North Carolina Department of Health and Human Services
Division of Health Service Regulation

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April 9, 2015

MEMORANDUM

TO: N.C. Adult Care Home & Family Care Home Providers
Directors, N.C. County Departments of Social Services
Supervisors, Adult Services, N.C. County Departments of Social Services
Adult Home Specialists, Adult Services, N.C. County Departments of Social Services

FROM: Megan Lamphere, MSW
Section Chief, DHSR Adult Care Licensure Section

RE: Amended Licensure Rules 10A NCAC 13F & 13G .1003 and .1010
(*Regarding medications for a resident's leave of absence*)

Effective April 1, 2015, the requirements for adult care and family care home facilities related to the provision of a resident's medications for a leave of absence (LOA) were amended. Specifically, the following rules have been amended:

10A NCAC 13F .1003 Medication Labels
10A NCAC 13F .1010 Pharmaceutical Services

10A NCAC 13G .1003 Medication Labels
10A NCAC 13G .1010 Pharmaceutical Services

The N.C. Medical Care Commission initiated these rule changes on September 12, 2014 and adhered to the requirements of the rule-making process set forth in G.S. 150B. The Commission welcomed and incorporated feedback on the rule changes from a variety of stakeholders, including facility representatives, pharmacists, and other interested parties.

The final rule amendments, as well as the rule-making process, may be found on the DHSR Rule Actions webpage at http://www.ncdhhs.gov/dhsr/rules/acls2014 . The rules without the changes noted in the text of the rule are attached to this memo and will eventually be available on-line in the N.C. Administrative Code at http://reports.oah.state.nc.us/ncac .

In addition, the Adult Care Licensure Section has updated an optional form that has been available for providers to use when releasing a resident's medication for a LOA. Again, this form is optional. The form may be completed electronically, then printed out for signature by the staff and resident or person accompanying the resident on the LOA. We hope that facilities will find this form useful. The form can be found on the ACLS website at http://www.ncdhhs.gov/dhsr/acls/pdf/medreleaseform.pdf .

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10A NCAC 13F .1003 MEDICATION LABELS

(a) Labeling of prescription legend medications, except for medications prepared for a resident's leave of absence in accordance with Rule .1010(d)(4) of this Section, shall be legible and include 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) 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 information as required of the medication;

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

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

(b) For medication systems 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 at the refilling of the medication by the pharmacist or dispensing practitioner. The facility shall have a procedure for identifying direction changes until the container is correctly 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 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.

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

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 provides services that are in 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 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. 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, and disposition of medications are maintained in the facility and 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-2.16; 131D-4.5; 143B-165;*
Eff. July 1, 2005;
Amended Eff. April 1, 2015.

10A NCAC 13G .1003 MEDICATION LABELS

(a) Labeling of prescription legend medications, except for medications prepared for a resident's leave of absence in accordance with Rule .1010(d)(4) of this Section, shall be legible and include 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) 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 information as required of the medication;

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

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

(b) For medication systems 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 at the refilling of the medication by the pharmacist or dispensing practitioner. The facility shall have a procedure for identifying direction changes until the container is correctly 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 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.

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

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 provides services that are in 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 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. 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:

(5) 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;

(6) 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:

(D) the name and strength of the medication;

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

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

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

(8) 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, and disposition of medications are maintained in the facility and available upon request for review.

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