Minnesota Board of Pharmacy

Guidance Concerning Approval of Automated Drug Distribution Systems used in LTCF

Minnesota Statutes § 151.58, Subdivision 2 (a) defines the phrase "automated drug distribution system" to mean (emphasis added):

> "a mechanical system **approved** by the board that performs operations or activities, other than compounding or administration, related to the storage, packaging, or dispensing of drugs, and collects, controls, and maintains all required transaction information and records".

Under Minnesota Statutes § 214.108, the Board is allowed to offer guidance to licensees about the application of the statutes and rules that the Board enforces. Such guidance is not binding on any court or other adjudicatory body. This document has been approved by the Minnesota Board of Pharmacy and offers guidance to pharmacies and other interested parties that are seeking the required approval of automated drug distribution systems (ADDS). Some of the areas addressed below contain recommendations that do not have the force of law. **Other areas concern issues that *are* addressed in statutes or rules. For those areas, the requirements in the law control.** The Board strongly recommends that ADDS be developed with all of these issues in mind, even those that are not addressed in statutes and rules. While each policy review or variance request is considered on its own merits, the Board seeks to handle these reviews and requests so that the individuals and businesses that are regulated by the Board are treated in a fair manner.

To help the Board and its staff determine if your policies and procedures address the following areas, please provide a cross-reference that specifies the location in your P&Ps at which an area is addressed. Please address each area even if you believe that it does not apply to your request.

Section 1: Requirements and guidance related to approval of ADDS

1. Provide the name and model of the system for which approval is being sought. [see Minnesota Statutes §151.58, subd. 4].

2. Submit policies and procedures addressing:

    a. environmental requirements on placement of system (e.g. - does the device need to be located in a room with specified temperatures or humidity levels)

    b. security features - including limiting of access, timeouts, biometrics and/or logoffs [see MN Rules 6800.2600, subp. 3 (A) & (B)]

    c. accountability of access to the system [see MN Rules 6800.2600, subp. 3(C)]

    d. measures to prevent unauthorized or inappropriate use of protected health information [see HIPAA privacy rules]

e. loading/refilling/restocking of ADDS/canister type, back-up canister

f. tamper-proof bulk container (i.e. canisters or cassettes) / tamper-proof patient specific package (if applicable)

g. interface with pharmacy dispensing software/system

h. labeling of cartridges, cassettes or other bulk drug containers (if applicable)

i. labeling of patient-specific packages (e.g. unit dose packages) (if applicable)

j. drawer identity for removal of medications (if applicable)

k. return bin

l. handling of wasted drugs

m. accuracy of the system: initial accuracy studies (timeframe) and on-going quality assurance policies

n. handling of outdates (if applicable)

o. handling of downtime and provision of support services

p. cleaning/maintenance requirements, documented

q. cross-contamination

r. report capabilities of ADDS, tracking use – all functions

Section 2: Requirements and guidelines related to approval of a pharmacy's ADDS P&Ps

Minnesota Statutes §151.58, subd. 2 (c) defines "Managing pharmacy" to mean a pharmacy licensed by the board that controls and is responsible for the operation of an automated drug distribution system.

Minnesota Statutes §151.58, subd. 4 requires a managing pharmacy to provide the board with written notification of the address at which the automated drug distribution system will be located, the manufacturer and model of the automated drug distribution system, and written policies and procedures that govern the operation of the system. This information must be provided at least 60 days prior to the initial use of an automated drug distribution system.

The P&Ps submitted by the managing pharmacy should address all underlined above and:

a. prepackaging / repackaging at pharmacy (review Current Good Manufacturing Procedures for guidance) [see Minnesota Rules 6800.2600, subp. 2 (A)], pharmacist certification

b. continuous electronic audio-visual monitoring of ADDS by pharmacy (trackability, how long) and availability of a pharmacist 24 hours/day, 7 days per week [see Minnesota Statutes §151.58, subd. 5 (f)], licensed nurse supervision or pharmacy monitoring of field service tech.

c. transportation of drugs from pharmacy to long-term care facility- including limited access, tamper-proof package, reconcile/record delivery

d. pharmacist employed by and working at the managing pharmacy, or at a pharmacy that is acting as a central services pharmacy for the managing pharmacy, pursuant to Minnesota Rules, part 6800.4075, must review, interpret, and approve all prescription drug orders before any drug is distributed from the system to be administered to a patient (new orders, order changes, discontinued meds, overrides, high alert drugs) [see MN Statute §151.58, subd. 5(c)(1); MN Rules 6800.2600, subp. 3(a)].

e. handling of controlled substances – at least monthly inventory, daily review of discrepancies [see MN Rules 6800.2600, subp. 3 (K)]

f. daily quality assurance documented – [see MN Rules 6800.3950, Subp.4.A.]

g. errors – review by interdisciplinary committee with documented corrective action

h. training – initial and ongoing, including documentation that individuals using the ADDS have received training

i. DEA registration if controlled substances distributed from ADDS (See 21 CFR Part 1301.27)

j. removal of drugs from ADDS and distribution to patient, labeling (USP 681) and who can perform these functions

k. access to ADDS [see Minnesota Statutes §151.58, subd. 5(B), MN Rules 6800.2600, subp.3 (A) & (B)], data (pt info, reports) and meds (cells, return bin)

l. define when certification occurs, as required by MN Rules 6800.3100, subp. 3

m. explain consultant pharmacist involvement (if applicable)

n. handling of wasted drugs, handling of discontinued drugs already packaged, return bin secured by pharmacy

o. location/environment – lighting, uncluttered work area, counter space, drug storage (temp, humidity)

p. outdates

q. quality assurance plan for machine

r. leave of absence meds