

all state privacy laws. As explained in this section, the regulation would only preempt state laws where there is a direct conflict between state laws and the regulation, and where the regulation provides more stringent privacy protection than state law. We discussed this issue during our consultation with state representatives, who generally accepted our approach to the preemption issue. During the consultation, we requested further information from the states about whether they currently have laws requiring that providers have a "duty to warn" family members or third parties about a patient's condition other than in emergency circumstances. Since the consultation, we have not received additional comments or questions from the states.

X. Executive Order 13086; Consultation and Coordination With Indian Tribal Governments

In drafting the proposed rule, the Department consulted with representatives of the National Congress of American Indians and the National Indian Health Board, as well as with a representative of the self-governance Tribes. During the consultation, we discussed issues regarding the application of Title II of HIPAA to the Tribes, and potential variations based on the relationship of each Tribe with the IHS for the purpose of providing health services. Participants raised questions about the status of Tribal laws regarding the privacy of health information.

List of Subjects

45 CFR Part 160

Electronic transactions, Employer benefit plan, Health, Health care, Health facilities, Health insurance, Health records, Medicaid, Medical research, Medicare, Privacy, Reporting and record keeping requirements.

45 CFR Part 164

Electronic transactions, Employer benefit plan, Health, Health care, Health facilities, Health insurance, Health records, Medicaid, Medical research, Medicare, Privacy, Reporting and record keeping requirements.

Note to reader: This final rule is one of several proposed and final rules that are being published to implement the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996. 45 CFR subchapter C consisting of Parts 160 and 162 was added at 65 FR 50365, Aug. 17, 2000. Part 160 consists of general provisions, Part 162 consists of the various administrative simplification regulations relating to

transactions and identifiers, and new Part 164 consists of the regulations implementing the security and privacy requirements of the legislation.

Dated: December 19, 2000.

Donna Shalala,
Secretary,

For the reasons set forth in the preamble, 45 CFR Subtitle A, Subchapter C, is amended as follows:

1. Part 160 is revised to read as follows:

PART 160—GENERAL ADMINISTRATIVE REQUIREMENTS

Subpart A—General Provisions

- 160.101 Statutory basis and purpose.
- 160.102 Applicability.
- 160.103 Definitions.
- 160.104 Modifications.

Subpart B—Preemption of State Law

- 160.201 Applicability.
- 160.202 Definitions.
- 160.203 General rule and exceptions.
- 160.204 Process for requesting exception determinations.
- 160.205 Duration of effectiveness of exception determinations.

Subpart C—Compliance and Enforcement

- 160.300 Applicability.
- 160.302 Definitions.
- 160.304 Principles for achieving compliance.
- 160.306 Complaints to the Secretary.
- 160.308 Compliance reviews.
- 160.310 Responsibilities of covered entities.
- 160.312 Secretarial action regarding complaints and compliance reviews.

Authority: Sec. 1171 through 1179 of the Social Security Act, (42 U.S.C. 1320d–1329d–8) as added by sec. 262 of Pub. L. 104–191, 110 Stat. 2021–2031 and sec. 264 of Pub. L. 104–191 (42 U.S.C. 1320d–2(note)).

Subpart A—General Provisions

§ 160.101 Statutory basis and purpose.

The requirements of this subchapter implement sections 1171 through 1179 of the Social Security Act (the Act), as added by section 262 of Public Law 104–191, and section 264 of Public Law 104–191.

§ 160.102 Applicability.

(a) Except as otherwise provided, the standards, requirements, and implementation specifications adopted under this subchapter apply to the following entities:

- (1) A health plan.
- (2) A health care clearinghouse.
- (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

(b) To the extent required under section 201(a)(5) of the Health Insurance

Portability Act of 1996, (Pub. L. 104–191), nothing in this subchapter shall be construed to diminish the authority of any Inspector General, including such authority as provided in the Inspector General Act of 1978, as amended (5 U.S.C. App.).

§ 160.103 Definitions.

Except as otherwise provided, the following definitions apply to this subchapter:

Act means the Social Security Act. *ANSI* stands for the American National Standards Institute.

Business associate: (1) Except as provided in paragraph (2) of this definition, *business associate* means, with respect to a covered entity, a person who:

(i) On behalf of such covered entity or of an organized health care arrangement (as defined in § 164.501 of this subchapter) in which the covered entity participates, but other than in the capacity of a member of the workforce of such covered entity or arrangement, performs, or assists in the performance of:

(A) A function or activity involving the use or disclosure of individually identifiable health information, including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, billing, benefit management, practice management, and repricing; or

(B) Any other function or activity regulated by this subchapter; or

(ii) Provides, other than in the capacity of a member of the workforce of such covered entity, legal, actuarial, accounting, consulting, data aggregation (as defined in § 164.501 of this subchapter), management,

administrative, accreditation, or financial services to or for such covered entity, or to or for an organized health care arrangement in which the covered entity participates, where the provision of the service involves the disclosure of individually identifiable health information from such covered entity or arrangement, or from another business associate of such covered entity or arrangement, to the person.

(2) A covered entity participating in an organized health care arrangement that performs a function or activity as described by paragraph (1)(i) of this definition for or on behalf of such organized health care arrangement, or that provides a service as described in paragraph (1)(ii) of this definition to or for such organized health care arrangement, does not, simply through the performance of such function or activity or the provision of such service,

become a business associate of other covered entities participating in such organized health care arrangement.

(3) A covered entity may be a business associate of another covered entity.

Compliance date means the date by which a covered entity must comply with a standard, implementation specification, requirement, or modification adopted under this subchapter.

Covered entity means:

(1) A health plan.

(2) A health care clearinghouse.

(3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

Group health plan (also see definition of *health plan* in this section) means an employee welfare benefit plan (as defined in section 3(1) of the Employee Retirement Income and Security Act of 1974 (ERISA), 29 U.S.C. 1002(1)), including insured and self-insured plans, to the extent that the plan provides medical care (as defined in section 2791(a)(2) of the Public Health Service Act (PHS Act), 42 U.S.C. 300gg-91(a)(2)), including items and services paid for as medical care, to employees or their dependents directly or through insurance, reimbursement, or otherwise, that:

(1) Has 50 or more participants (as defined in section 3(7) of ERISA, 29 U.S.C. 1002(7)); or

(2) Is administered by an entity other than the employer that established and maintains the plan.

HCFA stands for Health Care Financing Administration within the Department of Health and Human Services.

HHS stands for the Department of Health and Human Services.

Health care means care, services, or supplies related to the health of an individual. *Health care* includes, but is not limited to, the following:

(1) Preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual or that affects the structure or function of the body; and

(2) Sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription.

Health care clearinghouse means a public or private entity, including a billing service, repricing company, community health management information system or community health information system, and "value-added" networks and switches, that does either of the following functions:

(1) Processes or facilitates the processing of health information received from another entity in a nonstandard format or containing nonstandard data content into standard data elements or a standard transaction.

(2) Receives a standard transaction from another entity and processes or facilitates the processing of health information into nonstandard format or nonstandard data content for the receiving entity.

Health care provider means a provider of services (as defined in section 1861(u) of the Act, 42 U.S.C. 1395x(u)), a provider of medical or health services (as defined in section 1861(s) of the Act, 42 U.S.C. 1395x(s)), and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business.

Health information means any information, whether oral or recorded in any form or medium, that:

(1) Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and

(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.

Health insurance issuer (as defined in section 2791(b)(2) of the PHS Act, 42 U.S.C. 300gg-91(b)(2) and used in the definition of *health plan* in this section) means an insurance company, insurance service, or insurance organization (including an HMO) that is licensed to engage in the business of insurance in a State and is subject to State law that regulates insurance. Such term does not include a group health plan.

Health maintenance organization (HMO) (as defined in section 2791(b)(3) of the PHS Act, 42 U.S.C. 300gg-91(b)(3) and used in the definition of *health plan* in this section) means a federally qualified HMO, an organization recognized as an HMO under State law, or a similar organization regulated for solvency under State law in the same manner and to the same extent as such an HMO.

Health plan means an individual or group plan that provides, or pays the cost of, medical care (as defined in section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg-91(a)(2)).

(1) *Health plan* includes the following, singly or in combination:

(i) A group health plan, as defined in this section.

(ii) A health insurance issuer, as defined in this section.

(iii) An HMO, as defined in this section.

(iv) Part A or Part B of the Medicare program under title XVIII of the Act.

(v) The Medicaid program under title XIX of the Act, 42 U.S.C. 1396, *et seq.*

(vi) An issuer of a Medicare supplemental policy (as defined in section 1882(g)(1) of the Act, 42 U.S.C. 1395ss(g)(1)).

(vii) An issuer of a long-term care policy, excluding a nursing home fixed-indemnity policy.

(viii) An employee welfare benefit plan or any other arrangement that is established or maintained for the purpose of offering or providing health benefits to the employees of two or more employers.

(ix) The health care program for active military personnel under title 10 of the United States Code.

(x) The veterans health care program under 38 U.S.C. chapter 17.

(xi) The Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) (as defined in 10 U.S.C. 1072(4)).

(xii) The Indian Health Service program under the Indian Health Care Improvement Act, 25 U.S.C. 1601, *et seq.*

(xiii) The Federal Employees Health Benefits Program under 5 U.S.C. 8902, *et seq.*

(xiv) An approved State child health plan under title XXI of the Act, providing benefits for child health assistance that meet the requirements of section 2103 of the Act, 42 U.S.C. 1397, *et seq.*

(xv) The Medicare+Choice program under Part C of title XVIII of the Act, 42 U.S.C. 1395w-21 through 1395w-28.

(xvi) A high risk pool that is a mechanism established under State law to provide health insurance coverage or comparable coverage to eligible individuals.

(xvii) Any other individual or group plan, or combination of individual or group plans, that provides or pays for the cost of medical care (as defined in section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg-91(a)(2)).

(2) *Health plan* excludes:

(i) Any policy, plan, or program to the extent that it provides, or pays for the cost of, excepted benefits that are listed in section 2791(c)(1) of the PHS Act, 42 U.S.C. 300gg-91(c)(1); and

(ii) A government-funded program (other than one listed in paragraph (1)(i)-(xvi) of this definition):

(A) Whose principal purpose is other than providing, or paying the cost of, health care; or

(B) Whose principal activity is:

(1) The direct provision of health care to persons; or

(2) The making of grants to fund the direct provision of health care to persons.

Implementation specification means specific requirements or instructions for implementing a standard.

Modify or *modification* refers to a change adopted by the Secretary, through regulation, to a standard or an implementation specification.

Secretary means the Secretary of Health and Human Services or any other officer or employee of HHS to whom the authority involved has been delegated.

Small health plan means a health plan with annual receipts of \$5 million or less.

Standard means a rule, condition, or requirement:

(1) Describing the following information for products, systems, services or practices:

(i) Classification of components.

(ii) Specification of materials, performance, or operations; or

(iii) Delineation of procedures; or

(2) With respect to the privacy of individually identifiable health information.

Standard setting organization (SSO) means an organization accredited by the American National Standards Institute that develops and maintains standards for information transactions or data elements, or any other standard that is necessary for, or will facilitate the implementation of, this part.

State refers to one of the following:

(1) For a health plan established or regulated by Federal law, State has the meaning set forth in the applicable section of the United States Code for such health plan.

(2) For all other purposes, *State* means any of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, and Guam.

Trading partner agreement means an agreement related to the exchange of information in electronic transactions, whether the agreement is distinct or part of a larger agreement, between each party to the agreement. (For example, a trading partner agreement may specify, among other things, the duties and responsibilities of each party to the agreement in conducting a standard transaction.)

Transaction means the transmission of information between two parties to carry out financial or administrative activities related to health care. It includes the following types of information transmissions:

(1) Health care claims or equivalent encounter information.

(2) Health care payment and remittance advice.

(3) Coordination of benefits.

(4) Health care claim status.

(5) Enrollment and disenrollment in a health plan.

(6) Eligibility for a health plan.

(7) Health plan premium payments.

(8) Referral certification and authorization.

(9) First report of injury.

(10) Health claims attachments.

(11) Other transactions that the Secretary may prescribe by regulation.

Workforce means employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a covered entity, is under the direct control of such entity, whether or not they are paid by the covered entity.

§ 160.104 Modifications.

(a) Except as provided in paragraph (b) of this section, the Secretary may adopt a modification to a standard or implementation specification adopted under this subchapter no more frequently than once every 12 months.

(b) The Secretary may adopt a modification at any time during the first year after the standard or implementation specification is initially adopted, if the Secretary determines that the modification is necessary to permit compliance with the standard or implementation specification.

(c) The Secretary will establish the compliance date for any standard or implementation specification modified under this section.

(1) The compliance date for a modification is no earlier than 180 days after the effective date of the final rule in which the Secretary adopts the modification.

(2) The Secretary may consider the extent of the modification and the time needed to comply with the modification in determining the compliance date for the modification.

(3) The Secretary may extend the compliance date for small health plans, as the Secretary determines is appropriate.

Subpart B—Preemption of State Law

§ 160.201 Applicability.

The provisions of this subpart implement section 1178 of the Act, as added by section 262 of Public Law 104–191.

§ 160.202 Definitions.

For purposes of this subpart, the following terms have the following meanings:

Contrary, when used to compare a provision of State law to a standard,

requirement, or implementation specification adopted under this subchapter, means:

(1) A covered entity would find it impossible to comply with both the State and federal requirements; or

(2) The provision of State law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of part C of title XI of the Act or section 264 of Pub. L. 104–191, as applicable.

More stringent means, in the context of a comparison of a provision of State law and a standard, requirement, or implementation specification adopted under subpart E of part 164 of this subchapter, a State law that meets one or more of the following criteria:

(1) With respect to a use or disclosure, the law prohibits or restricts a use or disclosure in circumstances under which such use or disclosure otherwise would be permitted under this subchapter, except if the disclosure is:

(i) Required by the Secretary in connection with determining whether a covered entity is in compliance with this subchapter; or

(ii) To the individual who is the subject of the individually identifiable health information.

(2) With respect to the rights of an individual who is the subject of the individually identifiable health information of access to or amendment of individually identifiable health information, permits greater rights of access or amendment, as applicable; provided that, nothing in this subchapter may be construed to preempt any State law to the extent that it authorizes or prohibits disclosure of protected health information about a minor to a parent, guardian, or person acting *in loco parentis* of such minor.

(3) With respect to information to be provided to an individual who is the subject of the individually identifiable health information about a use, a disclosure, rights, and remedies, provides the greater amount of information.

(4) With respect to the form or substance of an authorization or consent for use or disclosure of individually identifiable health information, provides requirements that narrow the scope or duration, increase the privacy protections afforded (such as by expanding the criteria for), or reduce the coercive effect of the circumstances surrounding the authorization or consent, as applicable.

(5) With respect to recordkeeping or requirements relating to accounting of disclosures, provides for the retention or reporting of more detailed information or for a longer duration.

(6) With respect to any other matter, provides greater privacy protection for the individual who is the subject of the individually identifiable health information.

Relates to the privacy of individually identifiable health information means, with respect to a State law, that the State law has the specific purpose of protecting the privacy of health information or affects the privacy of health information in a direct, clear, and substantial way.

State law means a constitution, statute, regulation, rule, common law, or other State action having the force and effect of law.

§ 160.203 General rule and exceptions.

A standard, requirement, or implementation specification adopted under this subchapter that is contrary to a provision of State law preempts the provision of State law. This general rule applies, except if one or more of the following conditions is met:

(a) A determination is made by the Secretary under § 160.204 that the provision of State law:

- (1) Is necessary;
- (i) To prevent fraud and abuse related to the provision of or payment for health care;
- (ii) To ensure appropriate State regulation of insurance and health plans to the extent expressly authorized by statute or regulation;
- (iii) For State reporting on health care delivery or costs; or
- (iv) For purposes of serving a compelling need related to public health, safety, or welfare, and, if a standard, requirement, or implementation specification under part 164 of this subchapter is at issue, if the Secretary determines that the intrusion into privacy is warranted when balanced against the need to be served; or

(2) Has as its principal purpose the regulation of the manufacture, registration, distribution, dispensing, or other control of any controlled substances (as defined in 21 U.S.C. 802), or that is deemed a controlled substance by State law.

(b) The provision of State law relates to the privacy of health information and is more stringent than a standard, requirement, or implementation specification adopted under subpart E of part 164 of this subchapter.

(c) The provision of State law, including State procedures established under such law, as applicable, provides for the reporting of disease or injury, child abuse, birth, or death, or for the conduct of public health surveillance, investigation, or intervention.

(d) The provision of State law requires a health plan to report, or to provide access to, information for the purpose of management audits, financial audits, program monitoring and evaluation, or the licensure or certification of facilities or individuals.

§ 160.204 Process for requesting exception determinations.

(a) A request to except a provision of State law from preemption under § 160.203(a) may be submitted to the Secretary. A request by a State must be submitted through its chief elected official, or his or her designee. The request must be in writing and include the following information:

- (1) The State law for which the exception is requested;
- (2) The particular standard, requirement, or implementation specification for which the exception is requested;
- (3) The part of the standard or other provision that will not be implemented based on the exception or the additional data to be collected based on the exception, as appropriate;
- (4) How health care providers, health plans, and other entities would be affected by the exception;
- (5) The reasons why the State law should not be preempted by the federal standard, requirement, or implementation specification, including how the State law meets one or more of the criteria at § 160.203(a); and
- (6) Any other information the Secretary may request in order to make the determination.

(b) Requests for exception under this section must be submitted to the Secretary at an address that will be published in the **Federal Register**. Until the Secretary's determination is made, the standard, requirement, or implementation specification under this subchapter remains in effect.

(c) The Secretary's determination under this section will be made on the basis of the extent to which the information provided and other factors demonstrate that one or more of the criteria at § 160.203(a) has been met.

§ 160.205 Duration of effectiveness of exception determinations.

An exception granted under this subpart remains in effect until:

(a) Either the State law or the federal standard, requirement, or implementation specification that provided the basis for the exception is materially changed such that the ground for the exception no longer exists; or

(b) The Secretary revokes the exception, based on a determination that the ground supporting the need for the exception no longer exists.

Subpart C—Compliance and Enforcement

§ 160.300 Applicability.

This subpart applies to actions by the Secretary, covered entities, and others with respect to ascertaining the compliance by covered entities with and the enforcement of the applicable requirements of this part 160 and the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter.

§ 160.302 Definitions.

As used in this subpart, terms defined in § 164.501 of this subchapter have the same meanings given to them in that section.

§ 160.304 Principles for achieving compliance.

(a) *Cooperation*. The Secretary will, to the extent practicable, seek the cooperation of covered entities in obtaining compliance with the applicable requirements of this part 160 and the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter.

(b) *Assistance*. The Secretary may provide technical assistance to covered entities to help them comply voluntarily with the applicable requirements of this part 160 or the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter.

§ 160.306 Complaints to the Secretary.

(a) *Right to file a complaint*. A person who believes a covered entity is not complying with the applicable requirements of this part 160 or the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter may file a complaint with the Secretary.

(b) *Requirements for filing complaints*. Complaints under this section must meet the following requirements:

(1) A complaint must be filed in writing, either on paper or electronically.

(2) A complaint must name the entity that is the subject of the complaint and describe the acts or omissions believed to be in violation of the applicable requirements of this part 160 or the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter.

(3) A complaint must be filed within 180 days of when the complainant knew or should have known that the act or omission complained of occurred, unless this time limit is waived by the Secretary for good cause shown.

(4) The Secretary may prescribe additional procedures for the filing of complaints, as well as the place and manner of filing, by notice in the **Federal Register**.

(c) *Investigation*. The Secretary may investigate complaints filed under this section. Such investigation may include a review of the pertinent policies, procedures, or practices of the covered entity and of the circumstances regarding any alleged acts or omissions concerning compliance.

§ 160.308 Compliance reviews.

The Secretary may conduct compliance reviews to determine whether covered entities are complying with the applicable requirements of this part 160 and the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter.

§ 160.310 Responsibilities of covered entities.

(a) *Provide records and compliance reports*. A covered entity must keep such records and submit such compliance reports, in such time and manner and containing such information, as the Secretary may determine to be necessary to enable the Secretary to ascertain whether the covered entity has complied or is complying with the applicable requirements of this part 160 and the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter.

(b) *Cooperate with complaint investigations and compliance reviews*. A covered entity must cooperate with the Secretary, if the Secretary undertakes an investigation or compliance review of the policies, procedures, or practices of a covered entity to determine whether it is complying with the applicable requirements of this part 160 and the standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter.

(c) *Permit access to information*. (1) A covered entity must permit access by the Secretary during normal business hours to its facilities, books, records, accounts, and other sources of information, including protected health information, that are pertinent to ascertaining compliance with the applicable requirements of this part 160 and the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter. If the Secretary determines that exigent circumstances exist, such as when documents may be hidden or destroyed, a covered entity

must permit access by the Secretary at any time and without notice.

(2) If any information required of a covered entity under this section is in the exclusive possession of any other agency, institution, or person and the other agency, institution, or person fails or refuses to furnish the information, the covered entity must so certify and set forth what efforts it has made to obtain the information.

(3) Protected health information obtained by the Secretary in connection with an investigation or compliance review under this subpart will not be disclosed by the Secretary, except if necessary for ascertaining or enforcing compliance with the applicable requirements of this part 160 and the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter, or if otherwise required by law.

§ 160.312 Secretarial action regarding complaints and compliance reviews.

(a) *Resolution where noncompliance is indicated*. (1) If an investigation pursuant to § 160.306 or a compliance review pursuant to § 160.308 indicates a failure to comply, the Secretary will so inform the covered entity and, if the matter arose from a complaint, the complainant, in writing and attempt to resolve the matter by informal means whenever possible.

(2) If the Secretary finds the covered entity is not in compliance and determines that the matter cannot be resolved by informal means, the Secretary may issue to the covered entity and, if the matter arose from a complaint, to the complainant written findings documenting the non-compliance.

(b) *Resolution when no violation is found*. If, after an investigation or compliance review, the Secretary determines that further action is not warranted, the Secretary will so inform the covered entity and, if the matter arose from a complaint, the complainant in writing.

2. A new Part 164 is added to read as follows:

PART 164—SECURITY AND PRIVACY

Subpart A—General Provisions

Sec.

- 164.102 Statutory basis.
- 164.104 Applicability.
- 164.106 Relationship to other parts.

Subparts B–D—[Reserved]

Subpart E—Privacy of Individually Identifiable Health Information

- 164.500 Applicability.
- 164.501 Definitions.

164.502 Uses and disclosures of protected health information: General rules.

164.504 Uses and disclosures: Organizational requirements.

164.506 Consent for uses or disclosures to carry out treatment, payment, and health care operations.

164.508 Uses and disclosures for which an authorization is required.

164.510 Uses and disclosures requiring an opportunity for the individual to agree or to object.

164.512 Uses and disclosures for which consent, an authorization, or opportunity to agree or object is not required.

164.514 Other requirements relating to uses and disclosures of protected health information.

164.520 Notice of privacy practices for protected health information.

164.522 Rights to request privacy protection for protected health information.

164.524 Access of individuals to protected health information.

164.526 Amendment of protected health information.

164.528 Accounting of disclosures of protected health information.

164.530 Administrative requirements.

164.532 Transition requirements.

164.534 Compliance dates for initial implementation of the privacy standards.

Authority: 42 U.S.C. 1320d–2 and 1320d–4, sec. 264 of Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320(d–2)(note)).

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.

§ 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.

Subpart B–D—[Reserved]

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 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;

(iv) Section 164.504 relating to the organizational requirements for covered entities, including the designation of health care components of a covered entity;

(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;

(vi) Section 164.532 relating to transition requirements; and

(vii) Section 164.534 relating to compliance dates for initial implementation of the privacy standards.

(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.

(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.

§ 164.501 Definitions.

As used in this subpart, the following terms have the following meanings:

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. *Other persons* held in lawful custody 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.

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.

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.

Designated record set means:

(1) A group of records maintained by or for a covered entity that is:

(i) The medical records and billing records about individuals maintained by or for a covered health care provider;

(ii) The enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or

(iii) Used, in whole or in part, by or for the covered entity to make decisions about individuals.

(2) For purposes of this paragraph, the term record 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.

Direct treatment relationship means a treatment relationship between an individual and a health care provider that is not an indirect treatment relationship.

Disclosure means the release, transfer, provision of access to, or divulging in any other manner of information outside the entity holding the information.

Health care operations 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:

(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;

(2) Reviewing the competence or qualifications of health care 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;

(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;

(4) Conducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs;

(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

(6) Business management and general administrative activities of the entity, including, but not limited to:

(i) Management activities relating to implementation of and compliance with the requirements of this subchapter;

(ii) Customer service, including the provision of data analyses for policy holders, plan sponsors, or other customers, provided that protected health information is not disclosed to such policy holder, plan sponsor, or customer.

(iii) Resolution of internal grievances;

(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

(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).

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.

Indirect treatment relationship means a relationship between an individual and a health care provider in which:

(1) The health care provider delivers health care to the individual based on the orders of another health care provider; and

(2) The health care provider typically provides services or products, or reports the diagnosis or results associated with the health care, directly to another health care provider, who provides the services or products or reports to the individual.

Individual means the person who is the subject of protected health information.

Individually identifiable health information is information that is a subset of health information, including demographic information collected from an individual, and:

(1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

(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

(i) That identifies the individual; or
(ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

Inmate means a person incarcerated in or otherwise confined to a correctional institution.

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:

(1) Investigate or conduct an official inquiry into a potential violation of law; or

(2) Prosecute or otherwise conduct a criminal, civil, or administrative proceeding arising from an alleged violation of law.

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.

(1) *Marketing* does not include communications that meet the requirements of paragraph (2) of this definition and that are made by a covered entity:

(i) For the purpose of describing the entities participating in a health care provider network or health plan network, or for the purpose of describing if and the extent to which a product or service (or payment for such product or service) is provided by a covered entity or included in a plan of benefits; or

(ii) That are tailored to the circumstances of a particular individual and the communications are:

(A) Made by a health care provider to an individual as part of the treatment of the individual, and for the purpose of furthering the treatment of that individual; or

(B) Made by a health care provider or health plan to an individual in the course of managing the treatment of that individual, or for the purpose of directing or recommending to that individual alternative treatments, therapies, health care providers, or settings of care.

(2) A communication described in paragraph (1) of this definition is not included in marketing if:

(i) The communication is made orally; or

(ii) The communication is in writing and the covered entity does not receive direct or indirect remuneration from a third party for making the communication.

Organized health care arrangement means:

(1) A clinically integrated care setting in which individuals typically receive health care from more than one health care provider;

(2) An organized system of health care in which more than one covered entity participates, and in which the participating covered entities:

(i) Hold themselves out to the public as participating in a joint arrangement; and

(ii) Participate in joint activities that include at least one of the following:

(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;

(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

(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.

(3) A group health plan and a health insurance issuer or HMO with respect to such group health plan, but only with respect to 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;

(4) A group health plan and one or more other group health plans each of which are maintained by the same plan sponsor; or

(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.

Payment means:

(1) The activities undertaken by:

(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

(ii) A covered health care provider or health plan to obtain or provide reimbursement for the provision of health care; and

(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:

(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;

(ii) Risk adjusting amounts due based on enrollee health status and demographic characteristics;

(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;

(iv) Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges;

(v) Utilization review activities, including precertification and preauthorization of services, concurrent and retrospective review of services; and

(vi) Disclosure to consumer reporting agencies of any of the following protected health information relating to collection of premiums or reimbursement:

(A) Name and address;

(B) Date of birth;

(C) Social security number;

(D) Payment history;

(E) Account number; and

(F) Name and address of the health care provider and/or health plan.

Plan sponsor is defined as defined at section 3(16)(B) of ERISA, 29 U.S.C. 1002(16)(B).

Protected health information means individually identifiable health information:

(1) Except as provided in paragraph (2) of this definition, that is:

(i) Transmitted by electronic media;

(ii) Maintained in any medium

described in the definition of *electronic media* at § 162.103 of this subchapter; or

(iii) Transmitted or maintained in any other form or medium.

(2) *Protected health information* excludes individually identifiable health information in:

(i) Education records covered by the Family Educational Right and Privacy Act, as amended, 20 U.S.C. 1232g; and

(ii) Records described at 20 U.S.C. 1232g(a)(4)(B)(iv).

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 individual's medical record.

Psychotherapy notes 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.

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.

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. *Required by law* 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.

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Treatment 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.

Use 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.

§ 164.502 Uses and disclosures of protected health information: general rules.

(a) *Standard*. 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.

(1) *Permitted uses and disclosures*. A covered entity is permitted to use or disclose protected health information as follows:

(i) To the individual;

(ii) Pursuant to and in compliance with a consent that complies with § 164.506, to carry out treatment, payment, or health care operations;

(iii) Without consent, if consent is not required under § 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;

(iv) Pursuant to and in compliance with a valid authorization under § 164.508;

(v) Pursuant to an agreement under, or as otherwise permitted by, § 164.510; and

(vi) As permitted by and in compliance with this section, § 164.512, or § 164.514(e), (f), and (g).

(2) *Required disclosures*. A covered entity is required to disclose protected health information:

(i) To an individual, when requested under, and required by § 164.524 or § 164.528; and

(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.

(b) *Standard: Minimum necessary*. (1) *Minimum necessary applies*. 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.

(2) *Minimum necessary does not apply*. This requirement does not apply to:

(i) Disclosures to or requests by a health care provider for treatment;

(ii) Uses or disclosures made to the individual, as permitted under paragraph (a)(1)(i) of this section, as required by paragraph (a)(2)(i) of this section, or pursuant to an authorization under § 164.508, except for authorizations requested by the covered entity under § 164.508(d), (e), or (f);

(iii) Disclosures made to the Secretary in accordance with subpart C of part 160 of this subchapter;

(iv) Uses or disclosures that are required by law, as described by § 164.512(a); and

(v) Uses or disclosures that are required for compliance with applicable requirements of this subchapter.

(c) *Standard: Uses and disclosures of protected health information subject to an agreed upon restriction.* A covered entity that has agreed to a restriction pursuant to § 164.522(a)(1) may not use or disclose the protected health information covered by the restriction in violation of such restriction, except as otherwise provided in § 164.522(a).

(d) *Standard: Uses and disclosures of de-identified protected health information.*

(1) *Uses and disclosures to create de-identified information.* A covered entity may use protected health information to create 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.

(2) *Uses and disclosures of de-identified information.* 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:

(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

(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.

(e)(1) *Standard: Disclosures to business associates.* (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.

(ii) This standard does not apply:

(A) With respect to disclosures by a covered entity to a health care provider concerning the treatment of the individual;

(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

(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.

(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).

(2) *Implementation specification: documentation.* A covered entity must document the satisfactory assurances required by paragraph (e)(1) of this section through a written contract or other written agreement or arrangement with the business associate that meets the applicable requirements of § 164.504(e).

(f) *Standard: Deceased individuals.* A covered entity must comply with the requirements of this subpart with respect to the protected health information of a deceased individual.

(g)(1) *Standard: Personal representatives.* 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.

(2) *Implementation specification: adults and emancipated minors.* 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.

(3) *Implementation specification: unemancipated minors.* If under applicable law a parent, guardian, or other person acting *in loco parentis* 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:

(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;

(ii) The minor may lawfully obtain such health care service without the consent of a parent, guardian, or other person acting *in loco parentis*, and the minor, a court, or another person authorized by law consents to such health care service; or

(iii) A parent, guardian, or other person acting *in loco parentis* assents to an agreement of confidentiality between a covered health care provider and the minor with respect to such health care service.

(4) *Implementation specification: Deceased individuals.* 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.

(5) *Implementation specification: Abuse, neglect, endangerment situations.* 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:

(i) The covered entity has a reasonable belief that:

(A) The individual has been or may be subjected to domestic violence, abuse, or neglect by such person; or

(B) Treating such person as the personal representative could endanger the individual; and

(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.

(h) *Standard: Confidential communications.* A covered health care provider or health plan must comply with the applicable requirements of § 164.522(b) in communicating protected health information.

(i) *Standard: Uses and disclosures consistent with notice.* 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.

(j) *Standard: Disclosures by whistleblowers and workforce member crime victims.*

(1) *Disclosures by whistleblowers.* 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:

(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

(ii) The disclosure is to:

(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

(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.

(2) *Disclosures by workforce members who are victims of a crime.* A covered entity is not considered to have violated the requirements of this subpart if a member of its workforce who is the victim of a criminal act discloses protected health information to a law enforcement official, provided that:

(i) The protected health information disclosed is about the suspected perpetrator of the criminal act; and

(ii) The protected health information disclosed is limited to the information listed in § 164.512(f)(2)(i).

§ 164.504 Uses and disclosures: Organizational requirements.

(a) *Definitions.* As used in this section:

Common control exists if an entity has the power, directly or indirectly, significantly to influence or direct the actions or policies of another entity.

Common ownership exists if an entity or entities possess an ownership or equity interest of 5 percent or more in another entity.

Health care component has the following meaning:

(1) Components of a covered entity that perform covered functions are part of the health care component.

(2) Another component of the covered entity is part of the entity's health care component to the extent that:

(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

(ii) The activities involve the use or disclosure of protected health information that such other component creates or receives from or on behalf of the component that performs covered functions.

Hybrid entity means a single legal entity that is a covered entity and whose covered functions are not its primary functions.

Plan administration functions 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.

Summary health information means information, that may be individually identifiable health information, and:

(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

(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.

(b) *Standard: Health care component.* 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.

(c)(1) *Implementation specification: Application of other provisions.* In applying a provision of this subpart, other than this section, to a hybrid entity:

(i) A reference in such provision to a "covered entity" refers to a health care component of the covered entity;

(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

(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.

(2) *Implementation specifications: Safeguard requirements.* 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:

(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;

(ii) A component that is described by paragraph (2)(i) of the definition of *health care component* 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 those described by paragraph (2)(i) of such definition in a way prohibited by this subpart; and

(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.

(3) *Implementation specifications: Responsibilities of the covered entity.* A covered entity that is a hybrid entity has the following responsibilities:

(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.

(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.

(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).

(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.

(2) *Implementation specifications: Requirements for designation of an affiliated covered entity.* (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.

(ii) The designation of an affiliated covered entity must be documented and the documentation maintained as required by § 164.530(j).

(3) *Implementation specifications: Safeguard requirements.* An affiliated covered entity must ensure that:

(i) The affiliated covered entity's use and disclosure of protected health information comply with the applicable requirements of this subpart; and

(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.

(e)(1) *Standard: Business associate contracts.* (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.

(ii) A covered entity is not in compliance with the standards in § 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:

(A) Terminated the contract or arrangement, if feasible; or

(B) If termination is not feasible, reported the problem to the Secretary.

(2) *Implementation specifications: Business associate contracts.* A contract between the covered entity and a business associate must:

(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:

(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

(B) The contract may permit the business associate to provide data aggregation services relating to the health care operations of the covered entity.

(ii) Provide that the business associate will:

(A) Not use or further disclose the information other than as permitted or required by the contract or as required by law;

(B) Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by its contract;

(C) Report to the covered entity any use or disclosure of the information not provided for by its contract of which it becomes aware;

(D) Ensure that any agents, including a subcontractor, to whom it provides protected health information received from, or created or received by the business associate on behalf of, the covered entity agrees to the same restrictions and conditions that apply to the business associate with respect to such information;

(E) Make available protected health information in accordance with § 164.524;

(F) Make available protected health information for amendment and incorporate any amendments to protected health information in accordance with § 164.526;

(G) Make available the information required to provide an accounting of disclosures in accordance with § 164.528;

(H) Make its internal practices, books, and records relating to the use and disclosure of protected health information received from, or created or received by the business associate on behalf of, the covered entity available to the Secretary for purposes of determining the covered entity's compliance with this subpart; and

(I) At termination of the contract, if feasible, return or destroy all protected health information received from, or created or received by the business associate on behalf of, the covered entity that the business associate still maintains in any form and retain no copies of such information or, if such return or destruction is not feasible, extend the protections of the information and limit further uses and disclosures to those purposes that make the return or destruction of the information infeasible.

(iii) Authorize termination of the contract by the covered entity, if the covered entity determines that the business associate has violated a material term of the contract.

(3) *Implementation specifications: Other arrangements.* (i) If a covered entity and its business associate are both governmental entities:

(A) The covered entity may comply with paragraph (e) of this section by entering into a memorandum of understanding with the business associate that contains terms that accomplish the objectives of paragraph (e)(2) of this section.

(B) The covered entity may comply with paragraph (e) of this section, if other law (including regulations adopted by the covered entity or its business associate) contains requirements applicable to the business associate that accomplish the objectives of paragraph (e)(2) of this section.

(ii) If a business associate is required by law to perform a function or activity on behalf of a covered entity or to provide a service described in the definition of *business associate* in § 160.103 of this subchapter to a covered entity, such covered entity may disclose protected health information to the business associate to the extent necessary to comply with the legal mandate without meeting the requirements of this paragraph (e), provided that the covered entity attempts in good faith to obtain satisfactory assurances as required by paragraph (e)(3)(i) of this section, and, if such attempt fails, documents the attempt and the reasons that such assurances cannot be obtained.

(iii) The covered entity may omit from its other arrangements the termination authorization required by paragraph (e)(2)(iii) of this section, if such authorization is inconsistent with the statutory obligations of the covered entity or its business associate.

(4) *Implementation specifications: Other requirements for contracts and other arrangements.* (i) The contract or other arrangement between the covered entity and the business associate may

permit the business associate to use the information received by the business associate in its capacity as a business associate to the covered entity, if necessary:

(A) For the proper management and administration of the business associate; or

(B) To carry out the legal responsibilities of the business associate.

(ii) The contract or other arrangement between the covered 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:

(A) The disclosure is required by law; or

(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.

(f)(1) *Standard: Requirements for group health plans.* (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.

(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:

(A) Obtaining premium bids from health plans for providing health insurance coverage under the group health plan; or

(B) Modifying, amending, or terminating the group health plan.

(2) *Implementation specifications: Requirements for plan documents.* The plan documents of the group health plan must be amended to incorporate provisions to:

(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.

(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:

(A) Not use or further disclose the information other than as permitted or required by the plan documents or as required by law;

(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;

(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;

(D) Report to the group health plan any use or disclosure of the information that is inconsistent with the uses or disclosures provided for of which it becomes aware;

(E) Make available protected health information in accordance with § 164.524;

(F) Make available protected health information for amendment and incorporate any amendments to protected health information in accordance with § 164.526;

(G) Make available the information required to provide an accounting of disclosures in accordance with § 164.528;

(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;

(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

(J) Ensure that the adequate separation required in paragraph (f)(2)(iii) of this section is established.

(iii) Provide for adequate separation between the group health plan and the

plan sponsor. The plan documents must:

(A) Describe those employees or classes of employees or other persons under the control of the plan sponsor to be given access 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;

(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

(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.

(3) *Implementation specifications: Uses and disclosures.* A group health plan may:

(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;

(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;

(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 appropriate notice; and

(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.

(g) *Standard: Requirements for a covered entity with multiple covered functions.*

(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.

(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.

§ 164.506 Consent for uses or disclosures to carry out treatment, payment, or health care operations.

(a) *Standard: Consent requirement.* (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.

(2) A covered health care provider may, without consent, use or disclose protected health information to carry out treatment, payment, or health care operations, if:

(i) The covered health care provider has an indirect treatment relationship with the individual; or

(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.

(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:

(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;

(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

(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.

(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 consent was not obtained.

(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.

(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.

(b) *Implementation specifications: General requirements.* (1) A covered health care provider may condition treatment on the provision by the individual of a consent under this section.

(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.

(3) A consent under this section may not be combined in a single document with the notice required by § 164.520.

(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:

(A) Is visually and organizationally separate from such other written legal permission; and

(B) Is separately signed by the individual and dated.

(ii) A consent for use or disclosure may be combined with a research authorization under § 164.508(f).

(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.

(6) A covered entity must document and retain any signed consent under this section as required by § 164.530(j).

(c) *Implementation specifications: Content requirements.* A consent under this section must be in plain language and:

(1) Inform the individual that protected health information may be used and disclosed to carry out treatment, payment, or health care operations;

(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;

(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;

(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 operations;

(ii) The covered entity is not required to agree to requested restrictions; and

(iii) If the covered entity agrees to a requested restriction, the restriction is binding on the covered entity;

(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

(6) Be signed by the individual and dated.

(d) *Implementation specifications: Defective consents.* There is no consent under this section, if the document submitted has any of the following defects:

(1) The consent lacks an element required by paragraph (c) of this section, as applicable; or

(2) The consent has been revoked in accordance with paragraph (b)(5) of this section.

(e) *Standard: Resolving conflicting consents and authorizations.* (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.

(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:

(i) Obtaining a new consent from the individual under this section for the disclosure to carry out treatment, payment, or health care operations; or

(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.