

The Health Insurance Portability and Accountability Act of 1996 (HIPAA)  
Covered Entities and Business Associates  
April, 2002

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Covered entities are subject to the requirements imposed by Title II, Administrative Simplification, and business associates are affected through their relationship with covered entities.

**A Covered Entity** is one or more of the following:

- a health plan
- a health care clearinghouse
- a health care provider who transmits any health information in electronic form in connection with a transaction specified in the HIPAA rules.

**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)). (See Appendix A for definition). A Health Plan **includes** the following, singly or in combination:

- A group health plan means a employee welfare benefit plan, as defined in the Employee Retirement Income Security Act of 1974 (ERISA), that provides medical care to 50 or more participants or is administered by an entity other than the employer that established and maintains the plan.
- A health insurance issuer;
- An Health Maintenance Organization (HMO);
- Part A or Part B of the Medicare program;
- The Medicaid program;
- An issuer of a Medicare supplemental policy (as defined in section 1882(g)(1) of the Act, 42 U.S.C. 1395ss(g)(1));
- An issuer of a long-term care policy, excluding a nursing home fixed- indemnity policy;
- 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.
- The health care program for active military personnel under title 10 of the United States Code.
- The veterans health care program under 38 U.S.C. chapter 17.
- The Civilian Health and Medical Program of the Uniformed Services;
- The Indian Health Service program under the Indian Health Care Improvement Act;
- The Federal Employees Health Benefits Program;

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- 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.;
- The Medicare + Choice program under Part C of title XVIII of the Act;
- A high risk pool that is a mechanism established under State law to provide health insurance coverage or comparable coverage to eligible individuals;
- 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)). (See Appendix A).

Health Plan **excludes** the following:

- Any policy, plan or program to the extent that it provides, or pays for the cost of, excepted benefits that are listed in section 27919(c)(1) of the PHS Act, 42 U.S.C.300gg-91(c)(1) (See Appendix A); and
- A government-funded program other than the one specifically listed as a health plan (1) whose principal purpose is other than providing, or paying for the cost of, health care; or (2) whose principal activity is the direct provision of health care to persons or the making of grants to fund the direct provision of health care to persons.
- An agency that “determines eligibility for or enrollment in a health plan that is a government program providing public benefits, when that agency is not the agency that administers the program”.
- Workers’ compensation programs.
- Nursing home fixed-indemnity policies.
- Correctional institutions.
- Disability insurance companies.
- Automobile insurance carriers.
- Property and casualty insurers.

**Health Care Clearinghouse** means a public or private entity including a billing service, repricing company, community health management information system, or community health management information system, and value-added networks and switches that performs either of the following functions:

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

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**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 other 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. (See Appendix B). Under HIPAA, a covered entity provider is a health care provider who transmits any health information in electronic form in connection with a transaction specified in the HIPAA rules.

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

- 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.

**Business Associate** may or may not be a covered entity.

Business Associate means with respect to a covered entity a person who on behalf of a covered entity or of an organized health care arrangement (as defined in 164.501 of the Privacy Rule) in which the covered entity participates, performs or assists the covered entity to perform a function of the covered entity, or who provides services listed in the rule such as legal, actuarial, administrative or consulting. Members of a covered entity's workforce are not considered business associates.

A covered entity must enter into a business associate agreements with all its business associates. The business associate agreement must contain specific provisions addressing the restrictions on the business associates use and disclosure of the health information transferred to it.

- 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.
- A covered entity is not compliant with HIPAA if it knew of a pattern of activity or practice by the business associate that constituted a material breach of the business associate agreement, and failed to take reasonable steps to end the violation (For example, contract termination or notification to DHHS of the problem).

## APPENDIX A

42 U.S.C. 300gg-91(a)(2)

**(2) Medical Care**

The term “medical care” means amounts paid for -

(A) the diagnosis, cure, mitigation, treatment, or prevention of disease, or amounts paid for the purpose of affecting any structure of function of the body,

(B) amounts paid for transportation primarily for and essential to medical care referred to in subparagraph (A), and

(C) amounts paid for insurance covering medical care referred to in subparagraphs (A) and (B).

## APPENDIX B

### Code Provisions Referred to in Definition of Provider

#### 42 U.S.C. 1395x Subsection (u) and (s)

##### (u) Provider of services

The term "provider of services" means a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, or, for purposes of section 1395f(g) and section 1395n(e) of this title, a fund.

##### (s) Medical and other health services

The term "medical and other health services" means any of the following items or services:

(1) physicians' services;

(2)

(A) services and supplies (including drugs and biologicals which cannot, as determined in accordance with regulations, be self-administered) furnished as an incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills;

(B) hospital services (including drugs and biologicals which cannot, as determined in accordance with regulations, be self-administered) incident to physicians' services rendered to outpatients and partial hospitalization services incident to such services;

(C) diagnostic services which are -

(i) furnished to an individual as an outpatient by a hospital or by others under arrangements with them made by a hospital, and

(ii) ordinarily furnished by such hospital (or by others under such arrangements) to its outpatients for the purpose of diagnostic study;

(D) outpatient physical therapy services and outpatient occupational therapy services;

(E) rural health clinic services and Federally qualified health center services;

(F) home dialysis supplies and equipment, self-care home dialysis support services, and institutional dialysis services and supplies;

(G) antigens (subject to quantity limitations prescribed in regulations by the Secretary) prepared by a physician, as defined in subsection (r)(1) of this section, for a particular patient, including antigens so prepared which are forwarded to another qualified person (including a rural health clinic) for administration to such

- patient, from time to time, by or under the supervision of another such physician;
- (H) (i) services furnished pursuant to a contract under section 1395mm of this title to a member of an eligible organization by a physician assistant or by a nurse practitioner (as defined in subsection (aa)(5) of this section) and such services and supplies furnished as an incident to his service to such a member as would otherwise be covered under this part if furnished by a physician or as an incident to a physician's service; and (ii) services furnished pursuant to a risk-sharing contract under section 1395mm(g) of this title to a member of an eligible organization by a clinical psychologist (as defined by the Secretary) or by a clinical social worker (as defined in subsection (hh)(2) of this section), and such services and supplies furnished as an incident to such clinical psychologist's services or clinical social worker's services to such a member as would otherwise be covered under this part if furnished by a physician or as an incident to a physician's service;
  - (I) blood clotting factors, for hemophilia patients competent to use such factors to control bleeding without medical or other supervision, and items related to the administration of such factors, subject to utilization controls deemed necessary by the Secretary for the efficient use of such factors;
  - (J) prescription drugs used in immunosuppressive therapy furnished, to an individual who receives an organ transplant for which payment is made under this subchapter, but only in the case of drugs furnished -
    - (i) before 1995, within 12 months after the date of the transplant procedure,
    - (ii) during 1995, within 18 months after the date of the transplant procedure,
    - (iii) during 1996, within 24 months after the date of the transplant procedure,
    - (iv) during 1997, within 30 months after the date of the transplant procedure, and
    - (v) during any year after 1997, within 36 months after the date of the transplant procedure;
  - (K) (i) services which would be physicians' services if furnished by a physician (as defined in subsection (r)(1) of this section) and which are performed by a physician assistant (as defined in subsection (aa)(5) of this section) under the supervision of a physician (as so defined) and which the physician assistant is legally authorized to perform by the State in which the services are performed, and such services and supplies furnished as incident to such services as would be covered under subparagraph (A) if furnished incident to a physician's professional service; and [1] but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services, [2] (ii) services which would be physicians' services if furnished by a physician (as defined in subsection (r)(1) of this section) and which are performed by a nurse practitioner or clinical nurse specialist (as

defined in subsection (aa)(5) of this section) working in collaboration (as defined in subsection (aa)(6) of this section) with a physician (as defined in subsection (r)(1) of this section) which the nurse practitioner or clinical nurse specialist is legally authorized to perform by the State in which the services are performed, and such services and supplies furnished as an incident to such services as would be covered under subparagraph (A) if furnished incident to a physician's professional service, but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services;

- (L) certified nurse-midwife services;
- (M) qualified psychologist services;
- (N) clinical social worker services (as defined in subsection (hh)(2) of this section);
- (O) erythropoietin for dialysis patients competent to use such drug without medical or other supervision with respect to the administration of such drug, subject to methods and standards established by the Secretary by regulation for the safe and effective use of such drug, and items related to the administration of such drug;
- (P) prostate cancer screening tests (as defined in subsection (oo) of this section);
- (Q) an oral drug (which is approved by the Federal Food and Drug Administration) prescribed for use as an anticancer chemotherapeutic agent for a given indication, and containing an active ingredient (or ingredients), which is the same indication and active ingredient (or ingredients) as a drug which the carrier determines would be covered pursuant to subparagraph (A) or (B) if the drug could not be self-administered;
- (R) colorectal cancer screening tests (as defined in subsection (pp) of this section); and [1]
- (S) diabetes outpatient self-management training services (as defined in subsection (qq) of this section); and
- (T) an oral drug (which is approved by the Federal Food and Drug Administration) prescribed for use as an acute anti-emetic used as part of an anticancer chemotherapeutic regimen if the drug is administered by a physician (or as prescribed by a physician) -
  - (i) for use immediately before, at, or within 48 hours after the time of the administration of the anticancer chemotherapeutic agent; and
  - (ii) as a full replacement for the anti-emetic therapy which would otherwise be administered intravenously. [3]

(3) diagnostic X-ray tests (including tests under the supervision of a physician, furnished in a place of residence used as the patient's home, if the performance of such tests meets such conditions relating to health and safety as the Secretary may find necessary and including diagnostic mammography if conducted by a facility that has a certificate (or provisional certificate) issued under section 354 of the Public Health Service Act (42

- U.S.C. 263b)), diagnostic laboratory tests, and other diagnostic tests;
- (4) X-ray, radium, and radioactive isotope therapy, including materials and services of technicians;
  - (5) surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations;
  - (6) durable medical equipment;
  - (7) ambulance service where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations;
  - (8) prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens;
  - (9) leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the patient's physical condition;
  - (10) (A) pneumococcal vaccine and its administration and, subject to section 4071(b) of the Omnibus Budget Reconciliation Act of 1987, influenza vaccine and its administration; and (B) hepatitis B vaccine and its administration, furnished to an individual who is at high or intermediate risk of contracting hepatitis B (as determined by the Secretary under regulations);
  - (11) services of a certified registered nurse anesthetist (as defined in subsection (bb) of this section);
  - (12) subject to section 4072(e) of the Omnibus Budget Reconciliation Act of 1987, extra-depth shoes with inserts or custom molded shoes with inserts for an individual with diabetes, if -
    - (A) the physician who is managing the individual's diabetic condition (i) documents that the individual has peripheral neuropathy with evidence of callus formation, a history of pre-ulcerative calluses, a history of previous ulceration, foot deformity, or previous amputation, or poor circulation, and
    - (ii) certifies that the individual needs such shoes under a comprehensive plan of care related to the individual's diabetic condition;
    - (B) the particular type of shoes are prescribed by a podiatrist or other qualified physician (as established by the Secretary); and
    - (C) the shoes are fitted and furnished by a podiatrist or other qualified individual (such as a pedorthist or orthotist, as established by the Secretary) who is not the physician described in subparagraph (A) (unless the Secretary finds that the physician is the only such qualified individual in the area);
  - (13) screening mammography (as defined in subsection (jj) of this section);
  - (14) screening pap smear and screening pelvic exam; and
  - (15) bone mass measurement (as defined in subsection (rr) of this section). No diagnostic tests performed in any laboratory, including a laboratory that is part of a rural health clinic, or a hospital (which, for purposes of this sentence, means an institution considered a hospital for purposes of section 1395f(d) of this title) shall be included within paragraph (3) unless such laboratory -

(16) if situated in any State in which State or applicable local law provides for licensing of establishments of this nature, (A) is licensed pursuant to such law, or (B) is approved, by the agency of such State or locality responsible for licensing establishments of this nature, as meeting the standards established for such licensing; and

(17)(A) meets the certification requirements under section 353 of the Public Health Service Act (42 U.S.C. 263a); and (B) meets such other conditions relating to the health and safety of individuals with respect to whom such tests are performed as the Secretary may find necessary. There shall be excluded from the diagnostic services specified in paragraph (2)(C) any item or service (except services referred to in paragraph (1)) which would not be included under subsection (b) of this section if it were furnished to an inpatient of a hospital. None of the items and services referred to in the preceding paragraphs (other than paragraphs (1) and (2)(A)) of this subsection which are furnished to a patient of an institution which meets the definition of a hospital for purposes of section 1395f(d) of this title shall be included unless such other conditions are met as the Secretary may find necessary relating to health and safety of individuals with respect to whom such items and services are furnished.