



NORTH CAROLINA ASSISTED LIVING ASSOCIATION

NCALA

3392 Six Forks Road
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Date: December 12, 2014

To: Members of the Medical Care Commission

Subject: Proposed amendments to the Adult Care Licensure rules, 10 A NCAC 13 F/G .1003 and 10 A NCAC 13 F/G .1010

I am commenting as Executive Director of the North Carolina Assisted Living Association (NCALA), whose members serve more than one hundred eighty assisted living communities and over fourteen thousand assisted living residents.

I appreciate the opportunity to comment on the proposed amendments to the Adult Care Licensure rules, 10 A NCAC 13 F/G .1003 and 10 A NCAC 13 F/G .1010

Comment A: Belief the proposed amendments to the current medication rules require unlicensed persons to dispense medication

NCALA members believe the proposed rule amendments conflict with current North Carolina General Statutes

§90-85.2 Legislative findings;

§90-85.3 (f) North Carolina Pharmacy Law and §90-85.40 Violations

MEDICINE AND ALLIED OCCUPATIONS

Article 4 A. North Carolina Pharmacy Practice Act. Part 1. North Carolina Pharmacy Practice Act.

§90-85.2. Legislative findings

The General Assembly of North Carolina finds that mandatory licensure of all who engage in the practice of pharmacy is necessary to insure minimum standards of competency and to protect the public from those who might otherwise present a danger to the public health, safety and welfare.

§90-85.3 Definitions:

(f) "Dispense" means preparing and packaging a prescription drug or device in a container and labeling the container with information required by State and federal law. Filling or refilling drug containers with prescription drugs for subsequent use by a patient is dispensing". Providing quantities of unit dose prescription drugs for subsequent administration is "dispensing".

§ 90-85.40. Violations

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- (a) It shall be unlawful for any owner or manager of a pharmacy or other place to allow or cause anyone other than a pharmacist to dispense or compound any prescription drug unless that person is a pharmacy technician or a pharmacy student who is enrolled in a school of pharmacy approved by the Board and is working under the supervision of a pharmacist. (b) Every person lawfully authorized to compound or dispense drugs shall comply with all the laws and regulations governing the labeling and packaging of such drugs by pharmacists.
- (c) It shall be unlawful for any person not licensed as a pharmacist to compound or dispense any prescription drug, unless that person is a pharmacy technician or a pharmacy student who is enrolled in a school of pharmacy approved by the Board and is working under the supervision of a pharmacist.

(h) A violation of this Article shall be a Class 1 misdemeanor. (1905, c. 108, ss. 4, 23, 24; Rev., ss. 3649, 3650, 4487; C.S., ss. 6667, 6668, 6669; 1921, c. 68, ss. 6, 7; Ex. Sess. 1924, c. 116; 1953, c. 1051; 1957, c. 617; 1959, c. 1222; 1981 (Reg. Sess., 1982), c. 1188, s. 1; 1993, c. 539, s. 621; 1994, Ex. Sess., c. 24, s. 14(c); 1993 (Reg. Sess., 1994), c. 692, s. 4; 2001-375, ss. 6, 7.)

As indicated in the History note of § 90-85.40, a violation of Article 4 A is a misdemeanor. Also please note this General Statute dates to 1905. If, for over 100 years, only registered pharmacists or pharmacy students, under the direction of a registered pharmacist, have been able to dispense drugs, why is it suddenly acceptable for an unlicensed individual to dispense drugs, as the amendments would propose?

Comment B: Reasons for proposed rule amendment.

The North Carolina Register Volume 29 Issue 08, 10/15/14, states that the reason for proposing changes to 10A NCAC 13F/G .1003 and .1010 is:

Reason for Proposed Action: *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.

NCALA strongly disagrees with the sentence taken from the above statement: *“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.”*

In fact, the amended rule creates significantly more health and safety concerns for the resident. The opportunity for human error is far greater when an individual other than those allowed in **MEDICINE AND ALLIED OCCUPATIONS Article 4 A**, repackage and re-label medications that have previously been prepared and filled by a registered pharmacist.

In our current regulatory system, reliable documentation demonstrates medication errors are the number one reason for citations of non-compliance in assisted living communities. Transcription errors caused by the inability to read, write legibility, and understand the physician’s directions are the most common reasons for medication citations and violations.

These errors will become exponentially higher, if unlicensed individuals are allowed to remove unit dose medications from properly filled and labeled containers, i.e. Bubble pack, cartridge, to another container which has to be properly labeled with instructions for administration.

Comment C: No fiscal note required by G.S. 150B-21.4, but there are costs associated with the change

Although there is no fiscal note required by G.S. 150B-21.4, there is cost incurred by Medicaid, Part D Medicare, and the privately paying individual if these rules are amended as proposed.

- a) Medicaid will pay for only one dispensing fee and that is at the time the pharmacist fills the order. It has been suggested the facility ask the pharmacist to package the Leave of Absence (LOA) supply of medications in advance of the resident going on leave. This is an additional service that costs the pharmacy in labor as well as costs the Medicaid program for additional medications.
- b) If the resident is on leave and only has medications for the allowed leave time, and the resident decides they want to stay longer, there are additional costs and logistics of procurement of medication that would have been



avoided if the resident had been provided with the original container of medications from the pharmacy.

- c) If the resident does not take all of the repackaged medications while on leave or returns early, those medications will have to be wasted because there is no way to return loose medications to a unit dose package. It would be unsafe for the facility staff to administer medication that had been out of their control for the period of leave time.

Conclusion:

NCALA members agree that it may be unsafe to send all the resident's medications with the resident or responsible party. It is not the policy of the NCALA communities to send all of the resident's medications with the resident on LOA. It is our policy to send only the container that has the necessary quantity of medication to meet the resident's LOA needs. For example: the resident has three bubble packs of one medication which is a 90 day supply, the facility would only send the card that has the amount of medication necessary for the LOA. There is not a need to send the entire 90 day supply.

NCALA members believe the current rules 10A NCAC 13F/G .1003 MEDICATION LABELS and .1010 PHARMACEUTICAL SERVICES should not be amended as proposed as they would compromise resident safety. Furthermore; we believe 10A NCAC 13F/G contains sufficient language as they are written provide the best protections of the health, safety and welfare of the resident. The rule as it is currently written requires, education of resident or responsible party along with the requirement the facility document LOA medications, including quantity released and quantity returned to the facility. Should the Commission insist in moving forward with this proposed amendment, then NCALA members request that the amendment include an exemption from any legal liability for assisted living communities and their contracting pharmacies for a resident's or the resident's family or designee's failure to comply with the changes in the event of an adverse resident reaction or death.

If the community fails to comply with rules 10A NCAC 13F/G .1003 and .1010, then the Department of Health and Human Services/Division of Health Service Regulation/ Adult Care Licensure has the authority to cite the facility for non-compliance.

Enforcing a regulation that is already in effect is far better than amending the regulation just because a few providers have not fully complied with the current rule.

Thank you for allowing NCALA and other providers to provide comment on the proposed medication rule amendments.



Respectfully,

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