



FAQ: CONTROLLED SUBSTANCES

Question: What is a controlled substance?

Answer: a drug or chemical substance whose possession and use are regulated under the Controlled Substance Act of 1970.

Question: What laws and regulations govern controlled substances in New York State?

Answer: New York State Controlled Substance Prescribing Regulations are contained in 10 NYCRR Part 80: Rules and Regulations on Controlled Substances.
New York Public Health Law related to Controlled Substances is found in Public Health Law Article 33

QUESTION: What are the requirements for "double locking" controlled substances?

Answer: 14 NYCRR 633.17(19)(d) requires that controlled substances be kept in secure, double-locked storage. The term double-locked includes two barriers with separately keyed locks.

10 NYCRR Part 80.6 is the controlled substance regulation of New York Office of Health and is the controlling regulation in this situation. This section requires:

"(b) Access to controlled substances shall be limited to the minimum number of employees actually required to efficiently handle the manufacture, distribution, custody, dispensing, administration or other handling of such substances."

The minimum security standards of Part 80.50(c) includes the following:

"(1) Schedule I, II, III and IV controlled substances shall be kept in stationary, locked double cabinets. Both cabinets, inner and outer, shall have key-locked doors with separate keys; spring locks or combination locks are not acceptable. For new construction cabinets shall be made of steel or other approved metal.

(2) Schedule V controlled substances shall be stored in a stationary, securely locked cabinet of substantial construction.

(3) Limited supplies of controlled substances for use in emergency situations may be stocked in sealed emergency medication kits."

Historically, OMRDD has accepted the following as fulfilling the requirements of Part 80:

- A "medication locker" as would be found in a hospital medication room. This is essentially a cabinet that locks, that contains another, smaller cabinet that is also secured to the wall that is locked. This does not have to be in a locked room.
- A cabinet that is securely attached to the wall that locks and is located in a locked room.

The main concern in the regulations is that the locked cabinet must be immobile so no one could just pick it up and take it somewhere to break the lock.

QUESTION: We usually count controlled substances with two people and the regulations allow agencies to determine how often the counts are. We have typically done them each shift in a residence. However there are times when there is only one staff on duty and then no one is home for awhile while consumers are out and then the PM shift comes in. Must we always have two staff count together or can we determine how often those counts are and do them when we do have two staff on duty?

ANSWER: The purpose of controlled drug counts are to ensure accountability for these substances. 10 NYCRR Part 80 does not have a specific requirement for how often controlled drugs must be counted. The requirement is that the agency be "accountable." Therefore, it appears that the agency can determine how often counts are to be done, and can schedule them when there are two staff on duty.

QUESTION: What are the requirements for storing New York State official Prescription forms, also known as triplicate forms, used to prescribe controlled drugs?

ANSWER: 10 NYCRR Part 80.75(f) talks to the responsibility of the dispensing institution in relation to official prescription forms:

"(f) It is the responsibility of the dispensing institution to obtain all official prescriptions for outpatient use and to assign such prescriptions to staff practitioners and interns and to insure the security of all such official prescriptions. Institutions obtaining official New York State prescriptions shall establish a system of control and security which will include the following:

- (1) A record of all such prescriptions received.
- (2) A record of all such prescriptions assigned to staff practitioners.
- (3) A system requiring that such prescriptions be kept under lock and key when not in use.
- (4) A system whereby official prescriptions are surrendered to the institution if the practitioner to whom they were assigned terminates his affiliation with the institution
- (5) A system whereby the Bureau of Controlled Substances, New York State Department of Health, is immediately notified of the loss, destruction or theft of any prescriptions

assigned to the institution.

- (6) A system whereby the institution has a sufficient number of official prescriptions in reserve for use by the institution."

QUESTION: Are AMAPs allowed to given Ritalin and other controlled drugs?

Answer: There are no restrictions in the regulations regarding AMAPs administering controlled substances, provided that the medication is administered by a route that the aide is allowed (e.g., orally). As with any medication or treatment, it is ultimately up to the nurse supervising the AMAP to assess the AMAP, the consumer and the particular situation to determine if it is appropriate for the AMAP to administer any medication, including morphine derivatives and Ritalin, to a consumer. And as with any medication, it is the responsibility of the supervising RN to ensure that the AMAP has the appropriate training regarding the medication he/she is administering, including expected effects, side effects, untoward reactions, any administration requirements of the medication, and what reactions indicate that the RN and/or prescribing practitioner should be called.

Question: Is there a requirement for periodic counts of controlled meds in a day hab program? Counting isn't mentioned in the 633.17.

Answer: There is no requirement in 633.17 for periodic counts of controlled medications. However, DOH part 80 requires that any agency that accepts and holds controlled substances for a person be "accountable" for those medications. Therefore, it would be best practice to periodically count controlled medications, even in a day program. Each controlled substance shall be counted at a frequency per the agency or sponsoring agency's policies and procedures.

Question: What are the requirements for controlled substances recording?

Answer: (1) A chronological record shall be maintained for each controlled substance. The record shall specify the following:

- (i) name of the person for which the controlled substance was prescribed;
 - (ii) name and strength of the controlled substance;
 - (iii) name of the prescribing practitioner;
 - (iv) the prescription number;
 - (v) name of the dispensing pharmacy;
 - (vi) the quantity of the controlled substance received by the facility.
- (2) Prescription refills for each controlled substance shall be recorded on the appropriate chronological record for the person for which it was prescribed. The recording shall include the quantity received, the new prescription number (if applicable), and the resulting balance of the supply left on hand.
- (3) Each administration of a controlled substance shall be documented on the appropriate chronological record for that controlled substance. That documentation shall consist of the date and hour of the administration, the signature of the person administering the controlled substance, and the balance of supply on left hand after that administration.
- (4) In addition to paragraphs (i)(2) and (i)(3) above, each controlled substance shall be counted at a frequency per the agency or sponsoring agency=s policies and procedures.

Question: Can a narcotic pill go in the medication organizer/med bar?

Answer: Yes. Make sure it is marked off on narcotic sheet. The medication organizer/med bar does not need to be in locked storage. It must be maintained in such a manner to ensure its security and the safety of the individuals.

Question: How are controlled medications disposed of?

Answer: The disposal of controlled medication is to be carried out by two parties, both of whom need to be authorized to administer medication. One party is to dispose of the medication and the second party shall witness the disposal. Documentation acknowledging the disposal is to be completed and signed by both parties.