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Covered Entity (CE), Business Associate (BA), and members of a CE or BA workforce (45 CFR § 160.103)



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Covered Entity (CE), Business Associate (BA), and members of a CE or BA workforce (45 CFR § 160.103)

1. Are you a HIPAA Covered Entity?

(Only if you fall into one of these 3 categories)

- Healthcare providers who bill or receive payment for healthcare in the normal course of business through the electronic transmission of covered transactions (i.e., billing third party payers and fund transfers)
- Healthcare data clearinghouses which process health data health data
- Health plans which furnish payment for care (e.g., health insurers and self-administered employer-sponsored plans with 50+ participants)

2. Are you a Business Associate?

(Only if you fall into one of these 3 categories)

- Persons (other than a member of a CE workforce) or entities that perform services on behalf of a CE involving more than incidental access to (creating/receiving/maintaining/transmitting) Protected Health Information (PHI)
- Subcontractors of a BA whose services involve access to PHI
- Entities offering Personal Health Records (PHR) to individuals on behalf of a CE

3. Are you a Part 2 Program (42 CFR Part 2)?

Part 2 applies to substance use disorder (SUD) records identifying patients (including presence in a facility, diagnosis, prognosis, or treatment received) maintained by a federally assisted program providing substance abuse education, prevention, training, treatment, rehabilitation, or research.

Part 2 programs are often CEs and are subject to both HIPAA and Part 2.

Note: "Federally assisted" includes programs receiving federal funds, providers contracted, authorized, licensed, or registered with federal agencies (including CMS and DEA), and any program with 50+ tax-exempt status.

4. If you are a CE (including a Part 2 Program) or BA, what are your obligations under HIPAA?

(45 C.F.R. Part 160 and Part 164 (Privacy Rule, Security Rule, and Breach Notification Rule)

- Appoint a privacy officer to develop, implement, and maintain organizational privacy policies and procedures
- Appoint a security officer to develop, implement, and maintain policies and procedures to maintain the integrity of electronic Protected Health Information (PHI)
- Provide annual HIPAA training to new hires and entire workforce (employees and independent contractors alike)
- Perform and document annual risk assessments of physical and electronic security measures protecting ePHI (including data on computers, information systems, and mobile devices)
- Implement technical, physical, and administrative safeguards to prevent the misuse of ePHI/PHI and ensure its confidentiality, integrity, and availability
- Develop security incident investigation protocol and breach notification processes
- Respond immediately to potential security incidents and self-report confirmed breaches
- Implement internal privacy, security, and breach response policies and procedures and distribute to workforce for review and written acknowledgment

FEDERAL ANTI-FRAUD AND ABUSE LAWS AND REGULATIONS REFERENCE GUIDE

Federal Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7(b)(1)	Eliminating Kickbacks in Recovery Act (EKRA) 18 U.S.C. § 1301	Stark Law (Physician Self-Referral) 42 U.S.C. § 1352b	Federal False Claims Act (FCA) 18 U.S.C. §§ 3709-3732
AKS prohibits willful or knowing offering, paying, soliciting, or receiving "kickbacks" to induce or reward referral or purchase federal healthcare program business.	EKRA extends the AKS prohibitions to third-party agents other than federal healthcare programs (e.g., commercial or employer-sponsored insurance), with respect to recovery (not bill) for long-term care, medical devices, or clinical laboratories.	Stark prohibits physicians from referring patients to receive health care services payable by Medicare or Medicaid from entities with which the physician or an immediate family member has a "financial relationship" (ownership, investment, or compensation) – unless the referring falls under one of the exceptions.	The FCA prohibits any individual or entity from "knowingly presenting or making a false claim to the government."
Safe Harbors: 42 CFR § 101.12(a)	Safe Harbors: 18 U.S.C. § 1301(b)(4) (a)	Exceptions: 42 CFR § 41.161(a)	

IMPORTANT SAFE HARBORS

AKS/EKRA Recurring service and management contracts safe harbor (AKS and EKRA)

(42 C.F.R. § 101.12(b)(4)(i) / 18 U.S.C. § 1301(b)(4)(i))

- Agreement set out in writing, signed by parties, for a term of at least one year, specifying all services to be provided.
- Consideration (methodology set in advance, consistent with fair market value in arm's length transactions, and not performed in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties past or future or under federal healthcare programs).
- Services provided do not involve any activity that violates any state or federal law and
- Aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business outcome of the services.

AKS Safe Harbor for bona fide employees (42 U.S.C. § 1320a-7(b)(1)(2)) AKS does not apply to "any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of insured health services."

EKRA Safe Harbor for Employees (18 U.S.C. § 1301(b)(4)(2)) EKRA does not apply to "a payment made by an employer to an employee or independent contractor (who has a bona fide employment or contractor relationship with such employer) for employment, as long as the employee's payment is not determined by or does not vary by (a) the number of individuals referred to a particular facility, (b) the number of tests or procedures performed, or (c) the amount billed for or received from the insured."

Is it a "Designated Health Service" under Stark? (2 Stark Covers Ancillary Categories)

- Clinical laboratory services
- Physiotherapy services
- Occupational therapy services
- Diagnostic speech language services
- Radiology and certain other imaging services
- Research therapy services and supplies
- Certain medical equipment and supplies
- Parenteral and enteral nutrition equipment and supplies
- Prosthetics, orthotics, and prosthetic devices and supplies
- Home health services
- Outpatient prescription drugs
- Incident and equipment budget projects

Note: Stark (2) covers for Stark coverage (a) certain designated health services with some exceptions for certain designated health services.

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