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Complete Healthcare Compliance Manual 2024 Pharmacy: Drug Diversion

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What Is Drug Diversion?

Drug diversion by healthcare personnel involves stealing or taking medication from patients or healthcare settings for personal or unauthorized use. There are no valid statistics for how often healthcare personnel divert controlled substances, largely because diversion often goes undetected, and when it is identified, it is often underreported. When considering measures to combat drug diversion, it is important to understand that this is a very real risk in any healthcare facility that uses controlled substances. All facilities should expect to have diversion; if a facility isn't identifying diversion, it should review its processes and improve its controlled substance handling and auditing efforts.

Diversion is a substantial patient, staff, and community safety risk. There have been several outbreaks of hepatitis C and gram-negative bacteremia attributable to diversion in hospitals across the country.[2][3][4] Many facilities have faced tragedies in which staff have overdosed and died.[5][6] Risk to the community arises when healthcare personnel drive under the influence of diverted drugs.[7] Many diverting staff have admitted to me that they regularly drove to and from work in an impaired state.

Given the threats posed by diversion to patients, staff, facilities, and communities, instituting and maintaining a robust drug diversion prevention, detection, and response program is vital. Patient and staff safety considerations require that diversion be detected quickly and handled with effective, uniform procedures.

Risk Area Governance

The Controlled Substances Act is the foundation of regulatory guidance for pharmacies and health care facilities that use controlled substances.[8] The Drug Enforcement Administration (DEA) is the federal agency responsible for administering and enforcing the provisions of the Controlled Substances Act.[9] In several areas DEA recommendations are explicit and should be followed to the extent possible, even if they don't rise to the level of being officially required. In addition, the Medicare Conditions of Participation for Hospitals contain numerous regulations that are relevant to diversion prevention, detection, and response.[10]

Pharmacies should pay close attention to the specific requirements set forth regarding the authorization to manage controlled substances, how to manage them, and how to complete and maintain associated paperwork and documentation.[11] They must follow regulations for registration, inventory management, and record keeping. [12][13][14]

Paperwork

> Each application, attachment, or other document filed as part of an application, shall be signed by the applicant, if an individual; by a partner of the applicant, if a partnership; or by an officer of the applicant, if a corporation, corporate division,

> association, trust or other entity. An applicant may authorize one or more individuals, who would not otherwise be authorized to do so, to sign applications for the applicant by filing with the Registration Unit of the Administration a power of attorney for each such individual. The power of attorney shall be signed by a person who is authorized to sign applications under this paragraph and shall contain the signature of the individual being authorized to sign applications. The power of attorney shall be valid until revoked by the applicant.[15]

Power of Attorney

> A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records.[16]

Inventory Management

> Biennial inventory date. After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.[17]

Record Keeping

> Every registrant required to keep records pursuant to §1304.03 shall maintain, on a current basis, a complete and accurate record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him/her, and each inner liner, sealed inner liner, and unused and returned mail-back package, except that no registrant shall be required to maintain a perpetual inventory.[18]

Facilities are expected to adequately screen prospective employees who will have access to controlled substances. Specifically, they should assess each potential employee for the likelihood of a drug security breach.[19]

Facilities must keep controlled substances secure from procurement to administration and disposal.[20] Facilities should limit the quantities of controlled substances available to what is necessary to meet the needs of the patients being served. They must track and review procurement and usage so that diversion can be readily identified.

Staff with knowledge of diversion are expected to report that information to a security officer or supervisor.[21] Facilities, in turn, must immediately report theft or significant loss externally to the DEA.[22] They should also report diversion internally to the director of the pharmacy and to the CEO as appropriate.[23]