DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Assistant Secretary
Administration on Aging

Washington D.C. 20201

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INFORMATION MEMORANDUM
AOA-IM-03-01
February 4, 2003

TO	:	STATE AND AREA AGENCIES ON AGING ADMINISTERING PLANS UNDER TITLES III AND VII OF THE OLDER AMERICANS ACT OF 1965, AS AMENDED; OFFICES OF STATE LONG-TERM CARE OMBUDSMEN
SUBJECT	:	Ombudsman Access to Residents' Records and Other Information; the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule and its Effect on Access to Residents' Records by the Long-Term Care Ombudsman Program, Residents and Residents' Representatives
LEGAL AND RELATED REFERENCES	:	Older Americans Act, as amended, 42 U.S.C 305 8a Title VII of the Act et seq.; Health Insurance Portability and Accountability Act (HIPAA) of 1996, Pub. L. No. 104-191 (codified in scattered sections of 42 U.S.C.); "Standards for Privacy of Individually Identifiable Health Information," (The Privacy Rule) (45 CFR Parts 160 and 164)

In recent months, questions have been raised about the effect of the recently issued "Standards for Privacy of Individually Identifiable Health Information" (Privacy Rule), implementing provisions of the Health Insurance Portability and Accountability Act (HIPAA) on access to residents' records and other information by representatives of the Long-Term Care Ombudsman Program (LTCOP), residents of long-term care facilities and residents' representatives.

This memorandum:

1. Reviews the Older Americans Act (OAA) requirements regarding ombudsman access to residents' records and other information, and the Nursing Home Reform Act (the Omnibus Budget and Reconciliation Act of 1987 – OBRA '87) ombudsman access requirements;

2. Explains that the Privacy Rule does not negate those requirements; and

3. Provides additional information for state and area agencies on aging and ombudsmen about the Privacy Rule.

The memorandum addresses the following specific topics:

- Summary of Privacy Rule implications for ombudsman work and state agency on aging responsibilities;
- OAA requirements regarding ombudsman access to residents' records and other information;
- The ombudsman access to records requirement in the Nursing Home Reform Act of 1987, which governs nursing homes participating in Medicare and Medicaid;
- Background on HIPAA and the Privacy Rule;
- The Privacy Rule requirements; the LTCOP is a "Health Oversight Agency"
- How these statutory and regulatory requirements affect the work of long-term care ombudsmen; and
- How the Privacy Rule affects residents' and their representatives' access to residents' individual clinical files.

Summary of Implications of the Privacy Rule for Ombudsman Work State Agency on Aging Responsibility

Under the Privacy Rule, the LTCOP is a "health oversight agency." Therefore, the Privacy Rule does not preclude release of residents' clinical records to the LTCOP, with or without authorization of the resident or resident's legal representative. Also, since the LTCOP is a "health oversight agency," nursing homes and other "covered entities" may, in response to appropriate ombudsman inquiries, share other information without fear of violating the Privacy Rule.

State agencies on aging are required under the OAA to ensure appropriate ombudsman access to residents' records.

Nursing homes which participate in Medicare and Medicaid are required to provide ombudsmen access to residents' records with the permission of the resident or the resident's legal representative, consistent with state law.

To ensure that all facilities covered by the program, including nursing homes which do not participate in Medicare and Medicaid and board and care, assisted living and similar facilities, provide access to records under all the circumstances outlined in Section 712 (b) of the OAA (see below), state agencies on aging must ensure that the state has in place a statutory, regulatory or policy requirement sufficient to ensure that the facilities provide such access.

The following sections review and explain the Federal access and privacy requirements and how they affect each other.

OAA Requirements of State Agencies on Aging Regarding Ombudsman Access to Residents' Records and Other Information

The OAA specifies requirements for ombudsman access to facilities, residents, residents' records and other information as follows:

Sec. 712 STATE LONG-TERM CARE OMBUDSMAN PROGRAM

(b) Procedures for Access.–

(1) In general.– The State shall ensure that representatives of the Office shall have--

(A) access to long-term care facilities and residents;

(B) (i) appropriate access to review the medical and social records of a resident, if–

(I) the representative has the permission of the resident, or the legal representative of the resident; or

(II) the resident is unable to consent to the review and has no legal representative; or

(ii) access to the records as is necessary to investigate a complaint if–

(I) a legal guardian of the resident refuses to give the permission;

(II) a representative of the Office has reasonable cause to believe that the guardian is not acting in the best interests of the resident; and

(III) the representative obtains the approval of the Ombudsman;

(C) access to the administrative records, policies, and documents, to which the residents have, or the general public has access, of long-term care facilities; and

(D) access to and, on request, copies of all licensing and certification records maintained by the State with respect to long-term care facilities.

(2) **Procedures.--The State agency shall establish procedures to ensure the access described in paragraph (1).** (emphasis added)

OBRA '87 Requirement Regarding Ombudsman Access to Residents' Records

The Nursing Home Reform Act of 1987 amended Sections 1819 (Medicare) and 1919 (Medicaid) of the Social Security Act by adding the following provision:

> (c)(3)(E) ACCESS AND VISITATION RIGHTS.- A nursing facility must - (E) permit representatives of the State ombudsman...with the permission of the resident (or the resident's legal representative) and consistent with State law, to examine a resident's clinical records.

Thus, nursing homes which participate in Medicare and Medicaid are required by Federal law to permit ombudsman representatives to examine a resident's clinical records with permission of the resident or the resident's legal representative, consistent with state law.

(Note that neither the Older Americans Act nor the Social Security Act, as amended by OBRA, requires that permission must be in writing; however, it is strongly recommended that when ombudsmen examine a resident's records, they document in the case file that they have obtained permission to do so, in accordance with these statutory requirements.)

Background on HIPAA and the Privacy Rule

Title I of HIPAA, which became effective on July 1, 1997, protects health insurance coverage for workers and their families when they change or lose their jobs. The Administrative Simplification provisions in Title II authorized the Secretary of the U.S. Department of Health and Human Services (DHHS) to promulgate standards for electronic health data transactions. The Secretary is also authorized to promulgate standards for the privacy of individually identifiable health information if Congress does not enact health care privacy legislation by August 21, 1999. HIPAA also requires the Secretary to provide Congress with recommendations for legislation to protect the confidentiality of health care information.

The Secretary submitted such recommendations to Congress on September 11, 1997, but Congress did not pass such legislation within its self-imposed deadline. DHHS published a proposed rule setting forth privacy standards for individually identifiable health information on November 3, 1999 (64 # FR 59918). After reviewing and considering the public comments, DHHS issued a final rule (65 FR 82462) on December 28, 2000, establishing "Standards for Privacy of Individually Identifiable Health Information ("Privacy Rule")," which became effective on April 14, 2001. DHHS issued final modifications to the Privacy Rule on August 14, 2002 (67 FR 53182), which became effective October 14, 2002.

The Privacy Rule applies only to "covered entities," which are defined as 'health plans, health care clearinghouses, and health care providers who conduct certain financial and administrative transactions electronically.' (Covered entities have until April 2003 to comply, although they may comply prior to that date.) In contrast, the Ombudsman Program applies to long-term care facilities but not to health plans, health care clearinghouses or health providers other than long-term care facilities.

The Privacy Rule standards apply to nursing homes but not to board and care, assisted living and similar facilities unless they are health care providers who transmit information electronically in connection with certain financial and administrative transactions. Regulations at 45 CFR 160.103 define "health care provider" as 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 care" is defined in the Rule to include "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) the sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription."

Privacy Rule Requirements
LTCOPs Are "Health Oversight Agencies"

The regulations permit covered entities to release individually identifiable health information only with the authorization of the individual to whom the information pertains, or to the individual's personal representative, with certain exceptions. Among the exceptions is release of information to "health oversight agencies." Covered entities may release individuals' records to such agencies without the authorization of the resident or his/her legal representative, to the extent permitted by law or regulation, subject to the Privacy Rule's minimum necessary requirements.

The Rule defines a "health oversight agency" as follows:

> 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. (Section 164.501)

Section 164.512 (d) of the Rule specifies:

> A covered entity may disclose protected health information to a health oversight agency for 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:
>
> - The health care system;
> - Government benefit programs for which health information is relevant to beneficiary eligibility;
> - Entities subject to government regulatory programs for which health information is necessary for determining compliance with program standards; or
> - Entities subject to civil rights laws for which health information is necessary for determining compliance.
>
> *Exception to health oversight activities* 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:

- The receipt of health care;
- A claim for public benefits related to health; or
- Qualification for, or receipt of, public benefits or services when a patient's health is integral to the claim for public benefits or services.

The DHHS Office for Civil Rights (OCR), the federal agency which administers the Privacy Rule, concurs with the Administration on Aging's (AoA) determination that since LTCOPs have oversight responsibilities authorized by law for a component of the health care system, they are health oversight agencies, as defined in the Privacy Rule (see Section 164.501, cited above).

This determination hinges on LTCOPs being governmental agencies (e.g., state, territory or tribal entities) or entities "acting under a grant of authority from or contract with such public agency." This means that under HIPAA, the designated State Long-Term Care Ombudsman and ombudsman entities and representatives who are designated as part of the Office of the State Long-Term Care Ombudsman, in accordance with Section 712 (a) (1),(2) and (5) of the OAA, have the same right to access to residents' health records and other appropriate information as any other health oversight agency, including agencies that provide oversight of government programs in which health information is necessary to determine eligibility or compliance.

The following Privacy Rule provisions are also relevant to the LTCOP:

- "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." (Section 164.502(b)(1))

- A covered entity may make disclosures required by other laws. (Section 164.512 (a))

- 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: [m]aking disclosures to public officials that are permitted under [the health oversight provisions in] § 164.512, if the public official represents that the information requested is the minimum necessary for the stated purpose(s)." (Section 164.514(d)(3)(iii))

- A covered entity may disclose protected health information about victims of adult abuse or neglect or domestic violence. The preamble to the Privacy Rule, at 65 Fed. Reg. 82527, discusses disclosures under this provision to authorized government agencies and gives the example of "ombudsmen for the aging or those in long-term care facilities." The circumstances specified in the regulations are:

  - If disclosure is required by law and the disclosure complies with and is limited to the relevant requirements of such law,
  - If the victim of abuse agrees to disclosure, or
  - Without the individual's agreement if the disclosure is expressly authorized by

statute or regulation and either: (1) The covered entity, in the exercise of its professional judgment, believes that the disclosure is necessary to prevent serious harm to the individual or to other potential victims; or (2) if the individual is unable to agree due to incapacity, a law enforcement or other public official authorized to received 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 on the disclosure would be materially and adversely affected by waiting until the individual is able to agree to the disclosure. (Section 164.512(c))

See the attachment for the full text of these sections of the Privacy Rule.

Implications of the OAA, OBRA and HIPAA Privacy Rule Requirements for LTCOP Work

1. If an ombudsman program representative has the permission of the resident or the resident's legal representative, the facility is required, under the Federal conditions of participation for Medicare and Medicaid, to provide the ombudsman with access to the resident's clinical records, consistent with state law.

2. The LTCOP is a "health oversight agency" under the Privacy Rule. Nursing homes and other facilities which are "covered entities" under the Privacy Rule are permitted to release residents' records to health oversight agencies without the authorization of the resident or his or her representative, subject to the Privacy Rule's minimum necessary requirements.

3. Since the LTCOP is a "health oversight agency," nursing homes and other "covered entities" may, in response to appropriate ombudsman inquiries, share other information without fear of violating the Privacy Rule.

4. The OAA requires state agencies on aging to ensure that ombudsman program representatives have appropriate access to review residents' medical and social records, if:

   - the representative has the permission of the resident or the resident's legal representative, or
   - the resident is unable to give consent and has no legal representative, or
   - access is necessary to investigate a complaint, the resident's legal guardian refuses permission and the ombudsman representative has reasonable cause to believe that the guardian is not acting in the best interests of the resident and the representative obtains the approval of the State Ombudsman.

5. If, as required by the OAA, a state has ensured ombudsman access to residents' clinical records and other information through a state law, regulation or policy binding on long-term care facilities, the facility must permit ombudsman access to residents' records and other information, in accordance with the state requirements. The Privacy Rule does not affect that requirement.

HIPAA Impact on Residents' and Their Representatives' Access to Residents' Individual Clinical Files

The Privacy Rule offers the following rights to residents and their personal representatives regarding their protected health information:

The right to

- Inspect and obtain a copy of their health information; provider may charge reasonable fees for copying, postage, and preparation of a summary or explanation.
- Ask that corrections be made to their protected health information – if their request is denied, the entity must notify the resident with an explanation and must include the request, denial and additional information in the record.
- Receive written notice of privacy practices.
- Request restrictions on disclosure to particular entities and use of information.
- Accommodation of a reasonable request for alternative communication – e.g., request to use alternate mailing address.
- Receive an accounting of certain disclosures.
- File a written complaint to the Secretary of HHS or the entity without retaliation.

Resident's Representative's Access to Resident's Records

The Privacy Rule does not use the term "legal representative" (as in the OAA), but rather refers to "personal representative." Section 164.502(g) provides that a covered entity must treat a person as a personal representative 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." The information that may be disclosed is "with respect to protected health information relevant to such personal representation." See the attachment for this provision of the Privacy Rule.

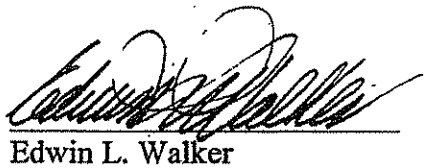
If a family member lacks the authority quoted above, the covered entity may provide access pursuant to an authorization that meets the requirements of Section 164.508 or the transition provisions at Section 164.532(b). An authorization under 164.508 may permit access to a resident's file and may be worded to terminate upon the discharge of the patient from the facility. In addition, family members who are involved in a resident's care or payment may have access to information necessary for these purposes under 164.510(b), subject to the minimum necessary provisions in the Rule. See the attachment for these provisions of the Privacy Rule.

For additional information, please contact AoA Ombudsman Program Specialist Sue Wheaton at 202-357-3587; e-mail sue.wheaton@aoa.com

EFFECTIVE DATE: Immediately

INQUIRIES TO: State agencies should address inquiries to Regional Administrators on Aging, DHHS regional offices.

ATTACHMENT: Selected provisions of the Privacy Rule



Edwin L. Walker
Deputy Assistant Secretary for Policy and Programs

Selected Provisions of the Privacy Rule

Section 164.502(g), Personal Representative

(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.... (doesn't pertain)
(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.

Section 164.508, Authorization Requirements

Uses and disclosures for which an authorization is required.
(a) Standard: Authorizations for uses and disclosures.
(1) Authorization required: General rule. 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.
Documentation required for authorization is specified in Section 164.508 (c):
(1)....A valid authorization under this section must contain at least the following elements:

(i) A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion;
(ii) The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure;
(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;
(iv) An expiration date or an expiration event that relates to the individual or the purpose

of the use or disclosure;
(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;
(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;
(vii) Signature of the individual and date; and
(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.
(2) Plain language requirement. The authorization must be written in plain language.

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

A covered entity may use or disclose protected health information without the written consent or authorization of the individual as described by Secs. 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.
(a) Standard: use and disclosure for facility directories.
(1) Permitted uses and disclosure. Except when an objection is expressed in accordance with paragraphs (a)(2) or (3) of this section, a covered health care provider may:
(i) Use the following protected health information to maintain a directory of individuals in its facility: (A) The individual's name; (B) The individual's location in the covered health care provider's facility; (C) The individual's condition described in general terms that does not communicate specific medical information about the individual; and (D) The individual's religious affiliation; and
(ii) Disclose for directory purposes such information: (A) To members of the clergy; or [[Page 82813]] (B) Except for religious affiliation, to other persons who ask for the individual by name.
(2) Opportunity to object. 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.
(3) Emergency circumstances. (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: (A) Consistent with a prior expressed preference of the individual, if any, that is known to the covered health care provider; and (B) In the individual's best interest as determined by the covered health care provider, in the exercise of professional judgment. (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 section when it becomes practicable to do so.

(b) Standard: uses and disclosures for involvement in the individual's care and notification purposes.

(1) Permitted uses and disclosures.

(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.

(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.

(2) Uses and disclosures with the individual present. 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:

(i) Obtains the individual's agreement;

(ii) Provides the individual with the opportunity to object to the disclosure, and the individual does not express an objection; or

(iii) Reasonably infers from the circumstances, based the exercise of professional judgment, that the individual does not object to the disclosure.

(3) Limited uses and disclosures when the individual is not present. 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.

(4) Use and disclosures for disaster relief purposes. 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 the ability to respond to the emergency circumstances.

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

A covered entity may use or disclose protected health information without the written consent or authorization of the individual as described in Secs. 164.506 and 164.508, respectively, or the

opportunity for the individual to agree or object as described in Sec. 164.510, in the situations covered by this section, subject to the applicable requirements of this section. When the covered entity is required by this section to inform the individual of, or when the individual may agree to, a use or disclosure permitted by this section, the covered entity's information and the individual's agreement may be given orally.

(a) Standard: Uses and disclosures required by law.

(1) A covered entity may use or disclose protected health information to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.

(2) A covered entity must meet the requirements described in paragraph (c), (e), or (f) of this section for uses or disclosures required by law.

(b) Standard: uses and disclosures for public health activities....

(c) Standard: Disclosures about victims of abuse, neglect or domestic violence.

(1) Permitted disclosures. 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:

(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;

(ii) If the individual agrees to the disclosure; or

(iii) To the extent the disclosure is expressly authorized by statute or regulation and:

(A) The covered entity, in the exercise of professional judgment, believes the disclosure is necessary to prevent serious harm to the individual or other potential victims; or

(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.

(2) Informing the individual. 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:

(i) The covered entity, in the exercise of professional judgment, believes informing the individual would place the individual at risk of serious harm; or

(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.

(d) Standard: Uses and disclosures for health oversight activities.

(1) Permitted disclosures. A covered entity may disclose protected health information to a health oversight agency for 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:

(i) The health care system;

(ii) Government benefit programs for which health information is relevant to beneficiary eligibility;
(iii) Entities subject to government regulatory programs for which health information is necessary for determining compliance with program standards; or
(iv) Entities subject to civil rights laws for which health information is necessary for determining compliance.

(2) Exception to health oversight activities. 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:
(i) The receipt of health care;
(ii) A claim for public benefits related to health; or
(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.

(3) Joint activities or investigations. Notwithstanding paragraph (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.

(4) Permitted uses. 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.

(e) Standard: Disclosures for judicial and administrative proceedings.

(1) Permitted disclosures. A covered entity may disclose protected health information in the course of any judicial or administrative proceeding:
(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
(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:
(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
(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.
(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:
(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);

(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
(C) The time for the individual to raise objections to the court or administrative tribunal has elapsed, and:
(1) No objections were filed; or
(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.
(iv) For the purposes of paragraph (e)(1)(ii)(B) of this section, a covered entity receives satisfactory assurances from a party seeking protected health information, if the covered entity receives from such party a written statement and accompanying documentation demonstrating that:
(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
(B) The party seeking the protected health information has requested a qualified protective order from such court or administrative tribunal.
(v) For purposes of paragraph (e)(1) of this section, a qualified protective order 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:
(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
(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.
(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 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.

(2) Other uses and disclosures under this section. 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.

(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.

(1) Permitted disclosures: Pursuant to process and as otherwise required by law. A covered entity may disclose protected health information:

(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

(ii) In compliance with and as limited by the relevant requirements of:
(A) A court order or court-ordered warrant, or a subpoena or summons issued by a judicial officer;
(B) A grand jury subpoena; or
(C) An administrative request, including an administrative subpoena or summons, a civil or an authorized investigative demand, or similar process authorized under law, provided that:
(1) The information sought is relevant and material to a legitimate law enforcement inquiry;
(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
(3) De-identified information could not reasonably be used.

(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:
(i) The covered entity may disclose only the following information:
(A) Name and address; (B) Date and place of birth;(C) Social security number; (D) ABO blood type and rh factor; (E) Type of injury; (F) Date and time of treatment; (G) Date and time of death, if applicable; and (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.
(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.

(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:
(ii) The individual agrees to the disclosure; or
(iii) The covered entity is unable to obtain the individual's agreement because of incapacity or other emergency circumstance,provided that:
(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;
(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
(C) The disclosure is in the best interests of the individual as determined by the covered entity, in the exercise of professional judgment.

(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.
(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.
(6) Permitted disclosure: Reporting crime in emergencies.

(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: (A) The commission and nature of a crime; (B) The location of such crime or of the victim(s) of such crime; and (C) The identity, description, and location of the perpetrator of such crime.

(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.

(g) Standard: Uses and disclosures about decedents.
(1) Coroners and medical examiners. 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.
(2) Funeral directors. 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.
(h) Standard: Uses and disclosures for cadaveric organ, eye or tissue donation purposes. ...
(i) Standard: Uses and disclosures for research purposes....
(j) Standard: Uses and disclosures to avert a serious threat to health or safety....
(k) Standard: Uses and disclosures for specialized government functions....

Section 164.532, Transition Provisions

(a) Standard: Effect of prior consents and authorizations. 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 Secs. 164.506 or 164.508 of this subpart consistent with paragraph (b) of this section.
(b) Implementation specification: Requirements for retaining effectiveness of prior consents and authorizations. 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, 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 Secs. 164.506 or 164.508 of this subpart.
(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: (i) The covered entity does 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 (ii) The covered entity complies with all limitations placed by the consent, authorization, or other express legal permission obtained from an individual.
(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 permission obtained from an individual applies, make such use or disclosure, provided that: (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 (ii) The covered entity complies with all limitations placed by the consent, authorization, or other express legal permission obtained from an individual.
(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: (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. (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 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.
(4) If, after the applicable compliance date of this subpart, a covered entity agrees to a restriction requested by an individual under Sec. 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.