

Ph 601.10 Security.

(a) That portion of the facility where drugs are stored, compounded or dispensed, shall be lockable so as to prevent entry into that area by any person or persons without the knowledge of the authorized individuals on duty, or when the facility is not open.

(b) If the facility contains controlled substances, it shall be equipped with an alarm system as referenced in Ph 1002.03.

(c) Methadone maintenance/detoxification facilities shall ensure that all access from outside their premises is secure. This shall include, but not be limited to, the installation of adequate lighting to illuminate the outside perimeter of the premises.

(d) All controlled substances shall be stored pursuant to the security provisions outlined in 21 CFR 1301.72(a).

(e) For ~~those~~**all** facilities which are open to the public 24 or more hours per week, the consultant pharmacist shall visit, at least ~~monthly~~**quarterly**, all areas of the facility where drugs are stored. ~~to ensure that they are properly labeled, have not reached their expiration date and show no signs of deterioration. Any drugs not conforming to these standards shall be removed from stock. For facilities which are open to the public less than 24 hours per week, such visits shall be conducted on a quarterly basis.~~

(f) The consultant pharmacist shall create a written record of each ~~monthly and/or~~ quarterly inspection, specified in (e), which shall be maintained on site and available to the board upon request.

(g) The pharmacist shall ensure that the areas specified in (e) above are in compliance with federal and state drug laws relative to security, drug distribution and product tampering. **The pharmacist shall ensure that all drugs are properly labeled, have not reached their expiration date and show no signs of deterioration. Any drugs not conforming to these standards shall be removed from stock.**

(h) The consultant pharmacist shall develop a distribution system that prevents the illegal diversion of drugs. Where applicable, the inventory of all schedule II controlled substances and other controlled drugs stored in any area of the facility, shall be checked by 2 persons at least every 24 hours and accountability records shall be completed by the nursing or medical staff and maintained on-site for inspection by the consultant pharmacist.

(i) Notwithstanding (h) above, in situations at the methadone maintenance/detoxification facilities that result in only one staff member being present, the inventory shall be counted, signed, dated and shall be “cosigned” immediately upon the presence of a second staff member. However, at no time shall there lapse more than 72 hours before this inventory verification by a second party.

Source. #8572, eff 2-23-06; amd by #9139-B, eff 4-25-08; paragraphs (a)-(g) EXPIRED: 2-23-14; paragraph (h) EXPIRED: 4-25-16

New. #12335, eff 7-22-17