



**Use and Disclosure of Protected Health Information for Marketing
Purposes and the Sale of Patient Protected Health Information
#1660.010**

INITIAL EFFECTIVE DATE:	LAST REVISION DATE:	RESPONSIBLE UNIVERSITY DIVISION/DEPARTMENT
September 1, 2009	February 29, 2024	Office of Compliance and Integrity

POLICY STATEMENT

Florida International University (FIU) and the Health Insurance Portability and Accountability Act (HIPAA) Hybrid Designated Health Care Components (Components) will not use or disclose patient Protected Health Information (PHI) for marketing purposes without first obtaining a specific written authorization from the patient.

FIU may not use or disclose patient PHI for the purpose of a “marketing communication” when the communication:

1. Occurs in a face-to-face encounter with the patient, and
2. Concerns products or services of nominal value (e.g., distribution of calendars, pens etc.).

FIU may disclose PHI to a Business Associate for purposes of marketing communications only if the Business Associate’s function is to assist FIU with conducting the marketing communications.

FIU will not sell and will not permit an individual or entity to sell patient PHI.

As a University-wide policy and procedure, this policy and procedure takes precedence over any Component-specific policies, procedures, or protocols that conflicts with this policy and procedure, unless prior approval is obtained from the Office of Compliance and Integrity. (FIU Policy and Procedure #1660.080) (Policies and Procedures, Changes to Policies and Procedures, and Documentation)

Components may maintain HIPAA documentation in either paper or electronic form, provided that any format is sufficiently protected to ensure it will be retrievable throughout the required retention period. Unless otherwise indicated in FIU HIPAA Privacy or Security Rule Policy and Procedure, each Component Privacy Coordinator will be responsible for maintaining all HIPAA documentation relevant to his/her Component. (FIU Policy and Procedure #1660.080) (Policies and Procedures, Changes to Policies and Procedures, and Documentation)



All Component Workforce members shall receive mandatory HIPAA Privacy and Security Rule training. (FIU Policy and Procedure #1640.010) (HIPAA Privacy and Security Rule Training)

Component Workforce members who fail to adhere to this policy and procedure may be subject to civil and criminal penalties as provided by law, and/or administrative and disciplinary action (FIU Policy and Procedure #1610.015) (Sanctions)

Each Component must designate a HIPAA Privacy Coordinator and a HIPAA Security. (FIU Policy and Procedure #1660.070) (Designation of HIPAA Privacy Officer and Component Privacy and Security Coordinators)

FIU reserves the right to amend, change or terminate this policy and procedure at any time, either prospectively or retroactively, without notice. Any ambiguities between this policy and procedure and the other policies and procedures should be accordingly made consistent with the requirements of HIPAA and state law and regulation. (FIU Policy and Procedure #1660.080) (Policies and Procedures, Changes to Policies and Procedures, and Documentation)

SCOPE

This policy applies to FIU's HIPAA Health Care Components that are contained within FIU's HIPAA Hybrid Designation (FIU Policy and Procedure #1610.005), any FIU department, division, office, and/or unit that may engage in marketing to Component patients, their Workforce members and Business Associates as defined in this policy and FIU Policy and Procedure #1660.015 regarding Business Associate Agreements.

REASON FOR POLICY

The intent of this policy is to address the specific and limited uses of patient Protected Health Information (PHI) for marketing purposes, the sale of patient PHI, and when patient written authorization is required.

DEFINITIONS

TERM	DEFINITIONS
Administrative Officer	Means the Component Workforce member responsible for financial management, human resources administration, management of facilities and equipment, and other administrative functions required to support the teaching and research missions of the FIU HIPAA Hybrid Designated Health Care Component. The Administrative Officer is the senior administrative staff position in the department, Division or Office and provides continuity as academic leadership changes.

Authorization	Means an individual's written permission to allow a covered entity to use or disclose specified PHI for a particular purpose. Except as otherwise permitted by the HIPAA Privacy Rule, a covered entity may not use or disclose PHI for research purposes without a valid Authorization.
Business Associate	<p>Generally an entity or person who performs a function involving the use or disclosure of Protected Health Information (PHI) on behalf of a covered entity (such as claims processing, case management, utilization review, quality assurance, billing) or provides services for a covered entity that require the disclosure of PHI (such as legal, actuarial, accounting, accreditation).</p> <p>NOTE: A business associate relationship exists when an individual or entity, acting on behalf of an FIU HIPAA Component(s), assists in the performance of a function or activity involving the creation, use, disclosure, or access of PHI. This includes, but not limited to, claims processing or administration, data analysis, utilization review, quality assurance, billing, benefit management or repricing.</p> <p>NOTE: A Business Associate may include any individual or entity that receives PHI from a HIPAA Component in the course of providing legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, software support, or financial services. A Business Associates does not, however, include HIPAA Component workforce members.</p>
Patient	The person who is the subject of PHI.
Code of Federal Regulations	Also known as CFR is the codification of the general and permanent regulations promulgated by the executive departments and agencies of the federal government of the United States.
Component	Means a component or combination of components of a hybrid entity designated by the hybrid entity (Florida International University). Those programs designated by FIU that must comply with the requirements of the Health Insurance Portability and Accountability Act of 1996, hereinafter referred to as "Components". Components of FIU are required to comply with the Administrative Simplification provisions of HIPAA because the Components perform a covered function.
Confidentiality	Means data or information is not made available or disclosed to unauthorized persons or processes.
Covered Entity	<p>An entity that is subject to HIPAA.</p> <ol style="list-style-type: none"> 1. a health plan;

	<ol style="list-style-type: none"> 2. a health care clearinghouse; and/or 3. a health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.
Direct Payment	Means financial remuneration that flows from the third party whose product or service is being described directly to the Covered Entity (e.g., FIU and the Health Care Components/Units).
Disclosure	Means the release, transfer, provision of access to, or divulging in any other manner of protected health information outside of the entity holding the information.
Electronic Protected Health Information (ePHI)	PHI in electronic form. See also: <u>PHI</u> .
Face-to-Face Communication	<p>Means is a conversation in which two or more people are physically located in the same room.</p> <p>A face-to-face communication does not include any communications made over the telephone, sent through the mail or via e-mail.</p>
Financial Remuneration	Means direct or indirect payment from or on behalf of a third party whose product or service is being described. Direct or indirect payment does not include any payment for treatment of an individual.
Florida Statutes	Also known as F.S. are the codified, statutory laws of Florida
Health Care	<p>Means the care, services, or supplies related to the health of a patient, including:</p> <ol style="list-style-type: none"> 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 a patient 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.
Health Care Component	See "Component"
Health Care Operations	<p>Means any of a number of business and administrative activities, including:</p> <ul style="list-style-type: none"> • Conducting quality assessment and improvement activities. • Reviewing the competence or qualifications of health care professionals. • Conducting training programs. • Accreditation.

	<ul style="list-style-type: none"> • Credentialing. • Conducting or arranging for medical review, legal services and auditing functions. • Business planning and development. • Business management and general administrative activities Health care operations do not include research and many fundraising and marketing activities. (See in addition to this policy, FIU Policy and Procedure #1660.035) (Uses and Disclosures of Protected Health Information for Fundraising).
Health Care Provider	Means a provider of medical or health services and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business.
HIPAA	Means the Health Insurance Portability and Accountability Act of 1996.
Hybrid Covered Entity	Means a single legal entity that performs both covered and non-covered functions. The entity has a defined health care component that engages in HIPAA electronic transactions.
Indirect Payment	Means financial remuneration that flows from an entity on behalf of the third party whose product or service is being described to the Covered Entity (e.g., FIU and the Health Care Components/Units).
Kickback	Specifically, under federal law, a healthcare professional may not “solicit or receive any remuneration” whether “directly or indirectly, overtly or covertly, in-cash or in-kind” in exchange for referring a patient for any item or service, or in exchange for business regarding any good, facility, service, or item exchange under a <u>federal healthcare program</u> (<i>Medicare, Medicaid, etc.</i>). Receiving any sort of payment in exchange for prescribing a particular drug, referring a patient to a particular service provider, or otherwise referring a patient to some provisioner in the healthcare industry <u>is illegal</u> .
Marketing	<p>Means:</p> <ul style="list-style-type: none"> • 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: <ol style="list-style-type: none"> 1. 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;

	<p>replacement of, or enhancements to, a health plan; and health-related products or services available only to a health plan enrollee that add value, but are not part of, a plan of benefits.</p> <ol style="list-style-type: none"> For treatment of the individual; or 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. <ul style="list-style-type: none"> An arrangement between a covered entity and any other entity whereby the covered entity 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 services.
Privacy Coordinator	<p>Means an FIU Workforce member, appointed by the director, manager, or supervisor of a HIPAA Designated Component to conduct and/or coordinate with necessary and appropriate Workforce members all HIPAA Privacy Rule activities and actions within the Component, including but not limited to tracking HIPAA training activities; coordinating HIPAA Privacy Rule implementation; participating in HIPAA Privacy and Security Rule violation investigations, as necessary and appropriate, communicating with the Director of Compliance and Privacy for Health Affairs, the HIPAA Security Officer, and the Office of General Counsel, as necessary and appropriate, regarding HIPAA Privacy and Security Rule activities and concerns; conducting and reporting monitoring activities; participate in assessments; and responding to, tracking and documenting HIPAA Privacy Rule activities. Maintain ongoing communication with the Director of Compliance and Privacy for Health Affairs and the HIPAA Security Officer.</p>
Protected Health Information (PHI)	<p>Means any individually identifiable health information collected or created in the course of the provision of health care services by a covered entity, in any form (written, verbal or electronic). PHI relates to the past, present, or future physical or mental health or condition of an individual or the past, present, or future payment for the provision of health care to an individual. Protected Health Information however specifically excludes:</p> <ol style="list-style-type: none"> Education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. § 1232g ("FERPA");

	<p>2. Records described at 20 U.S.C. § 1232g(a)(4)(B)(iv); and</p> <p>3. Employment records held by a covered entity in its role as an employer.</p>
Privacy Rule	The regulations at 45 CFR 160 and 164, which detail the requirements for complying with the standards for privacy under the administrative simplification provisions of HIPAA.
Treatment	<p>Means the provision, coordination, or management of health care and related services among health care providers or by a healthcare provider with a third party, or consultative services among providers regarding a patient.</p> <p>Treatment refers to activities undertaken on behalf of a single patient, not a population. Activities are considered treatment only if delivered by a health care provider or a health care provider working with another party. Activities of <u>health plans</u> are not considered to be treatment. Many services, such as a refill reminder communication or nursing assistance provided through a telephone service, are considered treatment activities if performed by or on behalf of a health care provider, such as a pharmacist, but are regarded as health care operations if done on behalf of a different type of entity, such as a health plan.</p>
Use	With respect to patient identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information.
Workforce	Means employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a covered entity (FIU HIPAA Component) or business associate, is under the direct control of such covered entity or business associate, whether or not they are paid by the covered entity or business associate.

ROLES AND RESPONSIBILITIES

1. **Compliance Oversight:** The Office of University Compliance and Integrity (University Compliance)
 - Evaluates all federal and state healthcare privacy laws, regulations, rules and ordinances (Rules) to ensure compliance with the Rules
 - Develops and maintains all University-wide health care Privacy Rule policies and procedures, procedures and associated forms
 - Develops and maintains HIPAA health care Privacy Rule training modules and ensures appropriate Workforce members complete the required training.

- Performs audits and assessments of the Components to ensure their compliance with the Privacy Rules and associated FIU Policies and Procedures.
- Partners with the Division of Information Technology HIPAA Security Officer to ensure compliance with all federal and state healthcare privacy and security laws, regulations rules, and ordinances.

2. HIPAA Components:

- Each FIU HIPAA Hybrid Designated Component must designate a Privacy Coordinator responsible for overseeing and ensuring the Component's implementation and compliance with the HIPAA Privacy Rule, FIU's associated HIPAA Privacy Policies and Procedures, and any applicable state laws and/or regulations governing the confidentiality, integrity and availability of PHI and electronic PHI (ePHI), including, but not limited to ensuring the use and disclosure of PHI for marketing and the sale of PHI is only done in a manner required by this policy and procedure.

RELATED RESOURCES

References

- 45 CFR §164.501
- 45 CFR §164.504
- 45 CFR §164.508
- 45 CFR §164.530
- Florida Statute §456.057
- Florida Statute §95.11

Related Policies

- FIU Policy # 1610.005 (Designated Health Care Components of FIU Community)
- FIU Policy and Procedure #1660.070 (Designation of HIPAA Privacy Officer and Component Privacy and Security Coordinators)
- FIU Procedure #1660.015 (Business Associate Agreements)
- FIU Policy and Procedure #1660.080 (Policies and Procedures, Changes to Policies and Procedures, and Documentation)
- FIU Policy and Procedure #1660.035 (Use and Disclosure of Patient Protected Health Information for Fundraising)
- FIU Policy and Procedure #1660.075 (HIPAA Privacy and Security Training)
- FIU Policy and Procedure #1660.085 (Sanctions)



CONTACTS

For further information concerning this policy, please contact the FIU Office of Compliance & Integrity at (305) 348-2216, compliance@fiu.edu, hipaaprivacy@fiu.edu, or the appropriate Component Privacy Coordinator.

HISTORY

Initial Effective Date: September 1, 2009

Review Dates (*review performed, no updates*): n/a

Revision Dates (*review performed, updates made to document*): December 31, 2017; October 13, 2020; February 29, 2024.



**Use and Disclosure of Patient Protected Health Information for
Marketing Purposes and the Sale of Patient Protected Health
Information #1660.010a**

INITIAL EFFECTIVE DATE:	LAST REVISION DATE:	RESPONSIBLE UNIVERSITY DIVISION/DEPARTMENT
September 1, 2009	February 29, 2024	Office of Compliance and Integrity

PROCEDURE STATEMENT

I. Marketing

Each HIPAA Component must designate a Privacy Coordinator responsible for overseeing and ensuring the Component's implementation and compliance with the HIPAA Privacy Rule, FIU's associated HIPAA Privacy Policies and Procedures, and any applicable state laws and/or regulations governing the confidentiality, integrity and availability of PHI and electronic PHI (ePHI), including, but not limited to marketing to patients and sale of their PHI. Privacy Coordinators may delegate and share duties and responsibilities with Component Workforce members as necessary and appropriate but retain oversight responsibility. (FIU Policy and Procedure #1660.070) (Designation of HIPAA Privacy Officer and Component Privacy and Security Coordinators)

- A. Component Privacy Coordinators, Workforce members, and designated FIU staff members must not use or disclose patient PHI for marketing purposes, unless the patient provides a specific written release or authorization.
- B. Written Authorization is required from patients, or their legally authorized representative (Representative) when FIU, the FIU Health Care Component, and/or an FIU Business Associate (hereinafter Component) receive financial remuneration for making a communication(s) from a third party whose product or service is being marketed, and for any other use or disclosure of PHI which specifically qualify as marketing, unless an exception applies. (See FIU Policy and Procedure #1660.015) (Business Associates) and (FIU Policy and Procedure #1660.001) (Representative)
- C. If a marketing activity involves financial remuneration to the Component from a third party, then the written authorization must specifically state that such remuneration is involved.

For example: A patient's written authorization is required prior to the Component using the patient's PHI to make a communication to the patient regarding the acquisition of new state-of-the-art piece of medical equipment (such as a Transcranial

Magnetic Stimulation device) if the manufacturer of the medical equipment paid the Component to make the communication.

II. Uses or Disclosures of PHI That Do Not Constitute Marketing and Patient Written Authorization Is Not Required.

- A. Component Workforce members may use PHI to communicate with a patient about refill reminders or otherwise communicate about a drug or biologic currently prescribed for the patient so long as any financial remuneration the Component receives is reasonably related to the Component's cost of labor, supplies and postage to make the communication. This also includes but is not limited to communications regarding generic equivalent of a currently prescribed medication, communications to encourage the patient to take prescribed medications, and communications regarding all aspects of a drug delivery system related to a current prescribed medication or biologic.

For example: a clinical healthcare provider may, in a face-to-face conversation with the patient, recommend, verbally or by handing the patient written materials such as a pamphlet, that the individual take a specific alternative medication, even if the clinical healthcare provider is otherwise paid by a third party to make such communications.

NOTE: If the financial remuneration received is in excess of the costs of labor, supplies, and postage to make the communication, the Component must obtain the patient's written authorization prior to making the communication.

IMPORTANT: Although face-to-face communication directly with the individual; and a promotional gift of nominal value may be provided directly to the individual does not require patient written authorization and disclosure of any financial remuneration that the Component may receive, Workforce members **MUST** be aware that these actions may violate the Anti-Kickback Statute. Accordingly, Workforce members should review the relevant Anti-Kickback Rules and contact the Director of Compliance and Privacy for Health Affairs with the Office of Compliance and Integrity or the Office of General Counsel prior to engaging in such communications.

- B. A Component may use PHI to communicate with a patient about the following matters so long as the Component does not receive direct or indirect financial remuneration in exchange for making the communication:
1. For treatment of a patient by a health care provider, including case management or care coordination for the patient, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the patient to the extent that these activities do not fall within the definition of treatment.

2. To describe a health-related product or service, or payment for the product or service that is provided by or included in the patient's plan of benefits.
3. Replacement of, or enhancement to, a health plan.
- 4.

For example: The Components may mail or email flyers to patients announcing the opening of a new healthcare facility/wing where the funds for the new facility/wing were donated by a third party, because the financial remuneration to FIU received from the third party was not in exchange for the mailing or emailing of the flyers.

C. Written Authorizations Is Not Required From Patients to Make the Following Types of Marketing Communications, Regardless of Whether the Component Receives Financial Remuneration

1. A face-to-face communication made by the FIU Health Care Component/Unit Workforce members to an individual, which may consist of either a spoken recommendation or written materials handed to an individual but does not include telephone calls or mailings.
2. The Component provides the patients a promotional gift of nominal value.

For example: A clinical healthcare provider may, in a face-to-face conversation with the patient, recommend, verbally or by handing the patient written materials such as a pamphlet, that the patient take a specific alternative medication, even if the clinical healthcare provider is otherwise paid by a third party to make such communications.

III. Communications That Are Not Subject to the Health Insurance Portability and Accountability Act (HIPAA) and Florida State Statutes Regarding Marketing

- A. Communications promoting health in general and that do not promote a product or service from a particular healthcare provider, such as communications promoting a healthy diet or encouraging individuals to get certain routine diagnostic tests.
- B. Communications that do not use PHI to target a specific group of individuals, including mass mailings and communications such as newsletters that do not use PHI to identify the recipients of the mailing.
- C. Communications about government and government-sponsored programs, as there is no commercial component to communications about benefits through public programs.

IV. Record Retention

- A. If a communication, action, activity, or designation is required to be documented in writing, the document or record owner (e.g., Center for Children and Family) will maintain such writings, or an electronic copy, for seven (7) years from the date of its creation or the last effective date, whichever is later.

V. Form

- Marketing/Fundraising Authorization for Use/Disclosure of Medical Information.