

See Below

Your blood, sperm, and tissue are not necessarily protected under the final federal medical privacy rule! This is a major change from the proposed rule (announced last November 3, 1999).

to in section 1173(a)(1) of the Act (a "standard transaction").

We note that health care providers who do not submit HIPAA transactions in standard form become covered by this rule when other entities, such as a billing service or a hospital, transmit standard electronic transactions on their behalf. A provider could not circumvent these requirements by assigning the task to its business associate since the business associate would be considered to be acting on behalf of the provider. See the definition of "business associate."

Where a public agency is required or authorized by law to administer a health plan jointly with another entity, we consider each agency to be a covered entity with respect to the health plan functions it performs. Unlike private sector health plans, public plans are often required by or expressly authorized by law to jointly administer health programs that meet the definition of "health plan" under this regulation. In some instances the public entity is required or authorized to administer the program with another public agency. In other instances, the public entity is required or authorized to administer the program with a private entity. In either circumstance, we note that joint administration does not meet the definition of "business associate" in § 164.501. Examples of joint administration include state and federal administration of the Medicaid and SCHIP program, or joint administration of a Medicare+Choice plan by the Health Care Financing Administration and the issuer offering the plan.

Health Care

We proposed to define "health care" to mean the provision of care, services, or supplies to a patient and to include any: (1) Preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, counseling, service, or procedure with respect to the physical or mental condition, or functional status, of a patient or affecting the structure or function of the body; (2) sale or dispensing of a drug, device, equipment, or other item pursuant to a prescription; or (3) procurement or banking of blood, sperm, organs, or any other tissue for administration to patients.

The final rule revises both the NPRM definition and the definition as provided in the Transactions Rule, to now mean "care, services, or supplies related to the health of an individual. Health care includes 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.

We delete the term "providing" from the definition to delineate more clearly the relationship between "treatment," as the term is defined in § 164.501, and "health care." Other key revisions include adding the term "assessment" in subparagraph (1) and deleting proposed subparagraph (3) from the rule. Therefore, the procurement or banking of organs, blood (including autologous blood), sperm, eyes or any other tissue or human product is not considered to be health care under this rule and the organizations that perform such activities would not be considered health care providers when conducting these functions. As described in § 164.512(h), covered entities are permitted to disclose protected health information without individual authorization, consent, or agreement (see below for explanation of authorizations, consents, and agreements) as necessary to facilitate cadaveric donation.

Health Care Clearinghouse

In the NPRM, we defined "health care clearinghouse" as a public or private entity that processes or facilitates the processing of nonstandard data elements of health information into standard data elements. The entity receives health care transactions from health care providers or other entities, translates the data from a given format into one acceptable to the intended payor or payors, and forwards the processed transaction to appropriate payors and clearinghouses. Billing services, repricing companies, community health management information systems, community health information systems, and "value-added" networks and switches would have been considered to be health care clearinghouses for purposes of this part, if they perform the functions of health care clearinghouses as described in the preceding sentences.

In the final regulation, we modify the definition of health care clearinghouse to reflect changes in the definition published in the Transactions Rule. The definition in the final rule is:

Health care clearinghouse means a public or private entity, including billing services, repricing companies, community health management information systems or community health information systems, 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.

We note here that the term health care clearinghouse may have other meanings and connotations in other contexts, but the regulation defines it specifically, and an entity is considered a health care clearinghouse only to the extent that it meets the criteria in this definition. Telecommunications entities that provide connectivity or mechanisms to convey information, such as telephone companies and Internet Service Providers, are not health care clearinghouses as defined in the rule unless they actually carry out the functions outlined in our definition. Value added networks and switches are not health care clearinghouses unless they carry out the functions outlined in the definition. The examples of entities in our proposed definition we continue to consider to be health care clearinghouses, as well as any other entities that meet that definition, to the extent that they perform the functions in the definition.

In order to fall within this definition of clearinghouse, the covered entity must perform the clearinghouse function on health information received from some other entity. A department or component of a health plan or health care provider that transforms nonstandard information into standard data elements or standard transactions (or vice versa) is not a clearinghouse for purposes of this rule, unless it also performs these functions for another entity. As described in more detail in § 164.504(d), we allow affiliates to perform clearinghouse functions for each other without triggering the definition of "clearinghouse" if the conditions in § 164.504(d) are met.

Health Care Provider

We proposed to define health care provider to mean a provider of services as defined in section 1861(u) of the Act, a provider of medical or health services as defined in section 1861(s) of the Act, and any other person or organization who furnishes, bills, or is paid for health care services or supplies in the normal course of business.