657—22.7 (124,155A) Emergency/first dose drug supply. In any facility registered with the board under Iowa Code chapter 124 that does not have an institutional pharmacy, drugs may be supplied in one or more emergency/first dose drug supply containers located at the facility, provided that the emergency/first dose drug supply meets the requirements of this rule. The use of drugs from the emergency/first dose drug supply shall be limited to authorized personnel. The pharmacy supplying the emergency/first dose drug supply is responsible for verifying the qualifications of the facility.

22.7(1) *Emergency/first dose drug supplies.* Contents of the emergency/first dose drug supply shall be provided by a primary provider pharmacy designated by the facility, and the drug supply shall be available to meet the needs of all patients of the facility, without penalty or discrimination. If the primary provider pharmacy does not supply or is unable to supply all drugs and products needed for the emergency care of facility patients, a second provider pharmacy may provide an emergency/first dose drug supply consisting only of drugs and products not stocked or available from the primary provider pharmacy including, but not limited to, parenteral or compounded drug products. The provider pharmacies shall be properly registered with the federal Drug Enforcement Administration (DEA) and the board and shall be currently licensed by the board. The provider pharmacist or pharmacists, the consultant pharmacist, the director of nursing of the facility, and the medical director of the facility, or their respective designees, shall jointly determine and prepare a list of drugs necessary for prompt use in patient care that will be available in each emergency/first dose drug supply. Drugs shall be listed by identity and quantity, shall be limited to drugs necessary to meet the emergency needs of the patients served, and shall be periodically reviewed pursuant to policy. Careful patient planning should be a cooperative effort between the pharmacies and the facility to make drugs available, and emergency/first dose drug supplies shall only be used for emergency or unanticipated needs. The intent of the emergency/first dose drug supply is not to relieve a pharmacy of the responsibility for timely provision of a patient's routine drug needs and is not intended to relieve any provider pharmacy from the provider pharmacy's responsibility to provide 24-hour services to facility patients; the intent is to ensure that a supply of drugs is available to each patient in case of urgent need. The drugs in emergency/first dose drug supplies are the responsibility of the respective provider pharmacy and, therefore, shall not be used or altered in any way except as provided in this rule.

22.7(2) *Storage.* The emergency/first dose drug supply shall be stored in an area suitable to prevent unauthorized access and to ensure a proper environment for preservation of drugs contained therein as required in official compendia. The provider pharmacist is responsible for establishing procedures to maintain the security of the emergency/first dose drug supply.

22.7(3) *Labeling—exterior.* The exterior of an emergency/first dose drug supply shall be labeled clearly and shall unmistakably indicate that it is an emergency/first dose drug supply. Such label shall also contain a listing of the name, strength, and quantity of each drug contained therein and an expiration date of the supply based upon the earliest expiration date of any drug contained in the supply.

22.7(4) *Labeling—interior.* All drugs contained in the emergency/first dose drug supply shall be labeled in accordance with subrule 22.3(2) or 22.1(3), as appropriate.

22.7(5) *Removal of drugs.* A drug shall be removed from the emergency/first dose drug supply only pursuant to a valid prescription order and by authorized personnel or by the provider pharmacist. The patient's dispensing pharmacy shall be notified, prior to the administration of a second dose, that a drug was administered to a specific patient. Upon notification, the dispensing pharmacist shall perform drug use review to assess the appropriateness of the drug therapy for the patient. If the emergency/first dose drug supply contains a multidose package of a drug product that is removed from the supply for administration of one or more doses of the product to a patient and if following that administration the package contains one or more additional doses of the drug product and if the prescriber authorizes continuation of the drug product for that patient, the provider pharmacy shall complete either of the following processes.

a. Prepare and affix to the multidose package a label in compliance with rule 657—23.11(124,155A). The label shall be prepared and affixed to the package within 24 hours of administration of the emergency dose or doses.

b. Dispense, pursuant to a valid prescription order and in compliance with rule 657—23.11(124,155A), an appropriately labeled supply of the drug for the patient. The new prescription shall be delivered to the facility within 24 hours of administration of the emergency dose or doses.

22.7(6) *Notifications.* Whenever an emergency/first dose drug supply is opened or has expired, the provider pharmacy shall be notified and the pharmacist shall be responsible for replacing the drug within 72 hours to prevent risk of harm to patients. Pursuant to rule 657—8.3(155A), established policies and procedures shall address notification, record keeping, and documentation procedures for use of the supply.

22.7(7) *Procedures.*

a. The pharmacy, in communication with the director of nursing of the facility and the medical director of the facility, or their respective designees, and as provided in rule 657—8.3(155A), shall have written policies and procedures to ensure compliance with this rule.

b. The provider pharmacy shall keep a record of each prescription drug stored in the emergency/first dose drug supply and the number of doses provided.

c. The facility shall keep a complete record of the use of prescription drugs from the emergency/first dose drug supply for two years following such use. The record shall include the patient's name, the date of use, the name of the drug used, the strength of the drug, the number of doses used, the name of the prescriber authorizing the administration, and the initials or unique identification of the person administering the dose.

d. The drugs maintained in the emergency/first dose drug supply shall be available for the emergency pharmaceutical care of all facility patients, without penalty or discrimination. If a service charge is assessed for the administration of a drug from the emergency/first dose drug supply, the same reasonable service charge shall be assessed to each patient to whom a drug from the emergency/first dose drug supply is administered, regardless of the patient's choice of pharmacy for pharmaceutical services.

This rule is intended to implement Iowa Code sections 124.301, 124.306, 155A.13, and 155A.15.

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