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March 17, 2015

Via Email Only
Members of the Rules Review Commission and
Ms. Amber Cronk May, Commission Counsel

Re: Response to Comments to 10A NCAC 13F/G .1003 and .1010

Dear Commissioners and Ms. May:

This letter is written on behalf of the North Carolina Department of Health and Human Services, Division of Health Service Regulation and the N. C. Medical Care Commission (the Agency). The Agency was copied on a letter sent to the N.C. Rules Review Commission dated March 10, 2015 from the North Carolina Assisted Living Association (NCALA) regarding proposed Permanent Amendment to Rules 10A NCAC 13F/G .1003 and .1010. As the rulemaking body for rules that govern the operations of adult and family care homes in North Carolina, it is very important for us to hear and consider the opinions and concerns of our stakeholders, including residents, family members of residents, as well as the provider community. We, too, share NCALA's concern for the safety and well-being of the residents served in adult care homes, and strive to adopt rules to ensure that this goal is achieved in the most resident-centered, efficient, and cost-effective manner possible.

The Agency has proposed amendments to the rules that deal with Leave of Absence (LOA) medications for residents in Adult Care Homes and Family Care Homes. The Agency believes the amendments are necessary for the safety of the resident. Under the current rules, a resident can leave a facility with excessive quantities of medication, including narcotic medications, creating numerous possibilities for safety concerns. Under the amended rules, a resident could leave the facility with a smaller quantity of medication (simply the amount sufficient to cover the duration of the LOA), lessening the risk of these safety issues occurring.

The Agency adhered to G.S. 150B and facilitated an open and transparent rulemaking process when drafting the amendments to the above mentioned rules. Ample opportunity for stakeholder and public comment has been provided and the majority of the comments received were incorporated into the rules. The proposed amendments were originally published in the N.C. Register on October 15, 2014. Following the public hearing, the Agency initiated a meeting with providers and long term care pharmacists which was held on January 16, 2015. As a result of that meeting and comments received at the public hearing, numerous changes were made to the rules before they were submitted to the Medical Care Commission on February 13,

2015. At the Commission meeting, stakeholders were invited again to share their comments and concerns with the Commission. No objections were raised at that time. The Commission (which includes several physicians, a nurse and a pharmacist) unanimously approved and adopted the proposed rules, which included the changes recommended by stakeholders.

On March 10, 2015, the NCALA submitted written comments to the N.C. Rules Review Commission. The NCALA has now objected to the proposed rules on the basis of necessity and clarity.

The NCALA stated that it feels that 10A NCAC 13F/G .1003 is not necessary to make the process for LOA medications easier and safer and instead feels the rule "most definitely will cause resident harm." The NCALA gave no specifics as to how it believed the rules would create confusion and the Agency does not feel the rules will create confusion. The NCALA stated that the proposed rules would take up medication aide time. The Agency believes a majority of the facilities will not be affected with the medication aide time. The facilities that will be affected will be minimally affected with the time which is outweighed by the safety created by the rules. The NCALA stated that the new rules will increase the probability of medication errors, however, with facility policies and procedures and staff properly trained on those procedures, there should be less medication error or harm to the resident during an LOA.

The standard for a rule to meet criteria under N.C. Gen Stat. § 150B-21.9(a)(3) is that it is "reasonable necessary" to implement or interpret an enactment of the General Assembly." A rule does not need to be a necessity to meet the standard. It must be reasonably necessary. The Agency has authority to promulgate 10A NCAC 13F/G .1003 and .1010 from N.C. Gen Stat. § 131D-2.16 which charges the Agency with considering, "the need to ensure comparable quality of services provided to residents" and ensuring "that supervision is appropriate and adequate to meet the special needs of these residents." The proposed rules are reasonably necessary to ensure quality of service is provided to a resident in relation to LOA medications in all types of adult and family care homes. The Agency believes the rules are appropriate and adequate to meet the needs of the residents in all adult and family care facilities across the state.

The NCALA further claims that 10A NCAC 13F/G .1003 and .1010 are not a necessity because medication for leave of absence is covered under the requirement for written policies and procedures from 10A NCAC 13F/G .1211. The NCLA stated that it believes there are sufficient rules in place to protect the health and safety of the resident. The Agency believes the proposed amendments to the rules go beyond the guidelines for policies and procedures by directing that policies and procedures must be written and written and verbal instructions for LOA medications should be provided to resident or responsible party to facilitate safe administration of the medications. The proposed rules provide an additional layer to help enable safety of the resident.

The NCALA has also commented on the clarity of the proposed amendments to the rules. The first concern is in reference to describing how the second container would be labeled for LOA medications. This concern is recognized by the Agency and the proposed rules have been amended to clarify and strengthen the language used to describe an acceptable container and manner of labeling the container for LOA medications. The NCALA provided a link to a

website in its comments to the Rules Review Commission with illustrations of possible problems. The illustrations in the link in the bottom two photographs depicting medications prepared in plastic baggies, mixed together, and labeled with a sticky note are not in compliance with the proposed rule and would not be an acceptable manner in which to prepare medications for a LOA. The proposed rule states that the resident or responsible party must be able to identify the medication, which in this case, one would not be able to do. Again, the Agency believes that the additional changes to the proposed rules provide the clarity and guidance to make this distinction and properly carry out the guidelines for LOA Medications.

The next written comment from the NCALA about clarity asserts that the language is vague, unclear, and impossible for the facility to achieve. No specifics about how the language was vague or unclear were provided. A general statement was made alleging that it is not safe for the facility to administer medications under the guidelines. It seems that this comment is not so much about clarity as it is about what is reasonable necessary. Again, the Agency believes the proposed rules are reasonably necessary to ensure quality of service is provided to a resident in relation to LOA medication and that the rules are appropriate and adequate to meet the needs of the residents.

Representatives from the Division of Health Service Regulation, Adult Care Licensure Section, and staff of the Medical Care Commission met with Ms. Frances Messer and Ms. Evelyn Hawthorne from the NCALA on March 11, 2015 to further discuss the association's concerns regarding the proposed rules. As a result of this meeting, the Agency made further revisions to the rules in an effort to provide clarification to ensure that facilities are able to facilitate safe administration of medications for a resident's leave of absence. These changes, which were submitted to the Rules Review Commission, have been sent via e-mail to the NCALA and other stakeholders for their consideration.

Also, as stated during the meeting with the NCALA on March 11, 2015, the Agency would like to reiterate the fact that the rules governing medication administration and leave of absence medications for adult care homes and family care homes must be applicable and reasonable for all facilities across North Carolina. As we know, there are many sizes of facilities, different resident populations, varying geographical locations, various levels of staff, and other challenges that individual providers face. The rules adopted by the Medical Care Commission must take into account all of these variances to ensure safety in all types of adult and family care homes.

The issues presented by the NCALA about clarity and necessity seem to be more about a difference of opinion as to what will create safety for the resident. For the reasons stated above, the Agency strongly believes that the proposed rules will create more safety and less harm for the resident. The Agency believes the proposed rules are clear and reasonably necessary, and that by including additional clarifying language to the proposed rules the NCALA will find the same. The North Carolina Long Term Care Facilities Association, which also represents a large number of adult and family care homes, has communicated that it does not have any objections to the proposed rules. The Agency asks that the Rules Review Commission determine that the proposed rules meet the standards outlined in N.C. Gen Stat. § 150B-21.9.

Thank you for your consideration in the matter. Do not hesitate to call me if you have any questions.

Thank you,

Bethany A. Burgon
Assistant Attorney General

Megan Lamphere, MSW
Chief, DHSR Adult Care Licensure Section

Jan Brickley, RPh
Lead Pharmacist, DHSR Adult Care Licensure Section

cc:
Dr. John Fagg, Chair, N.C. Medical Care Commission
Drexdal Pratt, Director, Division of Health Service Regulation
Frances Messer, Executive Director, NCALA
Rep. Marilyn Avila
Sen. Tamara Barringer