Date: March 10, 2015
To: Rules Review Commission
Subject: Medical Care Commission approved Adult Care Licensure Rules, 10A NCAC 13F/G .1003 and .1010.

I am commenting as Executive Director of the North Carolina Assisted Living Association (NCALA), whose members serve more than 180 assisted living communities with more than 14,000 assisted living residents. I appreciate the opportunity to provide written comments on the Medical Care Commission-approved Adult Care Licensure Rules, 10A NCAC 13F/G .1003 and .1010.

We object to the approval of 10A NCAC 13F/G .1003 and .1010 rules on the basis of *necessity* and *clarity.*

Necessity—Comment A:
10A NCAC 13F/G .1003 MEDICATION LABELS
One of the agency's stated reasons for the changes made to .1003 (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"—is to make the process easier and safer (North Carolina Register, Volume 29, Issue 08). The process of removing a resident's medication from a properly labeled container—as required in .1003(a) (1-10) in the same rule—creates confusion, takes more medication-aide time, increases the probability of medication errors, and most definitely will cause resident harm.

The agency also stated that another reason for the changes made to .1003 is: "The other alternative has been to send all of the resident's medications with the resident or responsible party" (North Carolina Register, Volume 29, Issue 08).
The practice of sending all of the resident's medications home with the resident or responsible party is not founded in rule or general statute. If this happens, and if this process creates resident health and safety concerns, the agency has the authority to cite the facility.

The agency chose to change a perfectly good rule instead of focusing on the one community that did not provide adequate care and services as provided for in G.S. 131D-21 (2), "To receive care and services which are adequate, appropriate, and in compliance with relevant federal and state laws and rules and regulations."

The agency also has the authority to cite the community for failure to have written policies and procedures as required in 10A NCAC 13F/G .1211 (a) (1) WRITTEN POLICIES AND PROCEDURES.

Our understanding of the origination of the proposed changes to 10A NCAC 13F/G .1003 is one complainant who, it must be said, has legitimate concerns with the way one facility handled Leave of Absence medications for his family members on one occasion.

To our knowledge, a formal complaint was not made against the facility; therefore, there was not a proper investigation into the circumstance surrounding the complaint. It seems as though, instead of investigating a legitimate complaint, the agency made rule changes that adversely affect thousands of residents residing in Adult Care Homes. This rule change is unnecessary.

Necessity—Comment B:
10A NCAC 13F/G .1010 PHARMACEUTICAL SERVICES
The unnecessary changes made to .1010 (d) begin with line 29: "The facility shall have written policies and procedures for a resident's temporary leave of absence…"

The current rule in place—10A NCAC 13F/G .1211(a) (1) WRITTEN POLICIES AND PROCEDURES—requires the facility to have medication policies and procedures; therefore, adding the requirement for specific Leave of Absence policies in .1010 is unnecessary.

In addition, The Department of Health and Human Services, Division of Health Service Regulation, Adult Care Licensure Section, has published "Guidelines for the Development of Medication Administration Policies and Procedures," which include Medication for Leave of Absence (http://www.ncala.org/resources/Guidelines_for_the_Development_of_Medication_Administration_Policies_and_Procedures.pdf).

Also, a facility cannot be licensed in the state without the Adult Care Licensure Section completing a thorough review of the medication policies and procedures. The published guidelines are used to determine whether or not the facility's policies and procedures are acceptable.

There are sufficient rules in place to protect resident health and safety; therefore, the proposed changes made by the agency are unnecessary.

Clarity—Comment A:
10A NCAC 13F/G .1003 MEDICATION LABELS
The changes made to section (e) of this rule, lines 30-31, are unclear. The change allows for medications, prescription and non-prescription, to be transferred from a properly labeled container, as described in 10A NCAC 13F .1003 (a), to another, "when prepared for a resident's leave of absence or administration to a resident" [10A NCAC 13F (e)]. It does not describe how the second container is to be labeled. Therefore, the labeling of the second container is up to the discretion of the unlicensed medication aide removing the medications from a properly labeled container—prescription, non-prescription, and controlled substances—and can take many shapes and forms as illustrated in the photos found here: http://www.ncala.org/regulatory/med-management.html.

It is our belief that lines 30-36 of the 10A NCAC 13F .1003 (f), which has been stricken from the current rule or amended, is clearly written, and it provides protection for resident welfare and safety that the amended rule does not:

(e) Medications, prescription and non-prescription, shall not be transferred from one container to another except when prepared for 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.

Clarity—Comment B:
10A NCAC 13F/G .1010 PHARMACEUTICAL SERVICES

It is our belief that lines 30-34 of the amended document for .1010 are vague, unclear, and impossible for the facility to achieve within the guidelines of the amended language found on line 31 of 10A NCAC 13F .1003(d).

The facility cannot facilitate safe administration of medications—prescription, non-prescription, and controlled substances—that have been removed from a container labeled by a pharmacist, to another unidentified container labeled by an unlicensed medication aide. The expectation of the rule is not possible without increasing the possibility of serious harm to the resident.

The only way to assure "that upon receipt of the medication for a leave of absence the resident or resident's responsible person is able to identify the medication, the dosage, and the administration time for each medication provided for temporary leave of absence" (lines 31-33 of .1010), is to leave both .1003 and .1010 as they are currently written.

Thank you for providing the North Carolina Assisted Living Association an opportunity to provide comment on the proposed medication rule amendments.

Respectfully,

Frances L Messer

Frances Messer, RN, BSN, Adult Care Administrator
Executive Director
North Carolina Assisted Living Association
919-467-2486 frances@ncala.org

Guidelines for the Development of Medication Administration Policies and Procedures

The Rules for Adult Care Homes (Family Care and Adult Care Homes >7) require the facility to develop and implement medication administration policies and procedures with the assistance of a licensed health professional that is authorized to dispense or administer medications. Orientation of policies and procedures is to be provided to new staff responsible for medication administration prior to staff administering medications.

It is recommended that the following items be considered in developing a facility's policies and procedures for medication management. There are regulations pertaining to items with "*" and in ***bold italicized*** print.

1. **Policies and Procedures**
    a. Frequency of review/revision of policies and procedures
    b. ****Consultation with pharmacist, registered nurse or prescribing practitioner***
    c. ****Orientation of staff***

2. **Pharmacy Services (Dispensing Services)**
    a. Name of Pharmacy, address and phone numbers
    b. ****Contract (for homes licensed with 13 or more beds)***
    c. Hours of Operations
    d. Delivery Schedule
    e. ****Emergency Services e.g. use of back-up pharmacy or "after hours" pharmacy***
    f. Medication Delivery System (Quantities to be dispensed and description of delivery system, i.e., 7 day unit dose, 30 day punch card, 30 day loose pak, 30 day unit dose, etc.)
    g. ****Non-contract Pharmacy provider (e.g., resident using outside pharmacy)***

3. **Pharmaceutical Care Services (Consultant Services)**
    a. ****Frequency of reviews and inspections***
    b. ****Qualified health professional responsible for review***
    c. ****Description of what review will involve, e.g., review of records, observation of medication passes, inspection of medication storage areas, training/inservices for staff***
    d. ****Documentation of medication review for each resident and other responsibilities***
    e. ****Method of reporting discrepancies and recommendations from medication review***
    f. ****Methods of documenting action taken, follow-up to reports by facility, physician, etc.***
    g. Sample of forms used

4. **Medication Staff (Identify who can administer medications and qualifications required)**
    a. ****Qualifications of unlicensed staff***
        1. ****Validation of Medication Administration Checklist***
        2. ****Written exam***
        3. Other requirements, i.e., CNA or HS diploma, facility training
        4. ****Medication Administration Tasks under Licensed Health Professional Support (Refer to item 11c) 13F/13G .0504, e.g., Validation and documentation***
    c. ****Training/In-services***
        1. ****Insulin***
        2. ****Psychotropics***
        3. ****Required CE hours***
    d. ****Documentation and verification of qualifications – Where is it maintained ?***

5. **Methods used in receiving, recording, transcribing, maintaining and implementing of physician's written, verbal and telephone orders, including at least:**
    a. ***Elements of complete order***
    b. ***Clarification of orders, e.g. Documentation of clarification obtained***
    c. ***Psychotropic orders***
        1. ***Specific indications for administration***
        2. ***Clarification***
        3. ***Care Plan regarding administration***
        4. ***Training on administration and side effects, e.g., frequency and documentation***
    d. Verbal/telephone orders
        1. ***Procedures for taking verbal orders***
        2. ***Time lapse for obtaining prescribing practitioner's signature***
        3. ***Maintaining copy***
    e. Admission/transfer orders
        1. ***Verification of orders on FL-2, i.e., when and who is responsible and documentation of verification***
        2. ***Readmission orders***
    f. Physician Order Sheets, (if used)
        1. ***Frequency and review by facility***
        2. ***Signature of prescribing practitioner***
    g. Written medication orders
        1. Prescriptions
        2. Fax Orders
    h. ***Changes in medication orders, e.g., new orders and discontinuing orders***
    i. Orders for and from outside agencies, e.g., home health

6. **Ordering medications from pharmacy and documentation of same:**
    a. New orders
    b. ***Admission orders***
    c. Refills
    d. ***Emergency or "after hours" pharmacy***

7. **Time lapse for starting administration of new orders:**
    a. Emergency or stat orders
    b. Antibiotics
    c. Routine Medications
    d. ***Methods of legal borrowing of doses***

8. **Medications for leave of absence**
    a. ***Methods of providing medications, e.g., for one administration time and multiple administration times***
    b. ***Reconciliation of meds returned from leave of absence***
    c. ***Forms – Documentation and Retention or filing of forms***

9. **Receipt of medications**
    a. ***Security – Who is authorized to receive deliveries?***
    b. ***Verification of receipt from pharmacy, e.g., invoice, manifest, delivery sheet, etc.***
    c. ***Medications brought in at admission or by families, e.g., documentation, forms, etc.***
    d. ***Retention of records, e.g., by whom and for how long?***
    e. ***Reporting discrepancies***

10. **Medication labeling and packaging guidelines and requirements:**
    a. ***Prescription medications***
    b. ***Non-prescription medications***

c. ***House Stock medications***
d. Samples supplied by prescribing practitioner
e. ***Medication label errors***
f. ***Medication label changes***

11. **Medication Administration:**
    a. ***Prepouring (if allowed by your facility)***
        1. ***Medications allowed to be prepared in advanced***
        2. ***Storage of medications prepared in advance***
        3. ***Labeling and documentation***
    b. ***Medication Administration Record (MAR)***
        1. ***Methods of recording:***
            a. ***Routine doses (not PRN)***
            b. ***Omitted dose, refused doses, etc.***
            c. ***PRN doses (i.e., justification and response)***
            d. ***Signature equivalents of initials***
        2. ***Scheduled hours of administration (e.g., frequency and administration times - if order states tid – scheduled times may be 8am-12pm-4pm, or 9am-1pm-5pm, etc.; insulin and oral hypoglycemic medications; medications prescribed in accordance with meals, ac and pc)***
        3. ***Procedures for identifying of residents, i.e., photos***
    c. ***Step by step procedures for the administration of, including infection control:***
        1. ***Oral solid medications, e.g., tablets and capsules, oral liquids***
        2. ***Sublingual medications***
        3. ***Oral Inhalers***
        4. ***Eye drops and ointments, ear drops***
        5. ***Nose drops and Nasal sprays/inhalers***
        6. ***Topical or External medications, e.g., creams and ointments***
        7. ***Transdermal medications/patches***
        8. ***Nebulizers*****
        9. ***Suppositories**, i.e., vaginal and rectal***
        10. ***Enemas*****
        11. ***Injections**, i.e., infection control policies for syringes, site rotation and documentation***
            a. ***Insulin***
                1. Parameters for when to hold insulin and notification of supervisor or appropriate health professional
                2. Interventions for abnormal blood glucose readings
            b. ***Other subcutaneous medications***
        14. ***Gastrostomy Tube*****

(Above tasks with ** require validation by RN – Refer to LHPS rules 13F/13G .0903)

    d. ***Crushing of solid dosage forms***
        1. ***Physician's Order***
        2. ***Proper technique***
        3. Identification of medications that can not be crushed, e.g., Do Not Crush List
    e. ***Self-Administration***
        1. ***Physician's Order***
        2. ***Storage of medications***
        3. ***Monitoring of resident's ability to self-administer and documentation of monitoring, e.g., form and who is responsible for monitoring***
    f. Medications brought in by residents/families
        1. How they are handled, e.g., obtaining medications (new orders or refills), change in medications
        2. Labeling

g. ***Medication Administration Errors***
    1. Definition of medication error
    2. ***Methods of reporting and taking corrective action***
    3. Methods of analyzing
h. Steps to be taken, e.g., notification of supervisor or appropriate health professional, when routinely prescribed medications are frequently omitted, e.g. refused or unavailable and "prn" or "as needed" medications are frequently administered

12. Disposition of medications
    a. ***Release of medications to discharged residents, e.g., forms and documentation***
    b. ***Storage of medications for destruction or return to pharmacy***
    c. ***Methods of destruction***
        1. ***Omissions/Refusals or contaminated doses***
        2. ***Medications discontinued, expired or belonging to deceased resident***
    d. ***Staff or Health Professionals authorized to dispose of medications***
    e. ***Records of disposition and retention of records***
    f. ***Disposition of controlled substances***
        1. ***Omissions/Refusals or contaminated doses***
        2. ***Medications discontinued, expired or belonging to deceased resident***
    g. Disposition timeframes of special medications, e.g. insulin, Miacalcin, Xalatan, etc.

13. Medication storage
    a. ***Security***
    b. ***Internal and External Separation***
    c. Who has access to medication storage areas, i.e., authorization of keys?
    d. ***Refrigeration storage***
        1. ***Temperature***
        2. ***Separation of medications and food (when stored together)***
        3. Short expiration medications, e.g. insulin, Miacalcin, Xalatan, etc.
    e. ***Controlled Substances***
    f. ***Medications in residents' rooms***

14. Controlled Substances
    a. ***Method of accountability, i.e., declining count***
    b. ***Reporting discrepancies***
    c. ***Retention of records***
    d. ***Storage and security***

15. Quality Assurance (Methods of monitoring including frequency and staff and/or health professionals responsible for monitoring)
    a. Monitoring MARs
    b. Monitoring /observing actual act of medication administration
    c. Monitoring controlled substance accountability
    d. Monitoring medication storage
    e. Monitoring qualification of medication staff
    f. Monitoring medication reviews and follow-up
    g. Tracking or review of identified problem areas and corrective action

16. Accepted abbreviations
17. Tables of weights and measures conversion
18. References for staff