

481—554.7(155A) Standards for limited distributors.

554.7(1) *Examination of materials.* Limited distributors will ensure, upon receipt and prior to distribution, that a drug or device is suitable for distribution.

554.7(2) *Verification.* Orders will be verified, prior to distribution, to ensure that the drug or device being distributed matches the order.

554.7(3) *Instructions for use.* When a drug or device is distributed pursuant to a prescription order, the patient or patient's caregiver will be provided adequate instructions for use.

554.7(4) *Transaction records.* Each party to a transaction for the transfer of prescription drugs or devices will maintain documentation that includes the:

a. Source of the drugs or devices, including the name and address of the seller and the address of the location from which the drugs or devices were distributed.

b. Identity and quantity of the drugs or devices distributed. Medical gas prescriptions are valid for no more than 13 months.

c. Date of distribution.

d. Identity of the purchaser, including the name and address of the purchaser and the address of the location to which the drugs or devices were distributed.

554.7(5) *Prescription order records.* Each prescription for which a prescription drug or device is distributed will be maintained in the original format received.

554.7(6) *Patient confidentiality.* Any patient information in the possession of a limited distributor will be maintained in a secure and confidential manner.

[ARC 9340C, IAB 6/11/25, effective 7/16/25; see Delay note at end of chapter]