other national security activities authorized by the National Security Act (50 U.S.C. 401, <i>et seq.</i>) and</p>		<p>Not applicable to IHS.</p> <p>Requires legal review from OGC.</p> <p>May not be applicable to IHS, OGC review.</p> <p>Not applicable to IHS.</p>

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	<p>implementing authority (e.g., Executive Order 12333).</p> <p>(3) <u>Protective services for the President and others.</u> A covered entity may disclose protected health information to authorized federal officials for the provision of protective services to the President or other persons authorized by 18 U.S.C. 3056, or to foreign heads of state or other persons authorized by 22 U.S.C. 2709(a)(3), or to for the conduct of investigations authorized by 18 U.S.C. 871 and 879.</p> <p>(4) <u>Medical suitability determinations.</u> A covered entity that is a component of the Department of State may use protected health information to make medical suitability determinations and may disclose whether or not the individual was determined to be medically suitable to the officials in the Department of State who need access to such information for the following purposes:</p> <p>(i) For the purpose of a required security clearance conducted pursuant to Executive Orders 10450 and 12698;</p> <p>(ii) As necessary to determine worldwide availability or availability for mandatory service abroad under sections 101(a)(4) and 504 of the Foreign Service Act; or</p> <p>(iii) For a family to accompany a Foreign Service member abroad, consistent with section 101(b)(5) and 904 of the Foreign Service Act.</p> <p>(5) <u>Correctional institutions and other law enforcement custodial situations.</u></p> <p>(i) <u>Permitted disclosures.</u> A covered entity may disclose to a correctional institution or a law enforcement official having</p>	<p>5 USC 552a(b7); 45 CFR 5b.(b7); IHS SOR Routine Use #7.</p>	<p>Not applicable to IHS.</p> <p>Not applicable to IHS.</p> <p>Not applicable to IHS.</p> <p>Update SOR and/or policy.</p>

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	<p>lawful custody of an inmate or other individual protected health information about such inmate or individual, if the correctional institution or such law enforcement official represents that such protected health information is necessary for:</p> <p>(A) The provision of health care to such individuals;</p> <p>(B) The health and safety of such individual or other inmates;</p> <p>(C) The health and safety of the officers or employees of or others at the correctional institution;</p> <p>(D) The health and safety of such individuals and officers or other persons responsible for the transporting of inmates or their transfer from one institution, facility, or setting to another;</p> <p>(E) Law enforcement on the premises of the correctional institution; and</p> <p>(F) The administration and maintenance of the safety, security, and good order of the correctional institution.</p> <p>(ii) Permitted uses. A covered entity that is a correctional institution may use protected health information of individuals who are inmates for any purpose for which such protected health information may be disclosed.</p> <p>(iii) No application after release. For the purposes of this provision, an individual is no longer an inmate when released on parole, probation, supervised release, or otherwise is no longer in lawful custody.</p> <p>(6) Covered entities that are government programs providing public benefits.</p>		<p>Not applicable to IHS.</p> <p>Not applicable to IHS.</p> <p>Have workgroup consisting of appropriate staff develop the policy and procedures to implement.</p> <p>(OPH, medical, business office, chs, privacy staff, OGC, etc.)</p>

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	<p>(i) A health plan that is a government program providing public benefits may disclose protected health information relating to eligibility for or enrollment in the health plan to another agency administering a government program providing public benefits if the sharing of eligibility or enrollment information among such government agencies or the maintenance of such information in a single or combined data system accessible to all such government agencies is required or expressly authorized by statute or regulation.</p> <p>(ii) A covered entity that is a government agency administering a government program providing public benefits may disclose protected health information relating to the program to another covered entity that is a government agency administering a government program providing public benefits if the programs serve the same or similar populations and the disclosure of protected health information is necessary to coordinate the covered functions of such programs or to improve administration and management relating to the covered functions of such programs.</p> <p>(I) Standard: disclosures for workers' compensation. A covered entity may disclose protected health information as authorized by and to the extent necessary to comply with laws relating to workers' compensation or other similar programs, established by law, that provide benefits for work-related injuries or illness without regard to fault.</p>		<p>Have workgroup consisting of appropriate staff develop the policy and procedures to implement.</p> <p>(OPH, medical, business office, chs, privacy staff, OGC, etc.)</p>
§ 164.514 Other requirements relating to uses and disclosures of protected health	<p>(a) Standard: de-identification of protected health information. Health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual is not</p>	<p>5 USC 552a(b)(5); 45 CFR 5b.5; IHS SOR Purposes #7.</p>	<p>Update SOR and/or policy.</p>

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information	<p>individually identifiable health information.</p> <p>(b) <u>Implementation specifications: requirements for de-identification of protected health information.</u> A covered entity may determine that health information is not individually identifiable health information only if:</p> <p>(1) A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:</p> <p>(i) Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information; and</p> <p>(ii) Documents the methods and results of the analysis that justify such determination; or</p> <p>(2)(i) The following identifiers of the individual or of relatives, employers, or household members of the individual, are removed:</p> <p>(A) Names;</p> <p>(B) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:</p> <p>(I) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people;</p>	<p>Same as above.</p> <p>Same as above.</p> <p>5 USC 552a(b)(5); 45 CFR 5b.9(b)(5); IHS SOR Purposes #7</p> <p>Not in PA, HHS, or IHS.</p> <p>5 USC 552a(b)(5); 45 CFR 5b.9(b)(5); IHS SOR Purposes #7</p> <p>Same as above. Same as above.</p>	<p>Same as above</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p>

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	<p>and</p> <p>(2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.</p> <p>(C) All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;</p> <p>(D) Telephone numbers;</p> <p>(E) Fax numbers;</p> <p>(F) Electronic mail addresses;</p> <p>(G) Social security numbers;</p> <p>(H) Medical record numbers;</p> <p>(I) Health plan beneficiary numbers;</p> <p>(J) Account numbers;</p> <p>(K) Certificate/license numbers;</p> <p>(L) Vehicle identifiers and serial numbers, including license plate numbers;</p> <p>(M) Device identifiers and serial numbers;</p> <p>(N) Web Universal Resource Locators (URLs);</p>	<p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p>	<p>Same as above.</p> <p>Same as above.</p>

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	<p>(O) Internet Protocol (IP) address numbers;</p> <p>(P) Biometric identifiers, including finger and voice prints;</p> <p>(Q) Full face photographic images and any comparable images; and</p> <p>(R) Any other unique identifying number, characteristic, or code; and</p> <p>(ii) The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.</p>	Not in PA, HHS, or IHS	Update SOR and/or policy.
	<p>(c) <u>Implementation specifications: re-identification.</u> A covered entity may assign a code or other means of record identification to allow information de-identified under this section to be re-identified by the covered entity, provided that:</p> <p>(1) <u>Derivation.</u> The code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual; and</p> <p>(2) <u>Security.</u> The covered entity does not use or disclose the code or other means of record identification for any other purpose, and does not disclose the mechanism for re-identification.</p>	Not in PA, HHS, or IHS.	Update SOR and/or policy.
	<p>(d)(1) <u>Standard: minimum necessary requirements.</u> A covered entity must reasonably ensure that the standards, requirements,</p>	Same as above.	Same as above.
		Same as above.	Same as above.
		Not in PA, HHS, or IHS.	Update SOR and/or policy.

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	<p>and implementation specifications of § 164.502(b) and this section relating to a request for or the use and disclosure of the minimum necessary protected health information are met.</p> <p>(2) Implementation specifications: minimum necessary uses of protected health information.</p> <p>(i) A covered entity must identify:</p> <p>(A) Those persons or classes of persons, as appropriate, in its workforce who need access to protected health information to carry out their duties; and</p> <p>(B) For each such person or class of persons, the category or categories of protected health information to which access is needed and any conditions appropriate to such access.</p> <p>(ii) A covered entity must make reasonable efforts to limit the access of such persons or classes identified in paragraph (d)(2)(i)(A) of this section to protected health information consistent with paragraph (d)(2)(i)(B) of this section.</p> <p>(3) Implementation specification: minimum necessary disclosures of protected health information.</p> <p>(i) For any type of disclosure that it makes on a routine and recurring basis, a covered entity must implement policies and procedures (which may be standard protocols) that limit the protected health information disclosed to the amount reasonably necessary to achieve the purpose of the disclosure.</p> <p>(ii) For all other disclosures, a covered entity must:</p>	<p>5 USC 552a(b)(1); 45 CFR 5b.9(b)(1); IHS SOR Safeguards #1.</p> <p>Same as above.</p> <p>5 USC 552a(b); 45 CFR 5b.9; IHS SOR Routine Uses.</p> <p>5 USC 552a(b); 45 CFR</p>	<p>Adequate policies and procedures.</p> <p>Same as above.</p> <p>Adequate policies and procedures.</p> <p>Update SOR and/or policy.</p>

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	<p>(A) Develop criteria designed to limit the protected health information disclosed to the information reasonably necessary to accomplish the purpose for which disclosure is sought; and</p> <p>(B) Review requests for disclosure on an individual basis in accordance with such criteria.</p> <p>(iii) A covered entity may rely, if such reliance is reasonable under the circumstances, on a requested disclosure as the minimum necessary for the stated purpose when:</p> <p>(A) Making disclosures to public officials that are permitted under § 164.512, if the public official represents that the information requested is the minimum necessary for the stated purpose(s);</p> <p>(B) The information is requested by another covered entity;</p> <p>(C) The information is requested by a professional who is a member of its workforce or is a business associate of the covered entity for the purpose of providing professional services to the covered entity, if the professional represents that the information requested is the minimum necessary for the stated purpose(s); or</p> <p>(D) Documentation or representations that comply with the applicable requirements of § 164.512(i) have been provided by a person requesting the information for research purposes.</p> <p>(4) Implementation specifications: minimum necessary requests for protected health information.</p>	<p>5b.9; IHS SOR Routine Uses.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>5 USC 552a(b); 45 CFR 5b.9; IHS SOR Routine</p>	<p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Update SOR and/or policy.</p>

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	<p>(i) A covered entity must limit any request for protected health information to that which is reasonably necessary to accomplish the purpose for which the request is made, when requesting such information from other covered entities.</p> <p>(ii) For a request that is made on a routine and recurring basis, a covered entity must implement policies and procedures (which may be standard protocols) that limit the protected health information requested to the amount reasonably necessary to accomplish the purpose for which the request is made.</p> <p>(iii) For all other requests, a covered entity must review the request on an individual basis to determine that the protected health information sought is limited to the information reasonably necessary to accomplish the purpose for which the request is made.</p> <p>(5) <u>Implementation specification: other content requirement.</u> For all uses, disclosures, or requests to which the requirements in paragraph (d) of this section apply, a covered entity may not use, disclose or request an entire medical record, except when the entire medical record is specifically justified as the amount that is reasonably necessary to accomplish the purpose of the use, disclosure, or request.</p> <p>(e)(1) <u>Standard: uses and disclosures of protected health information for marketing.</u> A covered entity may not use or disclose protected health information for marketing without an authorization that meets the applicable requirements of § 164.508, except as provided for by paragraph (e)(2) of this section.</p> <p>(2) <u>Implementation specifications: requirements relating to</u></p>	<p>Uses.</p> <p>5 USC 552a(b); 45 CFR 5b.9; IHS SOR Routine Uses.</p> <p>Same as above.</p> <p>Same as above.</p>	<p>Update SOR and/or policy.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Not applicable to IHS but may apply to tribes and urbans.</p> <p>Not applicable to IHS but may apply to tribes and urbans.</p>

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	<p><u>marketing.</u> (i) A covered entity is not required to obtain an authorization under § 164.508 when it uses or discloses protected health information to make a marketing communication to an individual that:</p> <p>(A) Occurs in a face-to-face encounter with the individual;</p> <p>(B) Concerns products or services of nominal value; or</p> <p>(C) Concerns the health-related products and services of the covered entity or of a third party and the communication meets the applicable conditions in paragraph (e)(3) of this section.</p> <p>(ii) A covered entity may disclose protected health information for purposes of such communications only to a business associate that assists the covered entity with such communications.</p> <p>(3) <u>Implementation specifications: requirements for certain marketing communications.</u> For a marketing communication to qualify under paragraph (e)(2)(i) of this section, the following conditions must be met:</p> <p>(i) The communication must:</p> <p>(A) Identify the covered entity as the party making the communication;</p> <p>(B) If the covered entity has received or will receive direct or indirect remuneration for making the communication, prominently state that fact; and</p> <p>(C) Except when the communication is contained in a newsletter or similar type of general communication device that</p>		<p>Not applicable to IHS but may apply to tribes and urbans.</p>

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	<p>the covered entity distributes to a broad cross-section of patients, enrollees, or other broad groups of individuals, contain instructions describing how the individual may opt out of receiving future such communications.</p> <p>(ii) If the covered entity uses or discloses protected health information to target the communication to individuals based on their health status or condition:</p> <p>(A) The covered entity must make a determination prior to making the communication that the product or service being marketed may be beneficial to the health of the type or class of individual targeted; and</p> <p>(B) The communication must explain why the individual has been targeted and how the product or service relates to the health of the individual.</p> <p>(iii) The covered entity must make reasonable efforts to ensure that individuals who decide to opt out of receiving future marketing communications, under paragraph (e)(3)(i)(C) of this section, are not sent such communications.</p> <p>(f)(1) Standard: uses and disclosures for fundraising. A covered entity may use, or disclose to a business associate or to an institutionally related foundation, the following protected health information for the purpose of raising funds for its own benefit, without an authorization meeting the requirements of § 164.508:</p>		<p>Not applicable to IHS but may be applicable to tribal facilities and urban programs.</p>

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	<p>(i) Except with respect to disclosures under § 164.510, verify the identity of a person requesting protected health information and the authority of any such person to have access to protected health information under this subpart, if the identity or any such authority of such person is not known to the covered entity; and</p> <p>(ii) Obtain any documentation, statements, or representations, whether oral or written, from the person requesting the protected health information when such documentation, statement, or representation is a condition of the disclosure under this subpart.</p> <p>(2) Implementation specifications: verification.</p> <p>(i) <u>Conditions on disclosures</u>. If a disclosure is conditioned by this subpart on particular documentation, statements, or representations from the person requesting the protected health information, a covered entity may rely, if such reliance is reasonable under the circumstances, on documentation, statements, or representations that, on their face, meet the applicable requirements.</p> <p>(A) The conditions in § 164.512(f)(1)(ii)(C) may be satisfied by the administrative subpoena or similar process or by a separate written statement that, on its face, demonstrates that the applicable requirements have been met.</p> <p>(B) The documentation required by § 164.512(i)(2) may be satisfied by one or more written statements, provided that each is appropriately dated and signed in accordance with § 164.512(i)(2)(i) and (v).</p>		

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	<p>(ii) <u>Identity of public officials</u>. A covered entity may rely, if such reliance is reasonable under the circumstances, on any of the following to verify identity when the disclosure of protected health information is to a public official or a person acting on behalf of the public official:</p> <p>(A) If the request is made in person, presentation of an agency identification badge, other official credentials, or other proof of government status;</p> <p>(B) If the request is in writing, the request is on the appropriate government letterhead; or</p> <p>(C) If the disclosure is to a person acting on behalf of a public official, a written statement on appropriate government letterhead that the person is acting under the government's authority or other evidence or documentation of agency, such as a contract for services, memorandum of understanding, or purchase order, that establishes that the person is acting on behalf of the public official.</p> <p>(iii) <u>Authority of public officials</u>. A covered entity may rely, if such reliance is reasonable under the circumstances, on any of the following to verify authority when the disclosure of protected health information is to a public official or a person acting on behalf of the public official:</p> <p>(A) A written statement of the legal authority under which the information is requested, or, if a written statement would be impracticable, an oral statement of such legal authority;</p> <p>(B) If a request is made pursuant to legal process, warrant, subpoena, order, or other legal process issued by a grand jury or</p>		

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	<p>a judicial or administrative tribunal is presumed to constitute legal authority.</p> <p>(iv) <u>Exercise of professional judgment</u>. The verification requirements of this paragraph are met if the covered entity relies on the exercise of professional judgment in making a use or disclosure in accordance with § 164.510 or acts on a good faith belief in making a disclosure in accordance with §164.512(j).</p>		
<p>§ 164.520 Notice of privacy practices for protected health information</p>	<p>(a) Standard: notice of privacy practices.</p> <p>(1) <u>Right to notice</u>. Except as provided by paragraph (a)(2) or (3) of this section, an individual has a right to adequate notice of the uses and disclosures of protected health information that may be made by the covered entity, and of the individual's rights and the covered entity's legal duties with respect to protected health information.</p>	<p>5 USC 552a(c); 45 CFR 5b.5; IHS SOR 09-17-0001; IHS Medical Records Manual</p>	<p>Update SOR and/or policy.</p>
	<p>(2) Exception for group health plans.</p> <p>(i) An individual enrolled in a group health plan has a right to notice:</p>	<p>Same as above.</p>	<p>Same as above.</p>
	<p>(A) From the group health plan, if, and to the extent that, such an individual does not receive health benefits under the group health plan through an insurance contract with a health insurance issuer or HMO; or</p>	<p>5 USC 552a(c); 45 CFR 5b.5; IHS SOR 09-17-0001; IHS Medical Records Manual</p>	<p>Update SOR and/or policy.</p>
	<p>(B) From the health insurance issuer or HMO with respect to the group health plan through which such individuals receive their health benefits under the group health plan.</p> <p>(ii) A group health plan that provides health benefits solely</p>	<p>Same as above.</p>	<p>Same as above</p>

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	<p>through an insurance contract with a health insurance issuer or HMO, and that creates or receives protected health information in addition to summary health information as defined in § 164.504(a) or information on whether the individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan, must:</p> <p>(A) Maintain a notice under this section; and</p> <p>(B) Provide such notice upon request to any person. The provisions of paragraph (c)(1) of this section do not apply to such group health plan.</p> <p>(iii) A group health plan that provides health benefits solely through an insurance contract with a health insurance issuer or HMO, and does not create or receive protected health information other than summary health information as defined in § 164.504(a) or information on whether an individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan, is not required to maintain or provide a notice under this section.</p> <p>(3) <u>Exception for inmates.</u> An inmate does not have a right to notice under this section, and the requirements of this section do not apply to a correctional institution that is a covered entity.</p> <p>(b) Implementation specifications: content of notice.</p> <p>(1) <u>Required elements.</u> The covered entity must provide a notice that is written in plain language and that contains the elements required by this paragraph.</p>	<p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>5 USC 552a(c); 45 CFR 5b.5; IHS SOR 09-17-0001; IHS Medical Records Manual</p> <p>Same as above.</p> <p>Same as above.</p>	<p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Update SOR and/or policy.</p> <p>Same as above.</p> <p>Same as above.</p>

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	<p>(i) <u>Header</u>. The notice must contain the following statement as a header or otherwise prominently displayed: “THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.”</p>	Not in PA, HHS, or IHS	Update SOR and/or policy.
	<p>(ii) <u>Uses and disclosures</u>. The notice must contain:</p> <p>(A) A description, including at least one example, of the types of uses and disclosures that the covered entity is permitted by this subpart to make for each of the following purposes: treatment, payment, and health care operations.</p>	5 USC 552a(c); 45 CFR 5b.9; IHS SOR 09-17-0001	Same as above.
	<p>(B) A description of each of the other purposes for which the covered entity is permitted or required by this subpart to use or disclose protected health information without the individual’s written consent or authorization.</p>	Same as above.	Same as above.
	<p>(C) If a use or disclosure for any purpose described in paragraphs (b)(1)(ii)(A) or (B) of this section is prohibited or materially limited by other applicable law, the description of such use or disclosure must reflect the more stringent law as defined in § 160.202.</p>	Same as above.	Same as above.
	<p>(D) For each purpose described in paragraph (b)(1)(ii)(A) or (B) of this section, the description must include sufficient detail to place the individual on notice of the uses and disclosures that are permitted or required by this subpart and other applicable law.</p>	5 USC 552a(c); 45 CFR 5b.9; IHS SOR 09-17-0001	Update SOR and/or policy.
	<p>(E) A statement that other uses and disclosures will be made only with the individual's written authorization and that the</p>	Same as above.	Same as above.

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	<p>individual may revoke such authorization as provided by § 164.508(b)(5).</p> <p>(iii) <u>Separate statements for certain uses or disclosures.</u> If the covered entity intends to engage in any of the following activities, the description required by paragraph (b)(1)(ii)(A) of this section must include a separate statement, as applicable, that:</p> <p>(A) The covered entity may contact the individual to provide appointment reminders or information about treatment alternatives or other health-related benefits and services that may be of interest to the individual;</p> <p>(B) The covered entity may contact the individual to raise funds for the covered entity; or</p> <p>(C) A group health plan, or a health insurance issuer or HMO with respect to a group health plan, may disclose protected health information to the sponsor of the plan.</p> <p>(iv) <u>Individual rights.</u> The notice must contain a statement of the individual's rights with respect to protected health information and a brief description of how the individual may exercise these rights, as follows:</p> <p>(A) The right to request restrictions on certain uses and disclosures of protected health information as provided by § 164.522(a), including a statement that the covered entity is not required to agree to a requested restriction;</p> <p>(B) The right to receive confidential communications of protected health information as provided by § 164.522(b), as</p>	<p>Not covered in PA, HHS, or IHS.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Not covered in PA, HHS, or IHS</p>	<p>Update SOR and/or policy.</p> <p>Update SOR and/or policy. Legal review.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Update SOR and/or policy.</p>

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	<p>applicable;</p> <p>(C) The right to inspect and copy protected health information as provided by § 164.524;</p> <p>(D) The right to amend protected health information as provided by § 164.526;</p> <p>(E) The right to receive an accounting of disclosures of protected health information as provided by § 164.528; and</p> <p>(F) The right of an individual, including an individual who has agreed to receive the notice electronically in accordance with paragraph (c)(3) of this section, to obtain a paper copy of the notice from the covered entity upon request.</p> <p>(v) <u>Covered entity's duties</u>. The notice must contain:</p> <p>(A) A statement that the covered entity is required by law to maintain the privacy of protected health information and to provide individuals with notice of its legal duties and privacy practices with respect to protected health information;</p> <p>(B) A statement that the covered entity is required to abide by the terms of the notice currently in effect; and</p> <p>(C) For the covered entity to apply a change in a privacy practice that is described in the notice to protected health information that the covered entity created or received prior to issuing a revised notice, in accordance with § 164.530(i)(2)(ii), a statement that it reserves the right to change the terms of its notice and to make the new notice provisions effective for all protected health information that it maintains. The statement must also describe how it will provide individuals with a</p>	<p>5 USC 552a(d); 45 CFR 5b.5; IHS SOR 09-17-0001 Same as above.</p> <p>Same as above.</p> <p>Not covered in PA, HHS, or IHS.</p> <p>5 USC 552a(c); 45 CFR 5b.2; IHS SOR 09-17-0001</p> <p>Same as above.</p> <p>Same as above.</p>	<p>Update SOR and/or policy.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p>

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	<p>revised notice.</p> <p>(vi) <u>Complaints</u>. The notice must contain a statement that individuals may complain to the covered entity and to the Secretary if they believe their privacy rights have been violated, a brief description of how the individual may file a complaint with the covered entity, and a statement that the individual will not be retaliated against for filing a complaint.</p> <p>(vii) <u>Contact</u>. The notice must contain the name, or title, and telephone number of a person or office to contact for further information as required by § 164.530(a)(1)(ii).</p> <p>(viii) <u>Effective date</u>. The notice must contain the date on which the notice is first in effect, which may not be earlier than the date on which the notice is printed or otherwise published.</p> <p>(2) Optional elements.</p> <p>(i) In addition to the information required by paragraph (b)(1) of this section, if a covered entity elects to limit the uses or disclosures that it is permitted to make under this subpart, the covered entity may describe its more limited uses or disclosures in its notice, provided that the covered entity may not include in its notice a limitation affecting its right to make a use or disclosure that is required by law or permitted by § 164.512(j)(1)(i).</p> <p>(ii) For the covered entity to apply a change in its more limited uses and disclosures to protected health information created or received prior to issuing a revised notice, in accordance with § 164.530(i)(2)(ii), the notice must include the statements required by paragraph (b)(1)(v)(C) of this section.</p>	<p>5 USC 552a(c); 45 CFR 5b.5; IHS SOR 09-17-0001</p> <p>Same as above.</p> <p>Same as above.</p> <p>Not in PA, HHS, or IHS</p> <p>Same as above.</p> <p>Not in PA, HHS, or IHS</p>	<p>Update SOR and/or policy.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Update SOR and/or policy.</p> <p>Same as above.</p> <p>Update SOR and/or policy.</p>

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	<p>(3) <u>Revisions to the notice.</u> The covered entity must promptly revise and distribute its notice whenever there is a material change to the uses or disclosures, the individual's rights, the covered entity's legal duties, or other privacy practices stated in the notice. Except when required by law, a material change to any term of the notice may not be implemented prior to the effective date of the notice in which such material change is reflected.</p> <p>(c) <u>Implementation specifications: provision of notice.</u> A covered entity must make the notice required by this section available on request to any person and to individuals as specified in paragraphs (c)(1) through (c)(4) of this section, as applicable.</p> <p>(1) Specific requirements for health plans.</p> <p>(i) A health plan must provide notice:</p> <p>(A) No later than the compliance date for the health plan, to individuals then covered by the plan;</p> <p>(B) Thereafter, at the time of enrollment, to individuals who are new enrollees; and</p> <p>(C) Within 60 days of a material revision to the notice, to individuals then covered by the plan.</p> <p>(ii) No less frequently than once every three years, the health plan must notify individuals then covered by the plan of the availability of the notice and how to obtain the notice.</p> <p>(iii) The health plan satisfies the requirements of paragraph</p>	<p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p>	<p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p>

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	<p>(c)(1) of this section if notice is provided to the named insured of a policy under which coverage is provided to the named insured and one or more dependents.</p> <p>(iv) If a health plan has more than one notice, it satisfies the requirements of paragraph (c)(1) of this section by providing the notice that is relevant to the individual or other person requesting the notice.</p> <p>(2) <u>Specific requirements for certain covered health care providers.</u> A covered health care provider that has a direct treatment relationship with an individual must:</p> <p>(i) Provide the notice no later than the date of the first service delivery, including service delivered electronically, to such individual after the compliance date for the covered health care provider;</p> <p>(ii) If the covered health care provider maintains a physical service delivery site:</p> <p>(A) Have the notice available at the service delivery site for individuals to request to take with them; and</p> <p>(B) Post the notice in a clear and prominent location where it is reasonable to expect individuals seeking service from the covered health care provider to be able to read the notice; and</p> <p>(iii) Whenever the notice is revised, make the notice available upon request on or after the effective date of the revision and promptly comply with the requirements of paragraph (c)(2)(ii) of this section, if applicable.</p>	<p>Same as above.</p> <p>Not covered in PA, HHS, or IHS.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p>	<p>Same as above.</p> <p>Update SOR and/or policy.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p>

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	<p>(3) Specific requirements for electronic notice.</p> <p>(i) A covered entity that maintains a web site that provides information about the covered entity’s customer services or benefits must prominently post its notice on the web site and make the notice available electronically through the web site.</p> <p>(ii) A covered entity may provide the notice required by this section to an individual by e-mail, if the individual agrees to electronic notice and such agreement has not been withdrawn. If the covered entity knows that the e-mail transmission has failed, a paper copy of the notice must be provided to the individual.</p> <p>Provision of electronic notice by the covered entity will satisfy the provision requirements of paragraph (c) of this section when timely made in accordance with paragraph (c)(1) or (2) of this section.</p> <p>(iii) For purposes of paragraph (c)(2)(i) of this section, if the first service delivery to an individual is delivered electronically, the covered health care provider must provide electronic notice automatically and contemporaneously in response to the individual’s first request for service.</p> <p>(iv) The individual who is the recipient of electronic notice retains the right to obtain a paper copy of the notice from a covered entity upon request.</p> <p>(d) <u>Implementation specifications: joint notice by separate covered entities.</u> Covered entities that participate in organized health care arrangements may comply with this section by a joint notice, provided that:</p>	<p>Not covered in PA, HHS, or IHS.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p>	<p>Update SOR and/or policy.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p>

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	<p>(1) The covered entities participating in the organized health care arrangement agree to abide by the terms of the notice with respect to protected health information created or received by the covered entity as part of its participation in the organized health care arrangement;</p> <p>(2) The joint notice meets the implementation specifications in paragraph (b) of this section, except that the statements required by this section may be altered to reflect the fact that the notice covers more than one covered entity; and</p> <p>(i) Describes with reasonable specificity the covered entities, or class of entities, to which the joint notice applies;</p> <p>(ii) Describes with reasonable specificity the service delivery sites, or classes of service delivery sites, to which the joint notice applies; and</p> <p>(iii) If applicable, states that the covered entities participating in the organized health care arrangement will share protected health information with each other, as necessary to carry out treatment, payment, or health care operations relating to the organized health care arrangement.</p> <p>(3) The covered entities included in the joint notice must provide the notice to individuals in accordance with the applicable implementation specifications of paragraph (c) of this section. Provision of the joint notice to an individual by any one of the covered entities included in the joint notice will satisfy the provision requirement of paragraph (c) of this section with respect to all others covered by the joint notice.</p> <p>(e) <u>Implementation specifications: documentation.</u> A covered</p>	<p>Not covered in PA, HHS, or IHS.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p>	<p>Same as above.</p> <p>Update SOR and/or policy.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p>

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	entity must document compliance with the notice requirements by retaining copies of the notices issued by the covered entity as required by § 164.530(j).		
<u>§ 164.522 Rights to request privacy protection for protected health information</u>	<p>(a)(1) Standard: right of an individual to request restriction of uses and disclosures.</p> <p>(i) A covered entity must permit an individual to request that the covered entity restrict:</p> <p>(A) Uses or disclosures of protected health information about the individual to carry out treatment, payment, or health care operations; and</p> <p>(B) Disclosures permitted under § 164.510(b).</p> <p>(ii) A covered entity is not required to agree to a restriction.</p> <p>(iii) A covered entity that agrees to a restriction under paragraph (a)(1)(i) of this section may not use or disclose protected health information in violation of such restriction, except that, if the individual who requested the restriction is in need of emergency treatment and the restricted protected health information is needed to provide the emergency treatment, the covered entity may use the restricted protected health information, or may disclose such information to a health care provider, to provide such treatment to the individual.</p> <p>(iv) If restricted protected health information is disclosed to a health care provider for emergency treatment under paragraph (a)(1)(iii) of this section, the covered entity must request that such health care provider not further use or disclose the information.</p>	<p>Not covered in PA, HHS, of IHS</p> <p>Not covered in PA, HHS, of IHS</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p>	<p>Update SOR and/or policy.</p> <p>Update SOR and/or policy.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p>

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	<p>(v) A restriction agreed to by a covered entity under paragraph (a) of this section, is not effective under this subpart to prevent uses or disclosures permitted or required under §§164.502(a) (2) (i), 164.510(a) or 164.512.</p> <p>(2) <u>Implementation specifications: terminating a restriction.</u> A covered entity may terminate its agreement to a restriction, if :</p> <p>(i) The individual agrees to or requests the termination in writing;</p> <p>(ii) The individual orally agrees to the termination and the oral agreement is documented; or</p> <p>(iii) The covered entity informs the individual that it is terminating its agreement to a restriction, except that such termination is only effective with respect to protected health information created or received after it has so informed the individual.</p> <p>(3) <u>Implementation specification: documentation.</u> A covered entity that agrees to a restriction must document the restriction in accordance with § 164.530(j).</p> <p>(b)(1) Standard: confidential communications requirements.</p> <p>(i) A covered health care provider must permit individuals to request and must accommodate reasonable requests by individuals to receive communications of protected health information from the covered health care provider by alternative means or at alternative locations.</p> <p>(ii) A health plan must permit individuals to request and must</p>	<p>Same as above.</p> <p>Not covered in PA, HHS, or IHS</p> <p>Same as above.</p> <p>Not covered in PA, HHS, or IHS</p> <p>Same as above.</p> <p>Not covered in PA, HHS, or IHS.</p> <p>Not covered in PA, HHS, or IHS.</p>	<p>Same as above.</p> <p>Update SOR and/or policy.</p> <p>Same as above.</p> <p>Update SOR and/or policy.</p> <p>Same as above.</p> <p>Update SOR and/or policy.</p> <p>Update SOR and/or policy.</p>

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	<p>accommodate reasonable requests by individuals to receive communications of protected health information from the health plan by alternative means or at alternative locations, if the individual clearly states that the disclosure of all or part of that information could endanger the individual,</p> <p>(2) Implementation specifications: conditions on providing confidential communications.</p> <p>(i) A covered entity may require the individual to make a request for a confidential communication described in paragraph (b)(1) of this section in writing.</p> <p>(ii) A covered entity may condition the provision of a reasonable accommodation on:</p> <p>(A) When appropriate, information as to how payment, if any, will be handled; and</p> <p>(B) Specification of an alternative address or other method of contact.</p> <p>(iii) A covered health care provider may not require an explanation from the individual as to the basis for the request as a condition of providing communications on a confidential basis.</p> <p>(iv) A health plan may require that a request contain a statement that disclosure of all or part of the information to which the request pertains could endanger the individual.</p>	<p>Not covered in PA, HHS, or IHS. Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p>	<p>Update SOR and/or policy.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p> <p>Same as above.</p>
<p><u>§ 164.524 Access of individuals to protected</u></p>	<p>(a) Standard: access to protected health information.</p> <p>(1) <u>Right of access</u>. Except as otherwise provided in paragraph</p>	<p>5 USC 552a(d); 45 CFR</p>	<p>Update SOR and/or policy.</p>

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	<p>information, if obtaining such copy would jeopardize the health, safety, security, custody, or rehabilitation of the individual or of other inmates, or the safety of any officer, employee, or other person at the correctional institution or responsible for the transporting of the inmate.</p> <p>(iii) An individual's access to protected health information created or obtained by a covered health care provider in the course of research that includes treatment may be temporarily suspended for as long as the research is in progress, provided that the individual has agreed to the denial of access when consenting to participate in the research that includes treatment, and the covered health care provider has informed the individual that the right of access will be reinstated upon completion of the research.</p> <p>(iv) An individual's access to protected health information that is contained in records that are subject to the Privacy Act, 5 U.S.C. § 552a, may be denied, if the denial of access under the Privacy Act would meet the requirements of that law.</p> <p>(v) An individual's access may be denied if the protected health information was obtained from someone other than a health care provider under a promise of confidentiality and the access requested would be reasonably likely to reveal the source of the information.</p> <p>(3) Reviewable grounds for denial. A covered entity may deny an individual access, provided that the individual is given a right to have such denials reviewed, as required by paragraph (a)(4) of this section, in the following circumstances:</p> <p>(i) A licensed health care professional has determined, in the</p>	<p>5 USC 552a(d)(5); 45 CFR 5b.5; IHS SOR 09-17-0001</p> <p>Not covered under PA, HHS, or IHS</p> <p>Not covered in PA, HHS, or</p>	<p>Refer to Research for further review and input: implementation.</p> <p>Update SOR and/or policy.</p> <p>Update SOR and/or policy.</p> <p>Have workgroup consisting of appropriate staff develop written policy and procedure to implement.</p> <p>(OPH, medical, business</p>

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	<p>summary of the protected health information requested, in lieu of providing access to the protected health information or may provide an explanation of the protected health information to which access has been provided, if:</p> <p>(A) The individual agrees in advance to such a summary or explanation; and</p> <p>(B) The individual agrees in advance to the fees imposed, if any, by the covered entity for such summary or explanation.</p> <p>(3) <u>Time and manner of access.</u> The covered entity must provide the access as requested by the individual in a timely manner as required by paragraph (b)(2) of this section, including arranging with the individual for a convenient time and place to inspect or obtain a copy of the protected health information, or mailing the copy of the protected health information at the individual's request. The covered entity may discuss the scope, format, and other aspects of the request for access with the individual as necessary to facilitate the timely provision of access.</p> <p>(4) <u>Fees.</u> If the individual requests a copy of the protected health information or agrees to a summary or explanation of such information, the covered entity may impose a reasonable, cost-based fee, provided that the fee includes only the cost of:</p> <p>(i) Copying, including the cost of supplies for and labor of copying, the protected health information requested by the individual;</p> <p>(ii) Postage, when the individual has requested the copy, or the summary or explanation, be mailed; and</p>	<p>5 USC 552a(f); 45 CFR 5b.13; IHS SOR 09-17-0001</p> <p>Covered in PA, HHS, and IHS.</p>	<p>Update SOR and/or policy.</p> <p>Update SOR and/or policy.</p>

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<u>information</u>	<p>(1) <u>Right to amend.</u> An individual has the right to have a covered entity amend protected health information or a record about the individual in a designated record set for as long as the protected health information is maintained in the designated record set.</p>	5 USC 552a(c); 45 CFR 5b.9; IHS SOR 09-17-0001	Update SOR and/or policy.
	<p>(2) <u>Denial of amendment.</u> A covered entity may deny an individual's request for amendment, if it determines that the protected health information or record that is the subject of the request:</p> <p>(i) Was not created by the covered entity, unless the individual provides a reasonable basis to believe that the originator of protected health information is no longer available to act on the requested amendment;</p> <p>(ii) Is not part of the designated record set;</p> <p>(iii) Would not be available for inspection under § 164.524; or</p> <p>(iv) Is accurate and complete.</p> <p>(b) Implementation specifications: requests for amendment and timely action.</p>	5 USC 552a(c); 45 CFR 5b.9; IHS SOR 09-17-0001	Same as above.
	<p>(1) <u>Individual's request for amendment.</u> The covered entity must permit an individual to request that the covered entity amend the protected health information maintained in the designated record set. The covered entity may require individuals to make requests for amendment in writing and to provide a reason to support a requested amendment, provided that it informs individuals in advance of such requirements.</p>	5 USC 552a(c); 45 CFR 5b.9; IHS SOR 09-17-0001	Update SOR and/or policy. Have workgroup consisting of appropriate staff develop policy and procedure.

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	<p>(2) Timely action by the covered entity.</p> <p>(i) The covered entity must act on the individual’s request for an amendment no later than 60 days after receipt of such a request, as follows.</p> <p>(A) If the covered entity grants the requested amendment, in whole or in part, it must take the actions required by paragraphs (c)(1) and (2) of this section.</p> <p>(B) If the covered entity denies the requested amendment, in whole or in part, it must provide the individual with a written denial, in accordance with paragraph (d)(1) of this section.</p> <p>(ii) If the covered entity is unable to act on the amendment within the time required by paragraph (b)(2)(i) of this section, the covered entity may extend the time for such action by no more than 30 days, provided that:</p> <p>(A) The covered entity, within the time limit set by paragraph (b)(2)(i) of this section, provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will complete its action on the request; and</p> <p>(B) The covered entity may have only one such extension of time for action on a request for an amendment.</p> <p>(c) <u>Implementation specifications: accepting the amendment.</u> If the covered entity accepts the requested amendment, in whole or in part, the covered entity must comply with the following requirements.</p> <p>(1) <u>Making the amendment.</u> The covered entity must make the</p>	<p>5 USC 552a(c); 45 CFR 5b.9; IHS SOR 09-17-0001</p>	<p>Same as above.</p>

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	<p>(1) Denial. The covered entity must provide the individual with a timely, written denial, in accordance with paragraph (b)(2) of this section. The denial must use plain language and contain:</p> <p>(i) The basis for the denial, in accordance with paragraph (a)(2) of this section;</p> <p>(ii) The individual’s right to submit a written statement disagreeing with the denial and how the individual may file such a statement;</p> <p>(iii) A statement that, if the individual does not submit a statement of disagreement, the individual may request that the covered entity provide the individual’s request for amendment and the denial with any future disclosures of the protected health information that is the subject of the amendment; and</p> <p>(iv) A description of how the individual may complain to the covered entity pursuant to the complaint procedures established in § 164.530(d) or to the Secretary pursuant to the procedures established in § 160.306. The description must include the name, or title, and telephone number of the contact person or office designated in §164.530(a)(1)(ii).</p> <p>(2) Statement of disagreement. The covered entity must permit the individual to submit to the covered entity a written statement disagreeing with the denial of all or part of a requested amendment and the basis of such disagreement. The covered entity may reasonably limit the length of a statement of disagreement.</p> <p>(3) Rebuttal statement. The covered entity may prepare a written rebuttal to the individual’s statement of disagreement.</p>	<p>5 USC 552a(c); 45 CFR 5b.9; IHS SOR 09-17-0001</p> <p>5 USC 552a(c); 45 CFR 5b.9; IHS SOR 09-17-0001</p>	<p>Update SOR and/or policy. Have workgroup consisting of appropriate staff develop policy and procedure.</p> <p>Update SOR and/or policy. Have workgroup consisting of appropriate staff develop policy and procedure.</p>

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	<p>disclosure, the covered entity may separately transmit the material required by paragraph (d)(5)(i) or (ii) of this section, as applicable, to the recipient of the standard transaction.</p> <p>(e) Implementation specification: actions on notices of amendment. A covered entity that is informed by another covered entity of an amendment to an individual's protected health information, in accordance with paragraph (c)(3) of this section, must amend the protected health information in designated record sets as provided by paragraph (c)(1) of this section.</p> <p>(f) Implementation specification: documentation. A covered entity must document the titles of the persons or offices responsible for receiving and processing requests for amendments by individuals and retain the documentation as required by § 164.530(j).</p>		<p>Update SOR and/or policy. Have workgroup consisting of appropriate staff develop policy and procedure.</p> <p>Update SOR and/or policy. Have workgroup consisting of appropriate staff develop policy and procedure.</p>
<p><u>§ 164.528 Accounting of disclosures of protected health information</u></p>	<p>(a) Standard: right to an accounting of disclosures of protected health information.</p> <p>(1) An individual has a right to receive an accounting of disclosures of protected health information made by a covered entity in the six years prior to the date on which the accounting is requested, except for disclosures:</p> <p>(i) To carry out treatment, payment and health care operations as provided in § 164.502;</p> <p>(ii) To individuals of protected health information about them as provided in § 164.502;</p> <p>(iii) For the facility's directory or to persons involved in the individual's care or other notification purposes as provided in</p>	<p>5 USC 552a(c); 45 CFR 5b.9; IHS SOR 09-17-0001</p>	<p>Update SOR and/or policy.</p>

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	<p>§ 164.510;</p> <p>(iv) For national security or intelligence purposes as provided in § 164.512(k)(2);</p> <p>(v) To correctional institutions or law enforcement officials as provided in § 164.512(k)(5); or</p> <p>(vi) That occurred prior to the compliance date for the covered entity.</p> <p>(2)(i) The covered entity must temporarily suspend an individual's right to receive an accounting of disclosures to a health oversight agency or law enforcement official, as provided in § 164.512(d) or (f), respectively, for the time specified by such agency or official, if such agency or official provides the covered entity with a written statement that such an accounting to the individual would be reasonably likely to impede the agency's activities and specifying the time for which such a suspension is required.</p> <p>(ii) If the agency or official statement in paragraph (a)(2)(i) of this section is made orally, the covered entity must:</p> <p>(A) Document the statement, including the identity of the agency or official making the statement;</p> <p>(B) Temporarily suspend the individual's right to an accounting of disclosures subject to the statement; and</p> <p>(C) Limit the temporary suspension to no longer than 30 days from the date of the oral statement, unless a written statement pursuant to paragraph (a)(2)(i) of this section is submitted</p>		<p>Update SOR and/or policy. Have workgroup consisted of appropriate staff develop policy and procedure to implement.</p>

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	<p>during that time.</p> <p>(3) An individual may request an accounting of disclosures for a period of time less than six years from the date of the request.</p> <p>(b) <u>Implementation specifications: content of the accounting.</u> The covered entity must provide the individual with a written accounting that meets the following requirements.</p> <p>(1) Except as otherwise provided by paragraph (a) of this section, the accounting must include disclosures of protected health information that occurred during the six years (or such shorter time period at the request of the individual as provided in paragraph (a)(3) of this section) prior to the date of the request for an accounting, including disclosures to or by business associates of the covered entity.</p> <p>(2) The accounting must include for each disclosure:</p> <p>(i) The date of the disclosure;</p> <p>(ii) The name of the entity or person who received the protected health information and, if known, the address of such entity or person;</p> <p>(iii) A brief description of the protected health information disclosed; and</p> <p>(iv) A brief statement of the purpose of the disclosure that reasonably informs the individual of the basis for the disclosure; or, in lieu of such statement:</p>		<p>Have workgroup consisted of appropriate staff develop policy and procedure to implement.</p>

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	<p>(A) A copy of the individual’s written authorization pursuant to § 164.508; or</p> <p>(B) A copy of a written request for a disclosure under §§ 164.502(a)(2)(ii) or 164.512, if any.</p> <p>(3) If, during the period covered by the accounting, the covered entity has made multiple disclosures of protected health information to the same person or entity for a single purpose under §§ 164.502(a)(2)(ii) or 164.512, or pursuant to a single authorization under § 164.508, the accounting may, with respect to such multiple disclosures, provide:</p> <p>(i) The information required by paragraph (b)(2) of this section for the first disclosure during the accounting period;</p> <p>(ii) The frequency, periodicity, or number of the disclosures made during the accounting period; and</p> <p>(iii) The date of the last such disclosure during the accounting period.</p> <p>(c) Implementation specifications: provision of the accounting.</p> <p>(1) The covered entity must act on the individual’s request for an accounting, no later than 60 days after receipt of such a request, as follows.</p> <p>(i) The covered entity must provide the individual with the accounting requested; or</p> <p>(ii) If the covered entity is unable to provide the accounting within the time required by paragraph (c)(1) of this section, the covered entity may extend the time to provide the accounting by</p>	<p>5 USC 552a(c); 45 CFR 5b.9; IHS SOR 09-17-0001</p>	<p>Update SOR and/or policy.</p> <p>Have workgroup consisted of appropriate staff develop policy and procedure to implement.</p>

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	<p>no more than 30 days, provided that:</p> <p>(A) The covered entity, within the time limit set by paragraph (c)(1) of this section, provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will provide the accounting; and</p> <p>(B) The covered entity may have only one such extension of time for action on a request for an accounting.</p> <p>(2) The covered entity must provide the first accounting to an individual in any 12 month period without charge. The covered entity may impose a reasonable, cost-based fee for each subsequent request for an accounting by the same individual within the 12 month period, provided that the covered entity informs the individual in advance of the fee and provides the individual with an opportunity to withdraw or modify the request for a subsequent accounting in order to avoid or reduce the fee.</p> <p>(d) <u>Implementation specification: documentation.</u> A covered entity must document the following and retain the documentation as required by § 164.530(j):</p> <p>(1) The information required to be included in an accounting under paragraph (b) of this section for disclosures of protected health information that are subject to an accounting under paragraph (a) of this section;</p> <p>(2) The written accounting that is provided to the individual under this section; and</p>	<p>5 USC 552a(c); 45 CFR 5b.9; IHS SOR 09-17-0001</p>	<p>Update SOR and/or policy.</p> <p>Have workgroup consisted of appropriate staff develop policy and procedure to implement.</p>

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	(3) The titles of the persons or offices responsible for receiving and processing requests for an accounting by individuals.		
<u>§ 164.530 Administrative requirements</u>	<p>(a)(1) Standard: personnel designations.</p> <p>(i) A covered entity must designate a privacy official who is responsible for the development and implementation of the policies and procedures of the entity.</p> <p>(ii) A covered entity must designate a contact person or office who is responsible for receiving complaints under this section and who is able to provide further information about matters covered by the notice required by § 164.520.</p> <p>(2) <u>Implementation specification: personnel designations.</u> A covered entity must document the personnel designations in paragraph (a)(1) of this section as required by paragraph (j) of this section.</p> <p>(b)(1) <u>Standard: training.</u> A covered entity must train all members of its workforce on the policies and procedures with respect to protected health information required by this subpart, as necessary and appropriate for the members of the workforce to carry out their function within the covered entity.</p> <p>(2) <u>Implementation specifications: training.</u></p> <p>(i) A covered entity must provide training that meets the requirements of paragraph (b)(1) of this section, as follows:</p> <p>(A) To each member of the covered entity's workforce by no later than the compliance date for the covered entity;</p> <p>(B) Thereafter, to each new member of the workforce within a</p>	5 USC 552a(f); 45 CFR 5b.2; IHS Privacy Act Procedures.	At the HQ level, a PA Officer is a full-time position; Area-level, privacy act responsibilities are delegated in most cases to Medical Records positions; SU-level, PA responsibilities are covered by Medical Records Supv./HIMS staff. Have workgroup consisted of appropriate staff develop policy and procedure to implement. Existing Area PA and contracted trainers (designed specific to IHS) can accomplish training. Have workgroup consisted of appropriate staff develop policy and procedure to implement.

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	<p>reasonable period of time after the person joins the covered entity's workforce; and</p> <p>(C) To each member of the covered entity's workforce whose functions are affected by a material change in the policies or procedures required by this subpart, within a reasonable period of time after the material change becomes effective in accordance with paragraph (i) of this section.</p> <p>(ii) A covered entity must document that the training as described in paragraph (b)(2)(i) of this section has been provided, as required by paragraph (j) of this section.</p> <p>(c)(1) <u>Standard: safeguards.</u> A covered entity must have in place appropriate administrative, technical, and physical safeguards to protect the privacy of protected health information.</p> <p>(2) <u>Implementation specification: safeguards.</u> A covered entity must reasonably safeguard protected health information from any intentional or unintentional use or disclosure that is in violation of the standards, implementation specifications or other requirements of this subpart.</p> <p>(d)(1) <u>Standard: complaints to the covered entity.</u> A covered entity must provide a process for individuals to make complaints concerning the covered entity's policies and procedures required by this subpart or its compliance with such policies and procedures or the requirements of this subpart.</p> <p>(2) <u>Implementation specification: documentation of complaints.</u> As required by paragraph (j) of this section, a covered entity must document all complaints received, and their disposition, if any.</p>		<p>Have workgroup consisted of appropriate staff develop policy and procedure to implement.</p> <p>Have workgroup consisted of appropriate staff develop policy and procedure to implement.</p>

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	<p>(e)(1) <u>Standard: sanctions.</u> A covered entity must have and apply appropriate sanctions against members of its workforce who fail to comply with the privacy policies and procedures of the covered entity or the requirements of this subpart. This standard does not apply to a member of the covered entity's workforce with respect to actions that are covered by and that meet the conditions of § 164.502(j) or paragraph (g)(2) of this section.</p> <p>(2) <u>Implementation specification: documentation.</u> As required by paragraph (j) of this section, a covered entity must document the sanctions that are applied, if any.</p> <p>(f) <u>Standard: mitigation.</u> A covered entity must mitigate, to the extent practicable, any harmful effect that is known to the covered entity of a use or disclosure of protected health information in violation of its policies and procedures or the requirements of this subpart by the covered entity or its business associate.</p> <p>(g) <u>Standard: refraining from intimidating or retaliatory acts.</u> A covered entity may not intimidate, threaten, coerce, discriminate against, or take other retaliatory action against:</p> <p>(1) <u>Individuals.</u> Any individual for the exercise by the individual of any right under, or for participation by the individual in any process established by this subpart, including the filing of a complaint under this section;</p> <p>(2) <u>Individuals and others.</u> Any individual or other person for:</p> <p>(i) Filing of a complaint with the Secretary under subpart C of part 160 of this subchapter;</p>		<p>Have workgroup consisted of appropriate staff develop policy and procedure to implement.</p> <p>Have workgroup consisted of appropriate staff develop policy and procedure to implement.</p> <p>Have workgroup consisted of appropriate staff develop policy and procedure to implement.</p>

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	<p>(ii) Testifying, assisting, or participating in an investigation, compliance review, proceeding, or hearing under Part C of Title XI; or</p> <p>(iii) Opposing any act or practice made unlawful by this subpart, provided the individual or person has a good faith belief that the practice opposed is unlawful, and the manner of the opposition is reasonable and does not involve a disclosure of protected health information in violation of this subpart.</p> <p>(h) <u>Standard: waiver of rights.</u> A covered entity may not require individuals to waive their rights under § 160.306 of this subchapter or this subpart as a condition of the provision of treatment, payment, enrollment in a health plan, or eligibility for benefits.</p> <p>(i)(1) <u>Standard: policies and procedures.</u> A covered entity must implement policies and procedures with respect to protected health information that are designed to comply with the standards, implementation specifications, or other requirements of this subpart. The policies and procedures must be reasonably designed, taking into account the size of and the type of activities that relate to protected health information undertaken by the covered entity, to ensure such compliance. This standard is not to be construed to permit or excuse an action that violates any other standard, implementation specification, or other requirement of this subpart.</p> <p>(2) <u>Standard: changes to policies or procedures.</u></p> <p>(i) A covered entity must change its policies and procedures as necessary and appropriate to comply with changes in the law, including the standards, requirements, and implementation</p>		<p>Have workgroup consisted of appropriate staff develop policy and procedure to implement.</p> <p>Have workgroup consisted of appropriate staff develop policy and procedure to implement.</p> <p>(OPH, medical, business office, chs, privacy staff, OGC, etc.)</p> <p>Have workgroup consisted of appropriate staff develop policy and procedure to implement.</p>

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Section	HIPAA Requirement	Existing Policies & Practices	To Do List
	<p>specifications of this subpart;</p> <p>(ii) When a covered entity changes a privacy practice that is stated in the notice described in § 164.520, and makes corresponding changes to its policies and procedures, it may make the changes effective for protected health information that it created or received prior to the effective date of the notice revision, if the covered entity has, in accordance with § 164.520 (b)(1)(v)(C), included in the notice a statement reserving its right to make such a change in its privacy practices; or</p> <p>(iii) A covered entity may make any other changes to policies and procedures at any time, provided that the changes are documented and implemented in accordance with paragraph (i)(5) of this section.</p> <p>(3) <u>Implementation specification: changes in law.</u> Whenever there is a change in law that necessitates a change to the covered entity's policies or procedures, the covered entity must promptly document and implement the revised policy or procedure. If the change in law materially affects the content of the notice required by § 164.520, the covered entity must promptly make the appropriate revisions to the notice in accordance with § 164.520(b)(3). Nothing in this paragraph may be used by a covered entity to excuse a failure to comply with the law.</p> <p>(4) Implementation specifications: changes to privacy practices stated in the notice.</p> <p>(i) To implement a change as provided by paragraph (i)(2)(ii) of this section, a covered entity must:</p>		<p>(OPH, medical, business office, chs, privacy staff, OGC, etc.)</p> <p>Have workgroup consisted of appropriate staff develop policy and procedure to implement.</p> <p>(OPH, medical, business office, chs, privacy staff, OGC, etc.)</p> <p>Have workgroup consisted of appropriate staff develop policy and procedure to implement.</p> <p>(OPH, medical, business</p>

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	<p>notice required by § 164.520, provided that:</p> <p>(i) The policy or procedure, as revised, complies with the standards, requirements, and implementation specifications of this subpart; and</p> <p>(ii) Prior to the effective date of the change, the policy or procedure, as revised, is documented as required by paragraph (j) of this section.</p> <p>(j)(1) <u>Standard: documentation.</u> A covered entity must:</p> <p>(i) Maintain the policies and procedures provided for in paragraph (i) of this section in written or electronic form;</p> <p>(ii) If a communication is required by this subpart to be in writing, maintain such writing, or an electronic copy, as documentation; and</p> <p>(iii) If an action, activity, or designation is required by this subpart to be documented, maintain a written or electronic record of such action, activity, or designation.</p> <p>(2) <u>Implementation specification: retention period.</u> A covered entity must retain the documentation required by paragraph (j)(1) of this section for six years from the date of its creation or the date when it last was in effect, whichever is later.</p> <p>(k) <u>Standard: group health plans.</u></p> <p>(1) A group health plan is not subject to the standards or implementation specifications in paragraphs (a) through (f) and</p>		<p>(OPH, medical, business office, chs, privacy staff, OGC, etc.)</p> <p>Have workgroup consisted of appropriate staff develop policy and procedure to implement.</p> <p>(OPH, medical, business office, chs, privacy staff, OGC, etc.)</p> <p>Have workgroup consisted of appropriate staff develop policy and procedure to implement. (OPH, medical, business office, chs, privacy staff, OGC, etc.)</p> <p>May not be applicable to IHS.</p>

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	<p>(i) of this section, to the extent that:</p> <p>(i) The group health plan provides health benefits solely through an insurance contract with a health insurance issuer or an HMO; and ,</p> <p>(ii) The group health plan does not create or receive protected health information, except for:</p> <p>(A) Summary health information as defined in § 164.504(a); or</p> <p>(B) Information on whether the individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan.</p> <p>(2) A group health plan described in paragraph (k)(1) of this section is subject to the standard and implementation specification in paragraph (j) of this section only with respect to plan documents amended in accordance with § 164.504(f).</p>		
<p><u>§ 164.532 Transition provisions</u></p>	<p>(a) <u>Standard: effect of prior consents and authorizations.</u> Notwithstanding other sections of this subpart, a covered entity may continue to use or disclose protected health information pursuant to a consent, authorization, or other express legal permission obtained from an individual permitting the use or disclosure of protected health information that does not comply with §§ 164.506 or 164.508 of this subpart consistent with paragraph (b) of this section.</p> <p>(b) <u>Implementation specification: requirements for retaining effectiveness of prior consents and authorizations.</u> Notwithstanding other sections of this subpart, the following provisions apply to use or disclosure by a covered entity of protected health information pursuant to a consent,</p>		<p>Have workgroup consisted of appropriate staff develop policy and procedure to implement.</p> <p>(OPH, medical, business office, chs, privacy staff, OGC, etc.)</p> <p>Have workgroup consisted of appropriate staff develop policy and procedure to implement.</p>

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	<p>authorization, or other express legal permission obtained from an individual permitting the use or disclosure of protected health information, if the consent, authorization, or other express legal permission was obtained from an individual before the applicable compliance date of this subpart and does not comply with §§ 164.506 or 164.508 of this subpart.</p> <p>(1) If the consent, authorization, or other express legal permission obtained from an individual permits a use or disclosure for purposes of carrying out treatment, payment, or health care operations, the covered entity may, with respect to protected health information that it created or received before the applicable compliance date of this subpart and to which the consent, authorization, or other express legal permission obtained from an individual applies, use or disclose such information for purposes of carrying out treatment, payment, or health care operations, provided that:</p> <p>(i) The covered entity does may not make any use or disclosure that is expressly excluded from the a consent, authorization, or other express legal permission obtained from an individual; and</p> <p>(ii) The covered entity complies with all limitations placed by the consent, authorization, or other express legal permission obtained from an individual.</p> <p>(2) If the consent, authorization, or other express legal permission obtained from an individual specifically permits a use or disclosure for a purpose other than to carry out treatment, payment, or health care operations, the covered entity may, with respect to protected health information that it created or received before the applicable compliance date of this subpart and to which the consent, authorization, or other express legal</p>		<p>(OPH, medical, business office, chs, privacy staff, OGC, etc.)</p>

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	<p>permission obtained from an individual applies, make such use or disclosure, provided that:</p> <p>(i) The covered entity does not make any use or disclosure that is expressly excluded from the consent, authorization, or other express legal permission obtained from an individual; and</p> <p>(ii) The covered entity complies with all limitations placed by the consent, authorization, or other express legal permission obtained from an individual.</p> <p>(3) In the case of a consent, authorization, or other express legal permission obtained from an individual that identifies a specific research project that includes treatment of individuals:</p> <p>(i) If the consent, authorization, or other express legal permission obtained from an individual specifically permits a use or disclosure for purposes of the project, the covered entity may, with respect to protected health information that it created or received either before or after the applicable compliance date of this subpart and to which the consent or authorization applies, make such use or disclosure for purposes of that project, provided that the covered entity complies with all limitations placed by the consent, authorization, or other express legal permission obtained from an individual.</p> <p>(ii) If the consent, authorization, or other express legal permission obtained from an individual is a general consent to participate in the project, and a covered entity is conducting or participating in the research, such covered entity may, with respect to protected health information that it created or received as part of the project before or after the applicable compliance date of this subpart, make a use or disclosure for</p>		

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	<p>purposes of that project, provided that the covered entity complies with all limitations placed by the consent, authorization, or other express legal permission obtained from an individual.</p> <p>(4) If, after the applicable compliance date of this subpart, a covered entity agrees to a restriction requested by an individual under § 164.522(a), a subsequent use or disclosure of protected health information that is subject to the restriction based on a consent, authorization, or other express legal permission obtained from an individual as given effect by paragraph (b) of this section, must comply with such restriction.</p>		
<p><u>§ 164.534 Compliance dates for initial implementation of the privacy standards</u></p>	<p>(a) <u>Health care providers</u>. A covered health care provider must comply with the applicable requirements of this subpart no later than February 26, 2003. April 14, 2003.</p> <p>(b) <u>Health plans</u>. A health plan must comply with the applicable requirements of this subpart no later than the following date, as applicable:</p> <p>(1) <u>Health plans other than small health plans</u> – February 26, 2003. April 14, 2003.</p> <p>(2) <u>Small health plans</u> – February 26, 2004. April 14, 2004.</p> <p>(c) <u>Health care clearinghouses</u>. A health care clearinghouse must comply with the applicable requirements of this subpart no later than February 26, 2003. April 14, 2003.</p>		<p>Compliance info for implementing.</p>