

EXHIBIT D

Adult Care Homes

&

Family Care Homes

Medication Rules

10A NCAC 13F Licensing of Homes for the Aged & Infirm

10A NCAC 13G Licensing of Family Care Homes

DHSR Adult Care Licensure Section

Fiscal Impact Analysis

Permanent Rule Amendment without Substantial Economic Impact

Agency: North Carolina Medical Care Commission

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Impact: State government impact: No
Local government: No
Federal government Impact: No
Substantial economic impact: No

Authorizing Statutes: G.S. 131D-2.16; 131D-4.5; 143B-165

Introductory Note:

The rules have been amended to allow adult care homes (adult care homes of more than six beds and family care homes) to package medications needed for a resident in a leave of absence from the facility instead of only being able to send one dose of each medication with the resident, sending all of the medication with the resident, or having a dispensing practitioner package the amount of medications needed for the leave of absence. It is not unusual for some adult care home residents to take a leave of absence for several days during which time they need to continue their medication regimen. It can be difficult for facilities to get specific amounts of medications for a resident's leave repackaged by a pharmacy due to distance and time factors. Some pharmacies will not repackage. The other alternative has been to send all the resident's medications with the resident or responsible party, but this creates resident health and safety concerns since the facility is no longer accountable for the medications as well as their administration. The amended rule will make the process of sending the needed medications with the resident easier yet assuring accountability for the medications and promoting safety of the resident.

Summary of Changes:

10A NCAC 13F .1003 and 13G .1003 – amendment allows for transfer of medication(s) from one container to another by the facility in cases of a resident temporarily leaving the facility as opposed to only a dispensing practitioner being able to repackage or all the medications in original packaging having to be sent with resident.

10A NCAC 13F .1010 and 13G .1010 – amendment addresses how the medication(s) to be sent with the resident on leave is to be packaged and labeled, who can do the packaging and labeling, how the resident is to be informed about the medication and what documentation the facility must have.

Anticipated Fiscal Impact:

There would be no fiscal impact on federal, state and local governments.

The impact on private sector entities, namely adult care and family care home providers, would be minimal but cannot be quantified due to lack of data on numbers of residents leaving facilities temporarily and number of medications involved. There could be some cost savings to those facilities who have been getting pharmacies to repackage medications if they do not pass this cost along to the residents. Cost to facilities would be in the packaging they choose to use for medications to be released with the resident. The rules do not address what the packaging has to be, only that it has to be properly labeled.

1 10A NCAC 13F .1003 is proposed for amendment as follows:

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3 **10A NCAC 13F .1003 MEDICATION LABELS**

4 (a) Prescription legend medications shall have a legible printed label with the following information:

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

6 (2) the most recent date of issuance;

7 (3) the name of the prescriber;

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

9 (5) directions for use stated and not abbreviated;

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

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

14 (8) auxiliary statements as required of the medication;

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

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

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

20 (c) The facility shall assure the container is relabeled by a licensed pharmacist or a dispensing practitioner at the
21 refilling of the medication when there is a change in the directions by the prescriber. The facility shall have a procedure
22 for identifying direction changes until the container is correctly labeled. No person other than a licensed pharmacist
23 or dispensing practitioner shall alter a prescription label.

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

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

31 ~~(f) Prescription medications leaving the facility shall be in a form packaged and labeled by a licensed pharmacist or~~
32 ~~a dispensing practitioner. Non prescription medications that are not packaged or labeled by a licensed pharmacist or~~
33 ~~dispensing practitioner must be released in the original container and directions for administration must be provided~~
34 ~~to the resident or responsible party. The facility shall assure documentation of medications, including quantity~~
35 ~~released and returned to the facility.~~

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- 1 *History Note: Authority G.S. ~~131D-21~~131D-2.16; 131D-4.5; 143B-165;*
- 2 *Eff. July 1, 2005. 2005;*
- 3 *Amended Eff. March 1, 2015.*

1 10A NCAC 13F .1010 is proposed for amendment as follows:
2

3 **10A NCAC 13F .1010 PHARMACEUTICAL SERVICES**

4 (a) An adult care home shall allow the residents the right to choose a pharmacy provider as long as the pharmacy will
5 provides services that are in compliance with the facility's medication management policies and procedures.

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

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

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

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

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

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

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

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

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

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

Rules for: Adult Care Homes
Type of Rule: Permanent
MCC Action: Approve Rule

Exhibit D
8/28/2014



1 10A NCAC 13G .1003 is proposed for amendment as follows:

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3 **10A NCAC 13G .1003 MEDICATION LABELS**

4 (a) Prescription legend medications shall have a legible printed label with the following information:

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

6 (2) the most recent date of issuance;

7 (3) the name of the prescriber;

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

9 (5) directions for use stated and not abbreviated;

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

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

14 (8) auxiliary statements as required of the medication;

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

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

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

20 (c) The facility shall assure the container is relabeled by a licensed pharmacist or a dispensing practitioner at the
21 refilling of the medication when there is a change in the directions by the prescriber. The facility shall have a procedure
22 for identifying direction changes until the container is correctly labeled. No person other than a licensed pharmacist
23 or dispensing practitioner shall alter a prescription label.

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

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

31 ~~(f) Prescription medications leaving the facility shall be in a form packaged and labeled by a licensed pharmacist or~~
32 ~~a dispensing practitioner. Non-prescription medications that are not packaged or labeled by a licensed pharmacist or~~
33 ~~dispensing practitioner must be released in the original container and directions for administration must be provided~~
34 ~~to the resident or responsible party. The facility shall assure documentation of medications, including quantity~~
35 ~~released and returned to the facility.~~

Rules for: Family Care Homes

Type of Rule: Permanent

MCC Action: Approve Rule

Exhibit D

8/28/2014

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

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5 *History Note: Authority G.S. ~~131D-2~~131D-2.16; 131D-4.5; 143B-165; S.L. ~~1999-0334~~*

6 *Temporary Adoption Eff. December 1, 1999;*

7 *Eff. July 1, ~~2000~~. 2000;*

8 *Amended Eff. March 1, 2015.*

1 10A NCAC 13G .1010 is proposed for amendment as follows:
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3 **10A NCAC 13G .1010 PHARMACEUTICAL SERVICES**

4 (a) A family care home shall allow the residents the right to choose a pharmacy provider as long as the pharmacy will
5 provide services that are in compliance with the facility's medication management policies and procedures.

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

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

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

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

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

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

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

29 (e) The facility shall assure that accurate records of the receipt, use and disposition of medications are maintained in
30 the facility and readily available for review.
31

32 *History Note: Authority G.S. 131D-2, 131D-2.16; 131D-4.5; 143B-165; S.L. 1999-0334;*

33 *Temporary Adoption Eff. December 1, 1999;*

34 *Eff. July 1, 2000;*

35 *Amended Eff. July 1, 2005- 2005;*

36 *Amended Eff. March 1, 2015.*