

Missouri Division of Behavioral Health

Bulletin Number: FY15–Clinical - 29	CLINICAL SERVICES BULLETIN	Effective Date: August 1, 2014
New	Subject: Medications in Substance Use Disorder Treatment Programs	Number of Pages: 2

1. Programs Affected

- 1.1 Comprehensive Substance Treatment and Rehabilitation (CSTAR) programs: Adolescent, Women and Children, Women and Children Enhanced, General Population, General Population Enhanced, Modified Medical Detoxification; Primary Recovery Plus (PR+) programs; Social Setting Detoxification; and, any programs that provide medications or provide oversight of consumer medications during a treatment episode. This includes programs offering residential support and/or outpatient levels of care.

2. Purpose

- 2.1 For substance abuse treatment facilities that are **NOT** registered with the Drug Enforcement Administration (DEA) and the Missouri Department of Health, Bureau of Narcotics and Dangerous Drugs (BNDD), the purpose of this clinical bulletin is to provide general guidance for the administration (or observation of self-administration) of medications at substance abuse treatment facilities that provide or take possession of consumer medications.
- 2.2 Agencies that are required to maintain DEA and BNDD registration must defer to the guidelines set forth by those respective agencies.

3. Definitions and Procedures

- 3.1 If a substance abuse treatment facility is not registered with the DEA and the Missouri BNDD, it must adhere to the general guidelines hereby established by the Department of Mental Health, Division of Behavioral Health, for the administration (or observation of self-administration) of medications.
- 3.2 Medication services are generally defined as services that provide consumers with medications to assist with their substance use disorder recovery process. For the purposes of this bulletin, medication services include physician activities and oversight, consumer (or consumer's guardian) consent, pharmacy activities, medication transportation, on-site medication storage, and administration or observed self-administration of medications during an episode of care.
- 3.3 The attached *General Medication Guidelines* have been developed for use at all substance abuse treatment programs listed in section 1.1 of this bulletin. These guidelines are intended to comply with requirements of the Division of Behavioral Health, the Missouri BNDD and the DEA regarding the handling of controlled substances. The *General Medication Guidelines* document includes information on the following:
 - 3.3.1 Consumer (or guardian) delegation to the facility for the management and oversight of medications;
 - 3.3.2 Guidance on chain of custody and custodial responsibilities for medications during transport from a pharmacy and within the facility;

- 3.3.3 Requirements for documentation of medication services;
- 3.3.4 Requirements for physician oversight of consumer medications;
- 3.3.5 Policy, procedure, and tracking requirements for controlled medications stored at the facility;
- 3.3.6 Formal relationship agreements with partnering pharmacies;
- 3.3.7 On-site medication storage;
- 3.3.8 Quality assurance and compliance monitoring; and
- 3.3.9 Medication protocols.

4. Regulations

- 4.1 The content of the *General Medication Guidelines* will be included in future rule promulgation activities.

General Medication Guidelines

Companion Document to FY15—Clinical Bulletin 29

This guidance document is to assist providers in assuring the appropriate management of medications within substance use treatment programs that do NOT require Federal Drug Enforcement Administration (DEA) or Missouri Department of Health and Senior Services, Bureau of Narcotics and Dangerous Drugs (BNDD) registration. Agencies that require DEA and BNDD registration must comply with the guidelines and regulations set forth by those agencies.

1. The facility must be certified by the Department of Mental Health.
2. The consumer, or consumer's guardian, must delegate to the facility, per written consent, permission to manage medications. In order to show a custodial trail of the medication within the facility, the following is required:
 - a. The facility may act as the agent of the consumer to pick up or receive delivery of medications from pharmacies or other agents that will be providing medications to the consumer. There should be a log or other tracking instrument to record the pick up or delivery of the medications for the consumer. This log or other instrument must show the following: consumer name; prescription number; name of medication and strength; directions; quantity received; name of the delivery person or clerk from the pharmacy; person at the facility receiving the prescription; and, date and time of receipt.
 - b. The facility may store consumers' medications (controlled, non-controlled, and over-the-counter) within the facility using their normal medication delivery system that conforms to the delivery system outlined within the Core Rules for Psychiatric and Substance Abuse Programs, *9 CSR 10-7.070 (4)(K)*.
 - c. Medications will be disposed of by the facility and will not be returned to the consumer, or consumer's guardian, if the consumer leaves the facility without the approval of the facility or physician.
 - d. Missouri Certification Standards for Alcohol and Drug Abuse Programs indicate that consumers (or guardian) have 30 days to retrieve medications left at an agency after discharge or the medications will be disposed of by the facility. The facility will dispose of such medications in accordance with applicable Federal and State guidelines.
3. The facility shall record each observation of consumer's self-administration of medications or staff's administration of medications to consumers.
4. The agency physician must delegate to the facility the authority to use the consumer's own medications. This delegation may be on the admission form when the consumer is first admitted to the facility. The name and contact information of all prescribing physicians must be documented in the consumer file. Efforts to coordinate medical care with consumers' prescribing physician(s) must be made and documented.

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5. The facility will perform inventory counts of the controlled medications on a daily basis according to the agency's policies and procedures.
6. The facility will contract with a pharmacy to provide medications to consumers that are admitted to the facility. If the facility admits consumers at all hours of the day and night, the facility should make arrangements with a pharmacy, if feasible, for after-hour pharmacy services, and for the utilization of the "bubble pack" system.
7. Controlled medications must be stored in a substantially constructed and securely locked cabinet or other appropriate container.
8. The facility has policies and procedures for the disposal of medications that meet the recommendations of the DEA and BNDD and other State and Federal agencies.
9. The facility performs annual credential reviews of the pharmacy, nursing and medical staff to insure compliance with professional licensing requirements of the State.
 - a. Such reviews shall include primary source verification, as well as on-line checks with DEA and BNDD to obtain verification that the individuals are in good standing with the licensing entities.
 - b. Primary source verification can be completed by either viewing an original license and registration and providing an initialed and dated copy for the personnel record, or by obtaining verification from the Board of Professional Registration and the DEA and BNDD to insure compliance with current licensure and registration requirements.
 - c. Printouts from the Board of Professional Registration should also be initialed and dated by the staff member conducting the primary source verification.
 - d. All primary source documentation must be maintained by the agency and available for review by the DBH.
10. Medications that are discontinued, expired, or considered surplus cannot be returned to the pharmacy and will be disposed of using the facility's policies and procedures regarding the disposal of medications.
11. If the facility uses medication protocols (predefined written procedural methods) and these are used to order medications from the pharmacy, the protocols must meet the requirements of the Missouri Board of Pharmacy. These requirements include the name, address, city, state, and zip code of the facility. The protocol will have two signature lines giving the physician the choice of "Dispense as written" on the right of the signature line or "Substitution permitted" on the left of the signature line.

**Definition of Terms for Medication Clinical Services Bulletin
And General Guidelines**

- **Physician Oversight:** The physician that the agency uses for oversight of medical concerns and medications provided to consumers. This physician should either be employed or contracted with the agency. This physician should be available 24 hours a day/7 days per week for either phone or face-to-face consultation of a consumer.
- **IF** the agency does not have a specific physician and uses multiple physicians, each of the physicians must be available to consult on their particular agency consumer on a 24 hour a day/7 day per week basis.
- Per Medication General Guidelines, each agency should have written agreements or memorandum(s) of understanding (MOU) with each pharmacy used to ensure that consumer needs can be met as soon as possible.
- Medications that are un-used by a consumer, discontinued, or expired must be disposed and destroyed as stated in agency Policy and Procedure. Pharmacy take-back programs are not to be used for the un-used, discontinued or expired medications. Agency Policy and Procedure documentation should include all methods of disposal that the agency might use. There are disposal sites located at various law enforcement offices. An application that can be used on a smart phone is the **American Medicine Chest Challenge**. This application will assist in searching for the nearest location to your treatment site. Additionally, the following link to the Food and Drug Administration provides instructions on medication disposal methods:
<http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/ensuringSAFEUSEOFMEDICINE/safedisposalofmedicines/ucm186187.htm>.
- Primary Source Verification of any pharmacy or pharmacist consultant utilized is necessary to assure that it is in good standing with the Missouri Division of Professional Registration. This can be done by going to the website at <http://pr.mo.gov/>. A pharmacy or consulting pharmacist check must be completed to determine Current Discipline Status. If medications are necessary prior to a check being conducted, the Primary Source Verification should be completed within three business days. The agency should keep record of each pharmacy/pharmacist that has been primary source verified.