10A NCAC 13F .1003 is amended with changes as published in 29:08 NCR, pp. 907-909 as follows:

10A NCAC 13F .1003 MEDICATION LABELS

(a) Labeling of ~~Prescription~~ prescription legend ~~medications~~ medications, except for medications prepared for a resident's leave of absence in accordance with Rule .1010(d)(4) of this Section, shall ~~have a~~ be legible {~~printed~~} ~~label~~ and include ~~with~~ the following information:

(1) the name of the resident for whom the medication is prescribed;

(2) the most recent date of issuance;

(3) the name of the prescriber;

(4) the name and concentration of the medication, quantity dispensed, and prescription serial number;

(5) ~~directions for use stated and not abbreviated;~~ unabbreviated directions for use stated;

(6) a statement of generic equivalency shall be indicated if a brand other than the brand prescribed is dispensed;

(7) the expiration date, unless dispensed in a single unit or unit dose package that already has an expiration date;

(8) auxiliary ~~statements~~ information as required of the medication;

(9) the name, ~~address~~ address, and telephone number of the dispensing pharmacy; and

(10) the name or initials of the dispensing pharmacist.

(b) For medication systems ~~such as med paks and multi-paks when~~ in which two or more prescribed solid oral dosage forms are packaged and dispensed together, labeling shall be in accordance with Paragraph (a) of this Rule and the label or package shall also have a physical description or identification of each medication contained in the package.

(c) The facility shall assure any changes in directions of a resident's medication by the prescriber are on the container ~~is relabeled by a licensed pharmacist or a dispensing practitioner~~ at the refilling of the medication ~~when there is a change in the directions by the prescriber.~~ by the pharmacist or dispensing practitioner. The facility shall have a procedure for identifying direction changes until the container is correctly ~~labeled.~~ labeled in accordance with Paragraph (a) of this Rule. No person other than a licensed pharmacist or dispensing practitioner shall alter a prescription label.

(d) Non-prescription medications shall have the manufacturer's label with the expiration date visible, unless the container has been labeled by a licensed pharmacist or a dispensing ~~practitioner.~~ practitioner in accordance with Paragraph (a) of this Rule. Non-prescription medications in the original manufacturer's container shall be labeled with at least the resident's name and the name shall not obstruct any of the information on the container. Facility staff may label or write the resident's name on the container.

(e) Medications, prescription and non-prescription, shall not be transferred from one container to another except when prepared for a resident's leave of absence or administration to a resident.

~~(f) Prescription medications leaving the facility shall be in a form packaged and labeled by a licensed pharmacist or a dispensing practitioner. Non-prescription medications that are not packaged or labeled by a licensed pharmacist or dispensing practitioner must be released in the original container and directions for administration must be provided~~

~~to the resident or responsible party. The facility shall assure documentation of medications, including quantity released and returned to the facility.~~

History Note: *Authority G.S. ~~131D-2~~ 131D-2.16; 131D-4.5; 143B-165;*
Eff. July 1, ~~2005~~. 2005;
Amended Eff. April 1, 2015.

2

10A NCAC 13F .1010 is amended with changes as published in 29:08 NCR, pp. 907-909 as follows:

10A NCAC 13F .1010 PHARMACEUTICAL SERVICES

(a) An adult care home shall allow the residents the right to choose a pharmacy provider as long as the pharmacy ~~will~~ provides services that are in ~~compliance with~~ accordance with requirements of this Section and all applicable state and federal regulations and the facility's medication management policies and procedures.

(b) There shall be a current, written agreement with a licensed pharmacist or a prescribing practitioner for pharmaceutical care services ~~according to~~ in accordance with Rule .1009 of this Section. The written agreement shall include a statement of the responsibility of each party.

(c) The facility shall assure the provision of pharmaceutical services to meet the needs of the residents including procedures that assure the accurate ordering, receiving and administering of all medications prescribed on a routine, emergency, or as needed basis.

(d) The facility shall assure the provision of medication for residents on temporary leave from the facility or involved in day activities out of the facility. {~~Medications prepared for a resident's temporary leave of absence shall be packaged in a manner that facilitates safe administration and enables the resident or resident's responsible person to identify the correct medication and correct administration time for each medication. The amount of medications necessary to cover the duration of the resident's absence may be taken from the supply of medication already dispensed to the resident and prepared by a medication aide, or licensed health professional with authority to administer or dispense medications. The following information for each medication prepared for the resident's absence shall be provided verbally and in writing to the resident or the person who is designated as the resident's responsible person during the absence:~~

~~(1) the name and strength of the drug;~~

~~(2) the directions for administration as prescribed by the resident's physician; and~~

~~(3) any cautionary information from the original prescription package.~~

~~For medications removed from the resident's supply of medications, the name of the resident and the information provided in Subparagraphs (1) and (2) shall be provided directly on the container containing the medication. The facility shall maintain documentation of medications provided for the resident's leave of absence, including the quantity released from the facility, the quantity returned to the facility, and the name of the individual who prepared the medication for the resident's leave of absence.~~}

The facility shall have written policies and procedures for a resident's temporary leave of absence. The policies and procedures shall facilitate safe administration by assuring that upon receipt of the medication for a leave of absence the resident or the person accompanying the resident is able to identify the medication, dosage, and administration time for each medication provided for the temporary leave of absence. The policies and procedures shall include at least the following provisions:

(1) The amount of resident's medications provided shall be sufficient and necessary to cover the duration of the resident's absence. For the purposes of this Rule, sufficient and necessary means the amount of medication to be administered during the leave of absence or only a current dose

pack, card, or container if the current dose pack, card, or container has enough medication for the planned absence;

(2) Written and verbal instructions for each medication to be released for the resident's absence shall be provided to the resident or the person accompanying the resident upon the medication's release from the facility and shall include at least:

(A) the name and strength of the medication;

(B) the directions for administration as prescribed by the resident's physician;

(C) any cautionary information from the original prescription package if the information is not on the container released for the leave of absence;

(3) The resident's medication shall be provided in a capped or closed container that will protect the medications from contamination and spillage; and

(4) Labeling of each of the resident's individual medication containers for the leave of absence shall be legible, include at least the name of the resident and the name and strength of the medication, and be affixed to each container.

The facility shall maintain documentation in the resident's record of medications provided for the resident's leave of absence, including the quantity released from the facility and the quantity returned to the facility. The documentation of the quantities of medications released from and returned to the facility for a resident's leave of absence shall be verified by signature of the facility staff and resident or the person accompanying the resident upon the medications' release from and return to the facility.

(e) The facility shall assure that accurate records of the receipt, ~~use~~ use, and disposition of medications are maintained in the facility and ~~readily~~ available upon request for review.

(f) A facility with 12 or more beds shall have a current, written agreement with a pharmacy provider for dispensing services. The written agreement shall include a statement of the responsibility of each party.

History Note: *Authority G.S. ~~131D-2~~ 131D-2.16; 131D-4.5; 143B-165;*
Eff. July 1, ~~2005.~~ 2005;
Amended Eff. April 1, 2015.

10A NCAC 13G .1003 is amended with changes as published in 29:08 NCR, pp. 907-909 as follows:

10A NCAC 13G .1003 MEDICATION LABELS

(a) Labeling of ~~Prescription~~ prescription legend ~~medications~~ medications, except for medications prepared for a resident's leave of absence in accordance with Rule .1010(d)(4) of this Section, shall ~~have a~~ be legible {~~printed~~} ~~label~~ and include ~~with~~ the following information:

(1) the name of the resident for whom the medication is prescribed;

(2) the most recent date of issuance;

(3) the name of the prescriber;

(4) the name and concentration of the medication, quantity dispensed, and prescription serial number;

(5) ~~directions for use stated and not abbreviated;~~ unabbreviated directions for use stated;

(6) a statement of generic equivalency shall be indicated if a brand other than the brand prescribed is dispensed;

(7) the expiration date, unless dispensed in a single unit or unit dose package that already has an expiration date;

(8) auxiliary ~~statements~~ information as required of the medication;

(9) the name, ~~address~~ address, and telephone number of the dispensing pharmacy; and

(10) the name or initials of the dispensing pharmacist.

(b) For medication systems ~~such as med paks and multi-paks when~~ in which two or more prescribed solid oral dosage forms are packaged and dispensed together, labeling shall be in accordance with Paragraph (a) of this Rule and the label or package shall also have a physical description or identification of each medication contained in the package.

(c) The facility shall assure any changes in directions of a resident's medication by the prescriber are on the container ~~is relabeled by a licensed pharmacist or a dispensing practitioner~~ at the refilling of the medication ~~when there is a change in the directions by the prescriber.~~ by the pharmacist or dispensing practitioner. The facility shall have a procedure for identifying direction changes until the container is correctly ~~labeled.~~ labeled in accordance with Paragraph (a) of this Rule. No person other than a licensed pharmacist or dispensing practitioner shall alter a prescription label.

(d) Non-prescription medications shall have the manufacturer's label with the expiration date visible, unless the container has been labeled by a licensed pharmacist or a dispensing ~~practitioner.~~ practitioner in accordance with Paragraph (a) of this Rule. Non-prescription medications in the original manufacturer's container shall be labeled with at least the resident's name and the name shall not obstruct any of the information on the container. Facility staff may label or write the resident's name on the container.

(e) Medications, prescription and non-prescription, shall not be transferred from one container to another except when prepared for a resident's leave of absence or administration to a resident.

~~(f) Prescription medications leaving the facility shall be in a form packaged and labeled by a licensed pharmacist or a dispensing practitioner. Non-prescription medications that are not packaged or labeled by a licensed pharmacist or dispensing practitioner must be released in the original container and directions for administration must be provided~~

~~to the resident or responsible party. The facility shall assure documentation of medications, including quantity released and returned to the facility.~~

~~Note: Dispensing of medications is restricted to pharmacists or other health care practitioners that are approved by the North Carolina Board of Pharmacy. Repackaging or providing more than one dose of a prescription medication, including unit dose prescription medications, for subsequent administration is an act of dispensing.~~

History Note: *Authority G.S. ~~131D-2~~ 131D-2.16; 131D-4.5; 143B-165;~~S.L. 1999-0334~~*
Temporary Adoption Eff. December 1, 1999;
Eff. July 1, ~~2000.~~ 2000;
Amended Eff. April 1, 2015.

10A NCAC 13G .1010 is amended with changes as published in 29:08 NCR, pp. 907-909 as follows:

10A NCAC 13G .1010 PHARMACEUTICAL SERVICES

(a) A family care home shall allow the residents the right to choose a pharmacy provider as long as the pharmacy ~~will~~ provides services that are in ~~compliance with~~ accordance with requirements of this Section and all applicable state and federal regulations and the facility's medication management policies and procedures.

(b) There shall be a current, written agreement with a licensed pharmacist or a prescribing practitioner for pharmaceutical care services ~~according to~~ in accordance with Rule .1009 of this Section. The written agreement shall include a statement of the responsibility of each party.

(c) The facility shall assure the provision of pharmaceutical services to meet the needs of the residents including procedures that assure the accurate ordering, receiving and administering of all medications prescribed on a routine, emergency, or as needed basis.

(d) The facility shall assure the provision of medication for residents on temporary leave from the facility or involved in day activities out of the facility. {~~Medications prepared for a resident's temporary leave of absence shall be packaged in a manner that facilitates safe administration and enables the resident or resident's responsible person to identify the correct medication and correct administration time for each medication. The amount of medications necessary to cover the duration of the resident's absence may be taken from the supply of medication already dispensed to the resident and prepared by a medication aide, or licensed health professional with authority to administer or dispense medications. The following information for each medication prepared for the resident's absence shall be provided verbally and in writing to the resident or the person who is designated as the resident's responsible person during the absence:~~

~~(1) the name and strength of the drug;~~

~~(2) the directions for administration as prescribed by the resident's physician; and~~

~~(3) any cautionary information from the original prescription package.~~

~~For medications removed from the resident's supply of medications, the name of the resident and the information provided in Subparagraphs (1) and (2) shall be provided directly on the container containing the medication. The facility shall maintain documentation of medications provided for the resident's leave of absence, including the quantity released from the facility, the quantity returned to the facility, and the name of the individual who prepared the medication for the resident's leave of absence.~~}

The facility shall have written policies and procedures for a resident's temporary leave of absence. The policies and procedures shall facilitate safe administration by assuring that upon receipt of the medication for a leave of absence the resident or the person accompanying the resident is able to identify the medication, dosage, and administration time for each medication provided for the temporary leave of absence. The policies and procedures shall include at least the following provisions:

(1) The amount of resident's medications provided shall be sufficient and necessary to cover the duration of the resident's absence. For the purposes of this Rule, sufficient and necessary means the amount of medication to be administered during the leave of absence or only a current dose

pack, card, or container if the current dose pack, card, or container has enough medication for the planned absence;

(2) Written and verbal instructions for each medication to be released for the resident's absence shall be provided to the resident or the person accompanying the resident upon the medication's release from the facility and shall include at least:

(A) the name and strength of the medication;

(B) the directions for administration as prescribed by the resident's physician;

(C) any cautionary information from the original prescription package if the information is not on the container released for the leave of absence;

(3) The resident's medications shall be provided in a capped or closed container that will protect the medications from contamination and spillage; and

(4) Labeling of each of the resident's individual medication containers for the leave of absence shall be legible, include at least the name of the resident and the name and strength of the medication, and be affixed to each container.

The facility shall maintain documentation in the resident's record of medications provided for the resident's leave of absence, including the quantity released from the facility and the quantity returned to the facility. The documentation of the quantities of medications released from and returned to the facility for a resident's leave of absence shall be verified by signature of the facility staff and resident or the person accompanying the resident upon the medications' release from and return to the facility.

(e) The facility shall assure that accurate records of the receipt, ~~use~~ use, and disposition of medications are maintained in the facility and ~~readily~~ available upon request for review.

History Note: *Authority G.S. ~~131D-2~~ 131D-2.16; 131D-4.5; 143B-165;*
Eff. July 1, ~~2005.~~ 2005;
Amended Eff. April 1, 2015.