GENERAL STANDARDS AND GUIDELINES
DEFINTIONS

Authorization:

A customized document that gives a covered entity permission to use or disclose specified protected health information (PHI), for a purpose which is generally other than treatment, payment or health care operations (collectively, TPO).

Some general points regarding an authorization are:

- An authorization covers specific uses and disclosures of PHI, which must be identified in the authorization.
- An authorization has an expiration date (though there are exceptions with respect to research authorizations).
- An authorization specifies the purpose of each expected use and disclosure.

Business Associate:

Generally, a business associate is any person or entity who:

- On behalf of a covered entity, performs, or assists in the performance of, functions or activities involving the use or disclosure of individually identifiable health information (e.g., claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, billing, benefit management, practice management and re-pricing).
- To or for a covered entity, provides legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial services, where the service involves the disclosure of individually identifiable health information from a covered entity (or a third party) to the business associate.
- A member of a covered entity's workforce is not a business associate.

Other aspects of a "Business Associate" (BA) include the following:

- A covered entity may be a BA to another covered entity.
- The BA requirements of the Privacy Rule do not apply with respect to disclosures of PHI by a covered entity to a health care provider for treatment purposes.

Consent:

A general document that a covered entity may choose to obtain to permit it to use and disclose PHI for TPO. Such consent is optional, but may have significant value with respect to state law issues.

Correctional Institution:

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 Entity:

- A health care provider who transmits any health information in electronic form in connection with a transaction covered by the Privacy Rule.
- A health plan (e.g., a health insurer or group health plan).
- A health care clearinghouse (e.g., third-party billing center).

Covered Functions:

Those functions of a covered entity the performance of which makes the entity a health plan, health care provider, or health care clearinghouse.

Designated Record Set:

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

- The medical records and billing records about individuals maintained by or for a covered health care provider;
- The enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or
- Used, in whole or in part, by or for a covered entity to make decisions about individuals.

Note: "Records" include any item, collection, or grouping of information that includes PHI and is maintained, collected, used or disseminated by or for a covered entity.

Disclosure:

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

Health Care Operations:

Any of the following activities of the covered entity to the extent that the activities are related to covered functions:

(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) of the Privacy Rule (pertaining to underwriting and related purposes) 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 the Privacy Rule;

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

(iii) Resolution of internal grievances;

(iv) The sale, transfer, merger, or consolidation of all or part of the covered entity with another covered entity, or an entity that following such activity will become a covered entity and due diligence related to such activity; and

(v) Consistent with the applicable requirements of the Privacy Rule, creating de-identified health information or a limited data set, and fundraising for the benefit of the covered entity.

Indirect Treatment Relationship:

A relationship between an individual and a health care provider in which:

- The health care provider delivers health care to the individual based on the orders of another health care provider; and
- 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:

The person who is the subject of PHI.

Marketing:

(1) To make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service, **unless the communication is made**:

(i) To describe a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of the covered entity making the communication, including communications about: the entities participating in a health care provider network or health plan network; replacement of, or enhancements to, a health plan; and health-related products or services available only to a health plan enrollee that add value to, but are not part of, a plan of benefits;

(ii) For treatment of the individual; or

(iii) For case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual.

(2) An arrangement between a covered entity and any other entity whereby the covered entity discloses PHI to the other entity, in exchange for direct or indirect remuneration, for the other entity or its affiliate to make a communication about its own product or service that encourages recipients of the communication to purchase or use that product or service.

Minimum Necessary:

The minimum amount of PHI necessary to accomplish the intended purpose of a use, disclosure or request for PHI. Minimum necessary is based on the "need to know" principle

Organized Health Care Arrangement:

- A clinically-integrated care setting in which individuals typically receive health care from more than one health care provider;
- An organized system of health care in which more than one covered entity participates, and in which the participating covered entities hold themselves out to the public as participating in a joint arrangement, and they participate in joint activities that include at least one of the following:
    - 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;
    - 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
    - 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 PHI 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.
- A group health plan and a health insurance issuer or HMO with respect to such group health plan, but only with respect to PHI 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;
- A group health plan and one or more other group health plans each of which are maintained by the same plan sponsor; or
- The group health plans described in the above bullet and health insurance issuers or HMOs with respect to PHI 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:

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

(2) The activities in paragraph (1) above 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 PHI 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.

PHI:

Protected **H**ealth **I**nformation, means any information, whether oral or recorded and whether transmitted or maintained in any form or medium, that:

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

(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

(3) identifies the individual, or with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

PHI includes demographic information collected from an individual.

PHI does not include employment records held by a covered entity in its role as an employer, it also does not include certain student health records.

Psychotherapy Notes:

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 *exclude*:

- Medication prescription and monitoring;
- Counseling session start and stop times;
- Modalities and frequencies of treatment furnished;
- Results of clinical tests; and
- Summaries of diagnosis, functional status, treatment plans, symptoms, prognosis and progress to date.

Public Health Authority:

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.

TPO:

Treatment, **P**ayment or Health Care **O**perations

Treatment:

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:

The sharing, employment, application, utilization, examination, or analysis of individually identifiable health information within an entity that maintains such information.

Workforce:

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.