



Compliance Focus Areas for Behavioral Health and Addiction Treatment Providers

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Topics for Today

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- Overview of Behavioral Health and Addiction Treatment Compliance Programs
- Privacy Matters in Behavioral Health and Addiction Treatment
- Current Legislation Affecting Behavioral Health and Addiction Treatment Providers



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Behavioral Health and Addiction Treatment Compliance Programs

- The Seven Elements
 1. Compliance Officer and Compliance Committees
 2. Written Policies, Procedures, and Standards of Conduct (Code of Conduct)
 3. Training and Education – focus on:
 - a. Code of Conduct
 - b. Federal Healthcare Laws and Company's Compliance Program
 - c. HIPAA/42 CFR Part 2/Cybersecurity
 4. Effective Lines of Communication – chain of command, Compliance Hotline
 5. Internal Monitoring and Auditing – chart audits (billing, coding, provider documentation); EMR, paper records. Plans of correction; education; refunds.
 6. Enforcing Standards Through Well-Publicized Disciplinary Guidelines – written policies and consistency
 7. Responding Promptly to Detected Offenses and Taking Corrective Action – timely, yet thorough, investigations of issues raised and appropriate actions taken. Follow up to those who raised the issues.

Behavioral Health and Addiction Treatment Compliance Programs

- Additional Focus Areas
 - Quality of Care
 - Medical Necessity – voluntary vs. involuntary admissions (state law)
 - EMTALA
 - Stark Law – FMV for leases, physician contracts
 - Anti-kickback Statute – need for documented FMV also, Safe Harbor for free or discounted transportation, gift giving
 - Regulatory surveys (state licensing agencies, CMS, DEA)
 - Accreditation surveys (TJC, CARF)
 - Telehealth requirements
 - Payer requirements

Behavioral Health and Addiction Treatment Compliance Programs

- Eliminating Kickbacks in Recovery Act (EKRA)
 - EKRA targets the practice of referring substance abuse patients to “recovery homes, clinical treatment facilities, or laboratories” in exchange for “remuneration” (i.e., kickbacks, bribes, or rebates).
 - Unlike the federal Anti-Kickback Statute or Stark Law, EKRA is an “all-payor” statute. Its prohibitions apply regardless of whether an entity participates in Medicare or Medicaid.
 - The law broadly prohibits:
 - Solicitation or receipt of remuneration in return for referrals of these patients.
 - Remuneration or offers of remuneration to induce future referrals of these patients.
 - Remuneration or offers of remuneration to patients from a provider for using that provider’s services.

Behavioral Health and Addiction Treatment Compliance Programs

- Eliminating Kickbacks in Recovery Act (EKRA) (continued)
 - EKRA prohibits not only independent contractor but also employee compensation that is tied to the volume or value of referrals to laboratories, clinical treatment facilities, and recovery homes.
 - Thus, entities covered by EKRA must not compensate employees through incentive structures based on (1) volume or value of referrals, (2) number of tests or procedures performed or (3) amounts billed or received from referrals.
 - Such compensation is prohibited whether it is direct or indirect, covert or overt, in cash or in kind. Covered Entities who violate EKRA can be fined up to \$200,000, imprisoned up to 10 years, or both, for each occurrence.

Behavioral Health and Addiction Treatment Compliance Programs

- Eliminating Kickbacks in Recovery Act (EKRA) (continued)
 - As an all-payor statute, EKRA also criminalizes conduct already prohibited by the Civil Monetary Penalties rules (CMPs) regarding beneficiary inducement in the Medicare and Medicaid contexts.
 - The Beneficiary Inducement law, located at 42 U.S.C. § 1320a-7a(a)(5), states:
 - Any person that “offers to or transfers remuneration to any individual eligible for benefits under [Medicare or Medicaid] that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under [Medicare or Medicaid] ... shall be subject to a civil monetary penalty of not more than ... \$100,000 for each such act [in addition to treble damages].”
 - EKRA’s prohibition of remuneration to or offer of remuneration to patients in exchange for using a provider’s services mirrors the beneficiary inducement prohibition.

Privacy Matters in Behavioral Health and Addiction Treatment

- **HIPAA and HITECH**
 - Patient health information is protected under both Federal and state laws. Under Federal law, this is referred to as "protected health information" or PHI and is governed by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, and their implementing regulations, including the HIPAA Privacy Rule and the HIPAA Security Rule.
 - The **HIPAA Privacy Rule** provides federal privacy protections for PHI held by Covered Entities such as behavioral health and addiction treatment facilities and describes patient rights with respect to their PHI.
 - The **HIPAA Security Rule** requires Covered Entities and their Business Associates that use PHI to use administrative, physical, and technical safeguards to ensure the confidentiality, integrity, and availability of electronic PHI.
 - HIPAA helps protect the health information of a person from being disclosed without their knowledge or agreement. Covered Entities and their Business Associates are not permitted to access, obtain, disclose, or discuss PHI without written authorization from the patient or their legal representative, unless an applicable exception applies (i.e., the disclosure is necessary for treatment, payment, or healthcare operations, or is required by law.)

Privacy Matters in Behavioral Health and Addiction Treatment

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- **42 CFR Part 2**

- 42 CFR Part 2 ("Part 2") was enacted in 1987 to encourage patients to obtain Substance Use Disorder ("SUD") treatment by ensuring that patients receiving SUD diagnosis, referral or treatment by a Part 2 Program do not face adverse consequences in relation to issues such as criminal proceedings, domestic litigation, or employment opportunities.
- In order to be subject to Part 2 requirements, the program must:
 - Involve substance abuse education, treatment, or prevention; and
 - Be regulated or assisted by the federal government (e.g., receive payment from federal payers)
- Part 2 protects the confidentiality of SUD treatment records by imposing restrictions on their use and disclosure. In general, Part 2 Programs are prohibited from disclosing any information that would identify a person as having or having had a SUD unless that person provides specific written consent or an express exception under Part 2 applies. No TPO exceptions.

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- **42 CFR Part 2 (continued)**

- Written patient consent must specify:
 - The names or general designations of the programs making the disclosure
 - The name of the individual or organization that will receive the disclosure
 - The name of the patient who is the subject of the disclosure
 - The specific purpose of the disclosure
 - A description of how much and what kind of information will be disclosed
 - The patient's right to revoke the consent in writing and the exceptions to the right to revoke, or if the exceptions are included in the program's notice, a reference to the notice
 - The program's ability to condition treatment, payment, enrollment, or eligibility of benefits on the patient agreeing to sign the consent
 - The date, event, or condition upon which the consent expires if not previously revoked
 - The signature of the patient (and/or legally authorized representative)
 - The date on which the consent is signed
- When the information is disclosed pursuant to the patient's consent, this statement is also required:
This record which has been disclosed to you is protected by federal confidentiality rules (42 CFR part 2). The federal rules prohibit you from making any further disclosure of this record unless further disclosure is expressly permitted by the written consent of the individual whose information is being disclosed in this record or, is otherwise permitted by 42 CFR part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose (see § 2.31). The federal rules restrict any use of the information to investigate or prosecute with regard to a crime any patient with a substance use disorder, except as provided at §§ 2.12(c)(5) and 2.65.

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- **42 CFR Part 2 (continued)**

- Exceptions to patient consent:
 - Information provided in the course of internal program communications
 - Information provided to a Qualified Service Organization (QSO)
 - In bona fide medical emergencies
 - In response to a crime (or threat to commit a crime) against program personnel or on program premises
 - For research activities
 - For audit and evaluation activities
 - Reporting suspected child abuse or neglect
 - Circumstance involving certain minors or incompetent patients
 - In response to a valid court order and subpoena or similar compulsory order

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- **42 CFR Part 2 (continued)**

- The medical risks to patients created by not providing access to SUD information or records can also be significant. In an effort to appropriately balance these countervailing interests, the Substance Abuse and Mental Health Services Administration ("SAMHSA") has recently modified Part 2 in an attempt to permit disclosure of Part 2 Records in a manner that is more consistent with disclosure of other medical records, though is still significantly more stringent than HIPAA and its implementing regulations.
- Additional updates to Part 2 also occurred under legislative changes enacted as part of the Coronavirus Aid, Relief, and Economic Security ("CARES") Act.
- SAMHSA recently issued proposed rules covering the CARES Act which will better align Part 2 with HIPAA.

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Current Legislation Affecting Behavioral Health and Addiction Treatment Providers

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- **Behavioral Health Information Technology Coordination Act (BHITCA) (H.R. 5116 and S. 2688)**
 - Behavioral health hospitals and facilities were left out of the meaningful use incentives in the HITECH Act of 2009 for implementing Electronic Health Records (EHR) which drove rapid implementation of EHRs among medical surgical hospitals
 - There has been an ongoing effort to fill this gap & drive up EHR uptake in behavioral health facilities. In 2018 the SUPPORT Act (Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment) was passed. This Act requested that the Center for Medicare and Medicaid Initiatives (CMMI) conduct a behavioral health EHR demo., but no funding was provided and the work has not progressed.
 - If passed, the BHITCA would dedicate \$20 million a year in grant funding over five fiscal years (FY 25-29) to mental health, substance use disorder and other behavioral health providers to purchase or upgrade health information technology and support services.

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Current Legislation Affecting Behavioral Health and Addiction Treatment Providers

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- **Mental Health Parity and Addiction Equity Act (MHPAEA) Amendments**
 - The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) generally prevents group health plans and health insurance issuers that provide mental health and substance use disorder benefits from imposing less favorable benefit limitations on those benefits than on medical/surgical coverage.
 - Although this federal law exists, many people seeking mental health or substance use disorder treatment have continued to experience obstacles to having their treatments covered by their insurers.
 - Recent proposed amendments would add new regulations implementing the nonquantitative treatment limitation (NQTL) comparative analyses requirements under MHPAEA,.
 - Specifically, these proposed rules would amend the existing NQTL standard to prevent health plans and health insurance issuers from using NQTLs to place greater limits on access to mental health and substance use disorder benefits as compared to medical/surgical benefits.
- **Modernizing Opioid Treatment Access Act (MOTAA) (H.R. 1359 and S. 644)**
 - Proposes to eliminate laws that create a safe framework within Opioid Treatment Programs (OTPs) for the use of methadone in treating Opioid Use Disorder (OUD). MOTAA would allow board certified physicians to prescribe methadone for OUD and community pharmacies to dispense such prescriptions outside of the OTP setting with no safeguards or oversight.

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