

HIPAA PRIVACY RULE

Introduction

The “Standard for Privacy of Individually Identifiable Health Information (Privacy Rule) established a set of national standards for the protection of certain health information. The U.S. Department of Health and Human Services (HHS) issued the Privacy Rule to implement the requirement of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Privacy Rule standards address the use and disclosure of individuals’ health information – called protected health information or PHI – by organizations subject to the Privacy Rule – called covered entities, as well as standards for individuals’ privacy rights to understand and control how their health information is used.

The major goal of the Privacy Rule is to assure that individuals’ health information is properly protected while allowing the flow of health information needed to provide and promote high quality health care and to protect the public’s health and well being.

Statutory and Regulatory Background

The Health Insurance and Portability and Accountability Act (HIPAA) was enacted on August 21, 1996. Title I protects health insurance coverage for workers and their families when they change or lose their jobs. Title II required the Department of Health and Human Services (HHS) to establish national standards for electronic health care transactions and national identifiers for providers, health plans, and employers. It also addressed the security and privacy of health data. Adopting these standards will increase the efficiency and effectiveness of the nation's health care system and improve the use of electronic data interchange.

The Privacy Rule establishes, for the first time, a foundation of Federal protections for the privacy of protected health information. The Rule does not replace Federal, State, or other law that grants individuals even greater privacy protections, and covered entities are free to retain or adopt more protective policies or practices.

Who is Covered by HIPAA?

Health Plans. Individual and group plans that provide or pay the cost of medical care are covered entities and include, health, dental, vision, prescription drug insurers, HMOs, Medicare, Medicaid, Medicare+Choice and Medicare supplemental insurers and long-term care insurers (excluding nursing home fixed-indemnity policies). Health plans also include employer sponsored group health plans, government and church-sponsored health plans and multi-employer health plans.

Health Care Providers. Every health care provider who electronically transmit health information in connection with the following transactions is a covered entity: claims, benefit eligibility inquiries, referral authorization requests or other transactions for which HHS has established standards under the HIPAA Transaction Rule. The Privacy Rule covers a health care provider whether it electronically transmits these transactions directly or uses a billing service or other third party to do so on its behalf. Health care providers include all “provider services” (such as hospitals) and “providers of medical or health services (such as physicians, dentists and other practitioners) as defined by Medicare, and any other person or organization that furnishes, bills or is paid for health care.

Health Care Clearinghouses. Health care clearinghouses are entities that process nonstandard information they receive from another entity into a standard (standard format or data content) or visa versa. Usually, health care clearinghouses receive individually identifiable health information only when they are providing processing services to a health plan or health care provider as a business associate. Health care clearinghouses include billing services, repricing companies, community health management information systems and value-added networks and switches if these entities perform clearinghouse functions.

Business Associates.

Definition: In general, a person or organization, other than a member of a covered entity’s workforce, that performs certain functions or activities on behalf of, or provides certain services to, a covered entity (Electroease Corp. dba Electropedic Beds) that involve the use or disclosure of individually identifiable health information. Such functions on behalf of a covered entity (Electroease Corp. dba Electropedic Beds) include claims processing, data analysis, utilization review and billing. Business associates services to a covered entity are limited to legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation or financial services – but only if their functions or services involve the use or disclosure of protected health information and where access to protected health information is other than incidental. A covered entity can be the business associate of another covered entity.

Business Associate Contract. When a covered entity **Electroease Corp. dba Electropedic Beds** uses a contractor or other non-workforce member to perform business associate services, the Privacy Rule requires that the covered entity **Electroease Corp. dba Electropedic Beds** include certain protections for the information in a business associate agreement that imposes specified written safeguards on the individually identifiable health information used or disclosed by its business associates. The covered entity **Electroease Corp. dba Electropedic Beds** may not contractually authorize its business associate to make any use or disclosure of protected health information that would violate the Privacy Rule.

What Information is Protected?

Protected Health Information. The Privacy Rule protects all “individually identifiable health information” held or transmitted by a covered entity or its business associate, in any form or

media, whether electronic paper or oral. This information is defined in the Privacy Rule as “protected health information (PHI).

PHI is information, including demographic data, that relates to:

the individuals past, present or future physical or mental health or condition,
the provision of health care to the individual, or
the past, present or future payment for the provision of health care to the individual

and identifies that the individual or for which there us a reasonable basis to believe can be used to identify the individual. Individually identifiable health information includes many common identifiers such as name, address, birth date, social security number, etc.) Excluded from protected health information is employment records that a covered entity maintains in its capacity as an employer and education and certain other records subject to, or defined in, the Family Education al Rights and Privacy Act, 20 U.S.C. Section 1232g.

ELECTROEASE

INCIDENTAL USES AND DISCLOSURES

[45 CFR 164.502(a)(1)(iii)]

Many customary health care communications and practices play an important or even essential role in ensuring that individuals receive prompt and effective health care. Due to the nature of these communications and practices, as well as the various environments in which individuals receive health care or other services from covered entities, the potential exists for an individual's health information to be disclosed incidentally.

The Privacy Rule permits certain incidental uses and disclosures that occur as a by-product of another permissible or required use or disclosure, if **Electroease Corp. dba Electropedic Beds** has applied *reasonable safeguards* and implemented the *minimum necessary standard*, with respect to the primary use or disclosure. See 45 CFR 164.502(a)(1)(iii).

An incidental use or disclosure is a secondary use or disclosure that cannot reasonably be prevented, is limited in nature, and that occurs as a result of another use or disclosure that is permitted by the Rule. However, an incidental use or disclosure is not permitted if it is a by-product of an underlying use or disclosure which violates the Privacy Rule.

Reasonable Safeguards. **Electroease Corp. dba Electropedic Beds** follows appropriate administrative, technical, and physical safeguards that protect against uses and disclosures not permitted by the Privacy Rule, as well as that limit incidental uses or disclosures. See 45 CFR 164.530(c). While it is not expected that **Electroease Corp. dba Electropedic Beds** guarantees the privacy of protected health information from any and all potential risks, in implementing reasonable safeguards, **Electroease Corp. dba Electropedic Beds** analyzes its own needs and circumstances, such as the nature of the protected health information it holds, and assess the potential risks to patients' privacy. **Electroease Corp. dba Electropedic Beds** also takes into account the potential effects on patient care as well as other issues, such as the financial and administrative burden of implementing particular safeguards.

Electroease Corp. dba Electropedic Beds ensures reasonable safeguards for individuals' health information by implementing the following safeguards:

- X Speaking quietly when discussing a patient's condition with family members in a waiting room or other public area;
- X Avoiding using patients' names in public hallways and elevators, and posting signs to remind employees to protect patient confidentiality;
- X Isolating or locking file cabinets and/or records rooms;
- X Providing additional security, such as passwords, on computers maintaining personal information.

Minimum Necessary. Electroase Corp. dba Electropedic Beds has implemented reasonable minimum necessary policies and procedures that limit how much protected health information is used, disclosed, and requested for certain purposes, and reasonably limit who within **Electroase Corp. dba Electropedic Beds** has access to protected health information, and under what conditions, based on job responsibilities. The minimum necessary standard does not apply to disclosures, including oral disclosures, among health care providers for treatment purposes.

ELECTROEASE CORP

MINIMUM NECESSARY

[45 CFR 164.502(b), 164.514(d)]

The minimum necessary standard requires covered entities to evaluate their practices and enhance safeguards as needed to limit unnecessary or inappropriate access to and disclosure of protected health information.

The Privacy Rule generally requires covered entities to take reasonable steps to limit the use or disclosure of, and requests for, protected health information to the minimum necessary to accomplish the intended purpose. The minimum necessary standard does not apply to the following:

- X Disclosures to or requests by a health care provider for treatment purposes.
- X Disclosures to the individual who is the subject of the information.
- X Uses or disclosures made pursuant to an individual's authorization.
- X Uses or disclosures required for compliance with the Health Insurance Portability and Accountability Act (HIPAA) Administrative Simplification Rules.
- X Disclosures to the Department of Health and Human Services (HHS) when disclosure of information is required under the Privacy Rule for enforcement purposes.
- X Uses or disclosures that are required by other law.

Electroease Corp. dba Electropedic Beds develops and implements policies and procedures appropriate for its organization, reflecting **Electroease Corp. dba Electropedic Beds's** business practices and workforce. Access to protected health information is accessible on a need to know basis.

For routine disclosures and requests, **Electroease Corp. dba Electropedic Beds** limits the protected health information disclosed or requested to the minimum necessary for that particular type of disclosure or request

Non-routine disclosures and requests are reviewed by **Electroease Corp. dba Electropedic Beds** on an individual basis and are limited to only the minimum amount of protected health information necessary to accomplish the purpose of a non-routine disclosure or request.

Where protected health information is disclosed to, or requested by, health care providers for treatment purposes, the minimum necessary standard does not apply.

Reasonable Reliance. In certain circumstances, the Privacy Rule permits a covered entity to rely on the judgment of the party requesting the disclosure as to the minimum amount of information that is needed. Such reliance must be reasonable under the particular circumstances of the request. This reliance is permitted when the request is made by:

- X A public official or agency who states that the information requested is the minimum necessary for a purpose permitted under 45 CFR 164.512 of the Rule, such as for public health purposes (45 CFR 164.512(b)).
- X Another covered entity.
- X A professional who is a workforce member or business associate of the covered entity holding the information and who states that the information requested is the minimum necessary for the stated purpose.
- X A researcher with appropriate documentation from an Institutional Review Board (IRB) or Privacy Board.

The Rule does not require such reliance and **Electroease Corp. dba Electropedic Beds** always retains discretion to make its own minimum necessary determination for disclosures to which the standard applies.

PERSONAL REPRESENTATIVES

[45 CFR 164.502(g)]

The HIPAA Privacy Rule establishes a foundation of Federally-protected rights which permit individuals to control certain uses and disclosures of their protected health information.

Under the Rule, a person authorized (under State or other applicable law, e.g., tribal or military law) to act on behalf of the individual in making health care related decisions is the individual's "personal representative." Section 164.502(g) provides when, and to what extent, the personal representative must be treated as the individual for purposes of the Rule.

1. Except as otherwise provided in 45 CFR 164.502(g), the Privacy Rule, and therefore, **Electroease Corp. dba Electropedic Beds**, requires covered entities to treat an individual's personal representative as the individual with respect to uses and disclosures of the individual's protected health information, as well as the individual's rights under the Rule.
2. The personal representative stands in the shoes of the individual and has the ability to act for the individual and exercise the individual's rights. In accordance with 45 CFR 164.528, **Electroease Corp. dba Electropedic Beds** must provide the individual's personal representative with an accounting of disclosures, as well as provide the personal representative access to the individual's protected health information in accordance with 45 CFR 164.524 to the extent such information is relevant to such representation. **Electroease Corp. dba Electropedic Beds** recognizes that a personal representative may also authorize disclosures of the individual's protected health information.
3. Where the person has broad authority to act on the behalf of a living individual in making decisions related to health care, such as a parent with respect to a minor child or a legal guardian of a mentally incompetent adult, **Electroease Corp. dba Electropedic Beds** will treat the personal representative as the individual for all purposes under the Rule, unless an exception applies.
4. When a person with an individual's limited health care power of attorney regarding only a specific treatment, such as use of artificial life support, is that individual's personal representative only with respect to protected health information that relates to that health care decision, **Electroease Corp. dba Electropedic Beds** will not treat that person as the individual for other purposes, such as to sign an authorization for the disclosure of protected health information for marketing purposes.
5. Where the person has authority to act on the behalf of a deceased individual or his estate, which does not have to include the authority to make decisions related to health care, **Electroease Corp. dba Electropedic Beds** will treat the personal representative as the individual for all purposes under the Rule.

ELECTROEASE CORP

Electroease Corp. dba Electropedic Beds Recognizes as Personal Representative:

If the Individual Is:

The Personal Representative Is:

An Adult or
An Emancipated Minor

A person with legal authority to make health care decisions on behalf of the individual

Examples: Health care power of attorney
Court appointed legal guardian
General power of attorney

An Unemancipated Minor

A parent, guardian, or other person acting *in loco parentis* with legal authority to make health care decisions on behalf of the minor child

Exceptions: See parents and minors discussion below.

Deceased

A person with legal authority to act on behalf of the decedent or the estate (not restricted to health care decisions)

Examples: Executor of the estate
Next of kin or other family member
Durable power of attorney

Parents and Unemancipated Minors.

The Privacy Rule defers to State or other applicable laws that address the ability of a parent, guardian, or other person acting *in loco parentis* (collectively, “parent”) to obtain health information about a minor child. In most cases under the Rule, the parent is the personal representative of the minor child and can exercise the minor’s rights with respect to protected health information, because the parent usually has the authority to make health care decisions about his or her minor child. Regardless of whether a parent is the personal representative, the Privacy Rule permits a covered entity to disclose to a parent, or provide the parent with access to, a minor child’s protected health information when and to the extent it is expressly permitted or required by State or other laws (including relevant case law). Likewise, the Privacy Rule prohibits a covered entity from disclosing a minor child’s protected health information to a parent, or providing a parent with access to, such information when and to the extent it is expressly prohibited under State or other laws (including relevant case law). Thus, State and other applicable law governs when such law explicitly requires, permits, or prohibits the disclosure of, or access to, the health information about a minor child.

Three Exceptions:

1. When State or other law does not require the consent of a parent or other person before a minor can obtain a particular health care service, and the minor consents to the health care service;

Example: A State law provides an adolescent the right to obtain mental health treatment without the consent of his or her parent, and the adolescent consents to such treatment without the parent's consent.

2. When a court determines or other law authorizes someone other than the parent to make treatment decisions for a minor;

Example: A court may grant authority to make health care decisions for the minor to an adult other than the parent, to the minor, or the court may make the decision(s) itself.

3. When a parent agrees to a confidential relationship between the minor and the physician.

Example: A physician asks the parent of a 16-year-old if the physician can talk with the child confidentially about a medical condition and the parent agrees.

Abuse, Neglect, and Endangerment Situations.

When a physician or other covered entity reasonably believes that an individual, including an unemancipated minor, has been or may be subjected to domestic violence, abuse or neglect by the personal representative, or that treating a person as an individual's personal representative could endanger the individual, **Electroease Corp. dba Electropedic Beds** may choose not to treat that person as the individual's personal representative, if in the exercise of professional judgment, doing so would not be in the best interests of the individual.

BUSINESS ASSOCIATES

[45 CFR 164.502(e), 164.504(e), 164.532(d) and (e)]

By law, the HIPAA Privacy Rule applies only to covered entities – health plans, health care clearinghouses, and certain health care providers. However, most health care providers and health plans do not carry out all of their health care activities and functions by themselves. Instead, they often use the services of a variety of other persons or businesses.

The Privacy Rule allows covered providers and health plans to disclose protected health information to these “business associates” if the providers or plans obtain satisfactory assurances that the business associate will use the information only for the purposes for which it was engaged by the covered entity, will safeguard the information from misuse, and will help the covered entity comply with some of the covered entity’s duties under the Privacy Rule.

Covered entities may disclose protected health information to an entity in its role as a business associate *only* to help the covered entity carry out its health care functions – not for the business associate’s independent use or purposes, except as needed for the proper management and administration of the business associate.

The Privacy Rule requires **Electroease Corp. dba Electropedic Beds**, as a covered entity, to obtain satisfactory assurances, in writing, in the form of a contract or other agreement, from its business associate that the business associate will appropriately safeguard the protected health information it receives or creates on behalf of the **Electroease Corp. dba Electropedic Beds**.

Electroease Corp. dba Electropedic Beds defines a “business associate” as a person or entity that performs certain functions or activities that involve the use or disclosure of protected health information on behalf of, or provides services to, a covered entity. A member of **Electroease Corp. dba Electropedic Beds**’s workforce is not a business associate. A covered health care provider, health plan, or health care clearinghouse can be a business associate of another covered entity.

Electroease Corp. dba Electropedic Beds defines business associate functions and activities to include: claims processing or administration; data analysis, processing or administration; utilization review; quality assurance; billing; benefit management; practice management; and re-pricing.

Electroease Corp. dba Electropedic Beds defines business associate services as: legal; actuarial; accounting; consulting; data aggregation; management; administrative; accreditation; and financial.

Examples of Business Associates.

- X A third party administrator that assists a health plan with claims processing.
- X A CPA firm whose accounting services to a health care provider involve access to protected health information.
- X An attorney whose legal services to a health plan involve access to protected health information.
- X A consultant that performs utilization reviews for a hospital.
- X A health care clearinghouse that translates a claim from a non-standard format into a standard transaction on behalf of a health care provider and forwards the processed transaction to a payer.
- X An independent medical transcriptionist that provides transcription services to a physician.
- X A pharmacy benefits manager that manages a health plan's pharmacist network.

Business Associate Contracts.

Electroease Corp. dba Electropedic Beds's contract with its business associates contain the following provisions:

- X Description of the permitted and required uses of protected health information by the business associate;
- X That the business associate will not use or further disclose the protected health information other than as permitted or required by the contract or as required by law; and
- X That the business associate is required to use appropriate safeguards to prevent a use or disclosure of the protected health information other than as provided for by the contract.

If **Electroease Corp. dba Electropedic Beds** knows of a material breach or violation by the business associate of the contract or agreement, **Electroease Corp. dba Electropedic Beds** will take reasonable steps to cure the breach or end the violation, and if such steps are unsuccessful, to terminate the contract or arrangement. If termination of the contract or agreement is not feasible, **Electroease Corp. dba Electropedic Beds** will report the problem to the Department of Health and Human Services (HHS) Office for Civil Rights (OCR).

Exceptions to the Business Associate Standard:

Electroease Corp. dba Electropedic Beds is not required to have a business associate contract or other written agreement in place before protected health information may be disclosed:

1. to a health care provider for treatment of the individual
2. to a health plan
3. to a public benefits program such as Medicare, Social Security Administration, state Medicaid programs, that collects protected health information to determine eligibility or enrollment, or determines eligibility or enrollment, for the government program, where the joint activities are authorized by law
4. to a health plan for payment purposes, or when the health care provider simply accepts a discounted rate to participate in the health plan's network. A provider that submits a claim to a health plan and a health plan that assesses and pays the claim are each acting on its own behalf as a covered entity, and not as the "business associate" of the other
5. with persons or organizations (e.g., janitorial service or electrician) whose functions or services do not involve the use or disclosure of protected health information, and where any access to protected health information by such persons would be incidental, if at all

USES AND DISCLOSURES FOR TREATMENT, PAYMENT, AND HEALTH CARE OPERATIONS

[45 CFR 164.506]

The HIPAA Privacy Rule establishes a foundation of Federal protection for personal health information, carefully balanced to avoid creating unnecessary barriers to the delivery of quality health care.

The Rule generally prohibits a covered entity from using or disclosing protected health information unless authorized by patients, except where this prohibition would result in unnecessary interference with access to quality health care or with certain other important public benefits or national priorities.

Ready access to treatment and efficient payment for health care, both of which require use and disclosure of protected health information, are essential to the effective operation of the health care system. In addition, certain health care operations—such as administrative, financial, legal, and quality improvement activities—conducted by or for health care providers and health plans, are essential to support treatment and payment. Many individuals expect that their health information will be used and disclosed as necessary to treat them, bill for treatment, and, to some extent, operate the covered entity's health care business.

To avoid interfering with an individual's access to quality health care or the efficient payment for such health care, the Privacy Rule permits a covered entity to use and disclose protected health information, with certain limits and protections, for treatment, payment, and health care operations activities.

Treatment generally means the provision, coordination, or management of health care and related services among health care providers or by a health care provider with a third party, consultation between health care providers regarding a patient, or the referral of a patient from one health care provider to another.

Payment encompasses the various activities of health care providers to obtain payment or be reimbursed for their services and of a health plan to obtain premiums, to fulfill their coverage responsibilities and provide benefits under the plan, and to obtain or provide reimbursement for the provision of health care.

Minimum Necessary.

Electroease Corp. dba Electropedic Beds reasonably limit its disclosures of, and requests for, protected health information for payment and health care operations to the minimum necessary. **Electroease Corp. dba Electropedic Beds** also develops its policies and procedures to limit which members of its workforce may have access to protected health information for treatment, payment, and health care operations, based on those who need access to the information to do their jobs.

Electroease Corp. dba Electropedic Beds limits which members of its workforce may have access to protected health information for treatment, payment, and health care operations, based on those who need access to the information to do their jobs.

Electroease Corp. dba Electropedic Beds is required to apply the minimum necessary standard to disclosures to or requests by a health care provider for treatment purposes.

“Health care operations” are certain administrative, financial, legal, and quality improvement activities of a covered entity that are necessary to run its business and to support the core functions of treatment and payment. These activities, which are limited to the activities listed in the definition of “health care operations” at 45 CFR 164.501, include:

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

Business planning and development, such as conducting cost-management and planning analyses related to managing and operating **Electroease Corp. dba Electropedic Beds**; and

Business management and general administrative activities, including those related to implementing and complying with the Privacy Rule and other Administrative Simplification Rules, customer service, resolution of internal grievances, sale or transfer of assets, creating de-identified health information or a limited data set, and fundraising for the benefit of **Electroease Corp. dba Electropedic Beds**

Electroease Corp. dba Electropedic Beds may, without the individual’s authorization:

Use or disclose protected health information for its own treatment, payment, and health care operations activities

Disclose protected health information for the treatment activities of any health care provider (including providers not covered by the Privacy Rule)

Disclose protected health information to another covered entity or a health care provider (including providers not covered by the Privacy Rule) for the payment activities of the entity that receives the information

Disclose protected health information to another covered entity for certain health care operation activities of the entity that receives the information if:

Each entity either has or had a relationship with the individual who is the subject of the information, and the protected health information pertains to the relationship; and

The disclosure is for a quality-related health care operations activity (i.e., the activities listed in paragraphs (1) and (2) of the definition of “health care operations” at 45 CFR 164.501) or for the purpose of health care fraud and abuse detection or compliance.

Electroease Corp. dba Electropedic Beds may voluntarily choose, but is not required, to obtain the individual’s consent for it to use and disclose information about him or her for treatment, payment, and health care operations. If **Electroease Corp. dba Electropedic Beds** chooses to have a consent process, it has complete discretion under the Privacy Rule to design a process that works best for its business and consumers. **Electroease Corp. dba Electropedic Beds** recognizes that a consent document is not a valid permission to use or disclose protected health information for a purpose that requires an “authorization” under the Privacy Rule (see 45 CFR 164.508), or where other requirements or conditions exist under the Rule for the use or disclosure of protected health information.

While individuals have the right to request restrictions on how **Electroease Corp. dba Electropedic Beds** will use and disclose protected health information about them for treatment, payment, and health care operations, **Electroease Corp. dba Electropedic Beds** is not required to agree to an individual’s request for a restriction, but is bound by any restrictions to which it agrees. (45 CFR 164.522(a).

Electroease Corp. dba Electropedic Beds complies with individual’s reasonable requests to receive confidential communications from **Electroease Corp. dba Electropedic Beds**. (45 CFR 164.522(b).

Electroease Corp. dba Electropedic Beds provides individuals with adequate notice of its privacy practices, including the uses or disclosures **Electroease Corp. dba Electropedic Beds** may make of the individual’s information and the individual’s rights with respect to that information.

MARKETING

[45 CFR 164.501, 164.508(a)(3)]

The HIPAA Privacy Rule gives individuals important controls over whether and how their protected health information is used and disclosed for marketing purposes. With limited exceptions, the Rule requires an individual's written authorization before a use or disclosure of his or her protected health information can be made for marketing. So as not to interfere with core health care functions, the Rule distinguishes marketing communications from those communications about goods and services that are essential for quality health care.

What is Marketing ?

The Privacy Rule defines "marketing" as making "a communication about a product or service that encourages recipients of the communication to purchase or use the product or service." Generally, if the communication is "marketing," then the communication can occur only if **Electroease Corp. dba Electropedic Beds** first obtains an individual's "authorization."

Marketing also means: "An arrangement between **Electroease Corp. dba Electropedic Beds** and any other entity whereby **Electroease Corp. dba Electropedic Beds** discloses protected health information 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."

Electroease Corp. dba Electropedic Beds is **prohibited** by the Privacy Rule from selling protected health information to a business associate or any other third party for that party's own purposes. **Electroease Corp. dba Electropedic Beds** is also **prohibited** by the Privacy Rule from selling lists of patients or enrollees to third parties without obtaining authorization from each person on the list.

What is NOT Marketing?

The Privacy Rule carves out exceptions to the definition of marketing under the following categories:

- (1) A communication is not "marketing" if it is made 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.

This exception to the marketing definition permits communications by a covered entity about its own products or services.

(2) A communication is not “marketing” if it is made for treatment of the individual.

(3) A communication is not “marketing” if it is made 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.

ELECTROEASE CORP

DISCLOSURES FOR PUBLIC HEALTH ACTIVITIES

[45 CFR 164.512(b)]

The HIPAA Privacy Rule recognizes the legitimate need for public health authorities and others responsible for ensuring public health and safety to have access to protected health information to carry out their public health mission. The Rule also recognizes that public health reports made by covered entities are an important means of identifying threats to the health and safety of the public at large, as well as individuals. The Rule permits covered entities to disclose protected health information without authorization for specified public health purposes.

General Public Health Activities.

The Privacy Rule permits covered entities to disclose protected health information, without authorization, to public health authorities who are legally authorized to receive such reports for the purpose of preventing or controlling disease, injury, or disability. This would include, for example, the reporting of a disease or injury; reporting vital events, such as births or deaths; and conducting public health surveillance, investigations, or interventions.

Covered entities may, at the direction of a public health authority, disclose protected health information to a foreign government agency that is acting in collaboration with a public health authority.

Covered entities who are also a public health authority may use, as well as disclose, protected health information for these public health purposes.

Generally, covered entities are required reasonably to limit the protected health information disclosed for public health purposes to the minimum amount necessary to accomplish the public health purpose. However, covered entities are not required to make a minimum necessary determination for public health disclosures that are made pursuant to an individual's authorization, or for disclosures that are required by other law.

For disclosures to a public health authority, covered entities may reasonably rely on a minimum necessary determination made by the public health authority in requesting the protected health information.

Other Public Health Activities.

The Privacy Rule recognizes the important role that persons or entities other than public health authorities play in certain essential public health activities. Accordingly, the Rule permits covered entities to disclose protected health information, without authorization, to such persons or entities for the public health activities discussed below.

Child abuse or neglect;
Quality, safety or effectiveness of a product or activity regulated by the FDA
Persons at risk of contracting or spreading a disease
Workplace medical surveillance

ELECTROEASE CORP

RESEARCH

[45 CFR 164.501, 164.508, 164.512(i)]
[See also 45 CFR 164.514(e), 164.528, 164.532]

The HIPAA Privacy Rule establishes the conditions under which protected health information may be used or disclosed by covered entities for research purposes.

Research is defined in the Privacy Rule as, “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”

Electroease Corp. dba Electropedic Beds may always use or disclose for research purposes health information which has been de-identified.

Under the Privacy Rule, **Electroease Corp. dba Electropedic Beds** is permitted to use and disclose protected health information for research with individual authorization, or without individual authorization under limited circumstances set forth in the Privacy Rule.

Research Use/Disclosure Without Authorization. To use or disclose protected health information without authorization by the research participant, a covered entity must obtain one of the following:

- Documented Institutional Review Board (IRB) or Privacy Board Approval. Documentation that an alteration or waiver of research participants’ authorization for use/disclosure of information about them for research purposes has been approved by an IRB or a Privacy Board. This provision of the Privacy Rule might be used, for example, to conduct records research, when researchers are unable to use de-identified information, and the research could not practicably be conducted if research participants’ authorization were required.

The following three criteria must be satisfied for an IRB or Privacy Board to approve a waiver of authorization under the Privacy Rule:

The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:

- S an adequate plan to protect the identifiers from improper use and disclosure;
- S an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
- S adequate written assurances that the protected health information

will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

- < The research could not practicably be conducted without the waiver or alteration; and
 - < The research could not practicably be conducted without access to and use of the protected health information.
- Preparatory to Research. Representations from the researcher, either in writing or orally, that the use or disclosure of the protected health information is solely to prepare a research protocol or for similar purposes preparatory to research, that the researcher will not remove any protected health information from the covered entity, *and* representation that protected health information for which access is sought is necessary for the research purpose. This provision might be used, for example, to design a research study or to assess the feasibility of conducting a study.
 - Research on Protected Health Information of Decedents. Representations from the researcher, either in writing or orally, that the use or disclosure being sought is solely for research on the protected health information of decedents, that the protected health information being sought is necessary for the research, *and*, at the request of the covered entity, documentation of the death of the individuals about whom information is being sought.
 - Limited Data Sets with a Data Use Agreement. A data use agreement entered into by both the covered entity and the researcher, pursuant to which the covered entity may disclose a limited data set to the researcher for research, public health, or health care operations. A limited data set excludes specified direct identifiers of the individual or of relatives, employers, or household members of the individual. The data use agreement must:
 - < Establish the permitted uses and disclosures of the limited data set by the recipient, consistent with the purposes of the research, and which may not include any use or disclosure that would violate the Rule if done by the covered entity;
 - < Limit who can use or receive the data; and
 - < Require the recipient to agree to the following:

- S Not to use or disclose the information other than as permitted by the data use agreement or as otherwise required by law;
- S Use appropriate safeguards to prevent the use or disclosure of the information other than as provided for in the data use agreement;
- S Report to the covered entity any use or disclosure of the information not provided for by the data use agreement of which the recipient becomes aware;
- S Ensure that any agents, including a subcontractor, to whom the recipient provides the limited data set agrees to the same restrictions and conditions that apply to the recipient with respect to the limited data set; and
- S Not to identify the information or contact the individual.

Research Use/Disclosure With Individual Authorization. The Privacy Rule also permits covered entities to use or disclose protected health information for research purposes when a research participant authorizes the use or disclosure of information about him or herself.

To use or disclose protected health information with authorization by the research participant, the covered entity must obtain an authorization that satisfies the requirements of 45 CFR 164.508. The Privacy Rule has a general set of authorization requirements that apply to all uses and disclosures, including those for research purposes. However, several special provisions apply to research authorizations:

- Unlike other authorizations, an authorization for a research purpose may state that the authorization does not expire, that there is no expiration date or event, or that the authorization continues until the “end of the research study;” and
- An authorization for the use or disclosure of protected health information for research may be combined with a consent to participate in the research, or with any other legal permission related to the research study.

Accounting for Research Disclosures. In general, the Privacy Rule gives individuals the right to receive an accounting of certain disclosures of protected health information made by a covered entity. This accounting must include disclosures of protected health information that occurred during the six years prior to the individual’s request for an accounting, or since the applicable compliance date (whichever is sooner), and must include specified information regarding each disclosure. A more general accounting is permitted for subsequent multiple disclosures to the same person or entity for a single purpose. Among the types of disclosures that are exempt from this accounting requirement are:

- Research disclosures made pursuant to an individual’s authorization;

- Disclosures of the limited data set to researchers with a data use agreement under 45 CFR 164.514(e).

In addition, for disclosures of protected health information for research purposes without the individual's authorization pursuant to 45 CFR 164.512(i), and that involve at least 50 records, the Privacy Rule allows for a simplified accounting of such disclosures by covered entities. Under this simplified accounting provision, covered entities may provide individuals with a list of all protocols for which the patient's protected health information may have been disclosed under 45 CFR 164.512(i), as well as the researcher's name and contact information. Other requirements related to this simplified accounting provision are found in 45 CFR 164.528(b)(4).

Transition Provisions. Under the Privacy Rule, a covered entity may use and disclose protected health information that was created or received for research, either before or after the compliance date, if the covered entity obtained any one of the following prior to the compliance date:

- An authorization or other express legal permission from an individual to use or disclose protected health information for the research;
- The informed consent of the individual to participate in the research; or
- A waiver of informed consent by an IRB in accordance with the Common Rule or an exception under FDA's human subject protection regulations at 21 CFR 50.24.

However, if a waiver of informed consent was obtained prior to the compliance date, but informed consent is subsequently sought after the compliance date, the covered entity must obtain the individual's authorization as required at 45 CFR 164.508. For example, if there was a temporary waiver of informed consent for emergency research under the FDA's human subject protection regulations, and informed consent was later sought after the compliance date, individual authorization would be required before the covered entity could use or disclose protected health information for the research after the waiver of informed consent was no longer valid.

The Privacy Rule allows covered entities to rely on such express legal permission, informed consent, or IRB-approved waiver of informed consent, which they create or receive before the applicable compliance date, to use and disclose protected health information for specific research studies, as well as for future unspecified research that may be included in such permission.

DISCLOSURES FOR WORKERS' COMPENSATION PURPOSES

[45 CFR 164.512(l)]

The HIPAA Privacy Rule does not apply to entities that are either workers' compensation insurers, workers' compensation administrative agencies, or employers, except to the extent they may otherwise be covered entities. However, these entities need access to the health information of individuals who are injured on the job or who have a work-related illness to process or adjudicate claims, or to coordinate care under workers' compensation systems.

Generally, this health information is obtained from health care providers who treat these individuals and who may be covered by the Privacy Rule. The Privacy Rule recognizes the legitimate need of insurers and other entities involved in the workers' compensation systems to have access to individuals' health information as authorized by State or other law.

Due to the significant variability among such laws, the Privacy Rule permits disclosures of health information for workers' compensation purposes in a number of different ways.

Disclosures Without Individual Authorization. The Privacy Rule permits **Electroease Corp. dba Electropedic Beds** to disclose protected health information to workers' compensation insurers, State administrators, employers, and other persons or entities involved in workers' compensation systems, without the individual's authorization:

As authorized by and to the extent necessary to comply with laws relating to workers' compensation or similar programs established by law that provide benefits for work-related injuries or illness without regard to fault. This includes programs established by the Black Lung Benefits Act, the Federal Employees' Compensation Act, the Longshore and Harbor Workers' Compensation Act, and the Energy Employees' Occupational Illness Compensation Program Act. See 45 CFR 164.512(l).

To the extent the disclosure is required by State or other law. The disclosure must comply with and be limited to what the law requires. See 45 CFR 164.512(a).

For purposes of obtaining payment for any health care provided to the injured or ill worker. See 45 CFR 164.502(a)(1)(ii) and the definition of "payment" at 45 CFR 164.501.

Disclosures With Individual Authorization. In addition, **Electroease Corp. dba Electropedic Beds** may disclose protected health information to workers' compensation insurers and others involved in workers' compensation systems where the individual has provided his or her authorization for the release of the information to the entity. The authorization must contain the elements and otherwise meet the requirements specified at 45 CFR 164.508.

Minimum Necessary. Electroease Corp. dba Electropedic Beds is required reasonably to limit the amount of protected health information disclosed under 45 CFR 164.512(l) to the minimum necessary to accomplish the workers' compensation purpose. Under this requirement, protected health information may be shared for such purposes to the full extent authorized by State or other law.

In addition, **Electroease Corp. dba Electropedic Beds** is required reasonably to limit the amount of protected health information disclosed for payment purposes to the minimum necessary. **Electroease Corp. dba Electropedic Beds** is permitted to disclose the amount and types of protected health information that are necessary to obtain payment for health care provided to an injured or ill worker.

Where **Electroease Corp. dba Electropedic Beds** routinely makes disclosures for workers' compensation purposes under 45 CFR 164.512(l) or for payment purposes, **Electroease Corp. dba Electropedic Beds** may develop standard protocols as part of its minimum necessary policies and procedures that address the type and amount of protected health information to be disclosed for such purposes.

Where protected health information is requested by a State workers' compensation or other public official, **Electroease Corp. dba Electropedic Beds** is permitted to reasonably rely on the official's representations that the information requested is the minimum necessary for the intended purpose. See 45 CFR 164.514(d)(3)(iii)(A).

Electroease Corp. dba Electropedic Beds is not required to make a minimum necessary determination when disclosing protected health information as required by State or other law, or pursuant to the individual's authorization. See 45 CFR 164.502(b).

**NOTICE OF PRIVACY PRACTICES
FOR PROTECTED HEALTH INFORMATION**
[45 CFR 164.520]

The HIPAA Privacy Rule gives individuals a fundamental new right to be informed of the privacy practices of their health plans and of most of their health care providers, as well as to be informed of their privacy rights with respect to their personal health information. Health plans and covered health care providers are required to develop and distribute a notice that provides a clear explanation of these rights and practices.

General Rule. The Privacy Rule provides that an individual has a right to adequate notice of how **Electroease Corp. dba Electropedic Beds** may use and disclose protected health information about the individual, as well as his or her rights and the covered entity's obligations with respect to that information.

Electroease Corp. dba Electropedic Beds provides individuals with this notice of their privacy practices.

Electroease Corp. dba Electropedic Beds provides a notice in *plain language* that describes:

- X How the **Electroease Corp. dba Electropedic Beds** may use and disclose protected health information about an individual.
- X The individual's rights with respect to the information and how the individual may exercise these rights, including how the individual may complain to **Electroease Corp. dba Electropedic Beds**.
- X **Electroease Corp. dba Electropedic Beds**'s legal duties with respect to the information, including a statement that the covered entity is required by law to maintain the privacy of protected health information.
- X Whom individuals can contact for further information about the covered entity's privacy policies.
 - The notice must include an effective date.

Electroease Corp. dba Electropedic Beds promptly revises and distributes its notice whenever it makes material changes to any of its privacy practices.

Electroease Corp. dba Electropedic Beds makes its notice available to any person who asks for it.

Electroease Corp. dba Electropedic Beds will prominently post and make available its notice

on any web site it will maintain that provides information about its customer services or benefits.

Electroease Corp. dba Electropedic Beds will e-mail the notice to an individual if the individual agrees to receive an electronic notice.

ELECTROEASE CORP

RESTRICTIONS ON GOVERNMENT ACCESS TO HEALTH INFORMATION

[45 CFR Part 160, Subpart C; 164.512(f)]

Under the HIPAA Privacy Rule, government-operated health plans and health care providers must meet substantially the same requirements as private ones for protecting the privacy of individual identifiable health information.

Government-run health plans, such as Medicare and Medicaid plans, must take virtually the same steps to protect the claims and health information that they receive from beneficiaries as private insurance plans or health maintenance organizations (HMO).

All Federal agencies must also meet the requirements of the Privacy Act of 1974, which restricts what information about individual citizens – including any personal health information – can be shared with other agencies and with the public.

Electroease Corp. dba Electropedic Beds protects patients' privacy as required by the Privacy Rule by cooperating with efforts by the Department of Health and Human Services (HHS) Office for Civil Rights (OCR) to investigate complaints or otherwise ensure compliance.

ELECTROEASE CORP

ELECTROEASE CORP

ELECTROEASE CORP

ELECTROEASE CORP

ELECTROEASE CORP

ELECTROEASE CORP