**Section 240.1543 Minimum Equipment Specifications for Automated Medication Dispenser Service**

a) An AMD unit/equipment must be capable of portability to be temporarily transferred to another non-institutional residence in Illinois without additional fees.

b) AMD Unit Specifications

1) The AMD unit must be a portable mechanical system configured with:

A) all the cords and interfaces needed for installation;

B) an internal battery:

i) capable of operating as a power source for a minimum of 3 years;

ii) that automatically charges whenever the base unit is powered; and

iii) maintains a charge for at least 12 hours when the electric power to the base unit is interrupted;

C) the ability to verify whether the batteries on the base unit are charged and when the battery charge is low;

D) components certified as appropriate by the Federal Communications Commission (FCC) under 47 CFR 15 and 68;

E) appropriate Underwriters Laboratories (UL) safety standards (UL 60950 and 60950-1) certification for battery powered technology equipment;

F) an integrated unit that connects to either a telephone line or wireless/cellular system that does not interfere with the normal use of the telephone or other devices using the telephone line, such as Emergency Home Response Service;

G) an Underwriters Laboratory (UL) approved plug as the connector to a standard residential electrical outlet for its power supply; and

H) transmission capability to signal the support center or notify the participant/authorized representative/assisting party if the base unit battery fails or has a low charge, or if electric power to the base unit is interrupted.

2) The AMD unit must have the following operating features:

A) ability to be loaded, programmed and changed to add and remove medications, including:

i) local or remote programming accessibility;

ii) medication dispensed at least 4 times a day; and

iii) alerting the participant at the times programmed for dispensing medication;

B) ability to be filled with medications, including:

i) holding at least 7 days' supply of medications;

ii) holding multiple medications in individual compartments;

iii) access to medication for an early dose option; and

iv) locking after the medication is loaded;

C) ability to alert the participant when it is time to take medications at least every 5 to 10 minutes for at least 60 minutes until the dose is taken or the dose is locked, including:

i) using verbal, auditory or visual prompts such as flashing lights and audible tones or verbal instructions, which may also provide messages to take medication that cannot be stored in the machine (e.g., take medications with food; time to take insulin) based on the individual's needs; and

ii) dispensing medications at the correct time of day in the correct combinations and in the correct quantities;

D) use privacy-protected and secure methods of communication with the participant/authorized representative/assisting party, including:

i) notification when battery is low or unit is jammed, or if the participant has not taken the medication within 90 minutes after the prescribed time;

ii) contact by the unit or support center to the participant /authorized representative/assisting party to assure adherence or needed intervention; and

E) ability to securely transmit information and provide data to the participant/authorized representative/responsible party, the Department or its designees.

3) The AMD unit must be capable of conducting automatic battery testing and transmitting the results through the AMD unit to the support center on an ongoing basis.

4) If an AMD unit is a Class I medical device, the AMD unit is subject to the General Controls mandated by the Federal Food and Drug Administration, including provisions that relate to adulteration (21 USC 351); misbranding (21 USC 352); device registration and listing (21 USC 360); notification, including repair, replacement, or refund (21 USC 360h); records and reports (21 USC 360i); and restricted devices (21 USC 520(e)). In addition, the manufacturer of the device must fulfill requirements under 21 CFR 820.180 (Record keeping) and 820.198 (Complaint files). If an AMD unit has enhanced features, such as remote capability, it may be classified as a Class II medical device and must then meet applicable Special Controls under the FDA.

5) The AMD unit must have adaptations for operation by participants who have functional, hearing or visual impairments, and language barriers at no extra cost to the participants.

c) Support Center Specifications

1) The AMD support center must have back-up monitoring capacity to take over all medication dispenser notification functions, monitoring and technical support functions.

2) The AMD back-up monitoring center must be at a location different from the primary center, on a different power grid system, and on a different telephone trunk line.  It must have a back-up battery and electrical generating capacity, as well as telephone line and wireless/cellular system monitoring abilities. If the back-up center is in the same city as the support center, the AMD provider must provide assurances that back-up can be maintained in the event of a natural disaster.

3) All AMD support center and back-up center equipment, at a minimum, must:

A) monitor the AMD system for the receipt of incoming signals from an installed and programmed AMD unit in a participant's residence, including missed medication doses, power interruptions and outages, and test transmissions and fault conditions, on a continuous basis;

B) direct an appropriate response to the receipt of a signal immediately via texts/emails to the assisting party and other designees and call the assisting party and other designees within 90 minutes after missed medications and within 8 hours after power interruptions and outages;

C) provide technical support as required, 24 hours a day, 365 days a year;

D) identify each participant and simultaneously record all communication between the participant/authorized representative/assisting party and the support center, as applicable, for all signals, including missed medication doses, test transmissions and fault conditions;

E) display, print and archive the individual identifier, date, time, communication and response for each signal, test and fault condition, which must be maintained for at least a 3-year period of time for quality control and liability purposes;

F) have an uninterruptible power supply (UPS) back-up that will automatically take over system operation in the event electric power to the support center is interrupted, other type of malfunction occurs, or repairs are needed.  The back-up power supply must be sufficient to operate the entire system for a minimum of 7 calendar days;

G) have separate and independent primary and back-up systems, computer servers, databases, and other components to provide an uninterruptible monitoring system in the event of equipment malfunction;

H) perform self-diagnostic testing for malfunctions in the unit/equipment in a participant's residence and at the support center, and for fault conditions in the primary and back-up operating systems and power supply at the support center, that could interfere with receiving and responding to signals, such as non-operational AMD units, messages sent from the AMD unit to the participant/authorized representative/assisting party or designees without confirmation of receipt, telephone line outages, power loss, etc.;

I) capability to centrally generate medication compliance data and reports as requested by the Department;

J) have quality management systems that include tracking and trending of data, response times and dispositions; and

K) maintain appropriate certification by the FCC under 47 CFR 15 and 68, if applicable.

(Source: Amended at 44 Ill. Reg. 2780, effective January 29, 2020)