

657—11.13(124,147A,155A) Storage. Prescription drugs at primary program sites and program substations shall be stored in designated secure areas that are clean and free of debris, where temperature is appropriately controlled, and in a manner to protect identity and integrity.

11.13(1) Temperature. Each drug shall be stored within the temperature range required in the manufacturer labeling. The service program shall utilize a method to provide continuous temperature control or monitoring, such as a temperature indicator, which at a minimum identifies when the drugs have been exposed to extreme temperatures. The service program shall regularly, but at least weekly, verify and document verification that the drugs have not been exposed to extreme temperatures. Drugs that are subjected to extreme temperatures shall not be administered to patients and shall be quarantined and returned to the responsible individual for disposition. Extreme temperatures shall be defined as excessive heat greater than 40 degrees Celsius (104 degrees Fahrenheit) and, if the product requires protection from freezing temperatures, excessive cold less than -10 degrees Celsius (13 degrees Fahrenheit). Disposition of unusable drugs shall be in compliance with rule 657—11.32(124,147A,155A).

11.13(2) Security. The security of prescription drugs, records for such drugs, and patient records is the responsibility of the responsible individual and shall provide for the effective control against theft of, diversion of, or unauthorized access to drugs and records. Policies shall identify procedures that will utilize or require the signature of two service employees for each disbursement to ensure accountability for controlled substances.

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