North Carolina Department of Health and Human Services
Division of Health Service Regulation
Office of the Director

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Drexdal Pratt
Division Director

MINUTES OF PUBLIC HEARING
DECEMBER 9, 2014
10:00 A.M.

Division Staff Present:

Nadine Pfeiffer, Rule-making Coordinator
Jan Brickley, Adult Care Licensure Section
Wendy Williams, Adult Care Licensure Section
Megan Lamphere, Chief, Adult Care Licensure Section

Others Present:

Frances Messer, NC Assisted Living Association
Lisa Russell, Kerr Health LTC Pharmacy
Keri Medlin, Kerr Health LTC Pharmacy
Mary Ann Drummond, Carillon Assisted Living
Karen Moriarty, Carillon Assisted Living

1. Purpose of Hearing

The purpose of this public hearing was to solicit verbal and /or written comments from the public on the proposed rule amendment of rules for the Licensing of Homes for the Aged and Infirm, 10A NCAC 13F .1003 and .1010; the Licensing of Family Care Homes, 10A NCAC 13G .1003 and .1010; and for the proposed repeal of 10A NCAC 13H, Licensing for Homes for Developmentally Disabled Adults, as published in the NC Register, Volume 29, Issue 8, issued on October 15, 2014.

2. Hearing Summary

The public hearing was opened by Nadine Pfeiffer at 10:00 a.m. Attending were representatives from NC Assisted Living Association, Kerr Health LTC Pharmacy and Carillon Assisted Living. A total of four oral comments were recorded in opposition of the rules. A summary of these comments is as follows:

1) Frances Messer with the NC Assisted Living Association (NCALA) stated that changing the rule would cause unlicensed persons to dispense medications. The basis of this was these statutes: GS 90-85.2 (NC Pharmacy Law), GS 90-85.3 (Definition of Dispensing) and GS 90-85.40 (Violations). Per statute, a

violation was a misdemeanor, has been in law for 100 years and was there for the safety of the resident. Per statute, unlicensed individuals repackaging and relabeling medications was "dispensing." Ms. Messer quoted the reasons posted in the NC Register for the proposed rule amendments and stated that NCALA disagreed that the amended rule would make the process easier yet assure accountability for medications and promote safety to the resident. The rules would create more safety concerns because of the increased opportunity for human error by allowing unlicensed persons to remove medications and repackage them. By saying "no fiscal note required" it would not meet the level required for a fiscal note, but there were costs associated with the rule change for Medicaid, Medicare and for private pay residents. It was NCALA's policy to just send the container of medications to meet the leave of absence needs. The rules should not be amended as rule changes would compromise resident safety. However, if they are amended, an exemption for legal liability for the assisted living community and pharmacists for residents or resident families for failure to comply in the event of adverse reaction or death should be added.

2) Lisa Russell with Kerr Health LTC stated that the 13F and 13G rules were in violation of the NC Pharmacy Practice Act in the filling or refilling of drug containers with prescription drugs for subsequent use by patients because that was dispensing. She explained statute G.S. 90-85.40 (Violations), and stated the rule amendments were an increased safety risk to patients and a liability issue. Kerr Health would never send a pharmacy label without knowing what medication it would be put on. (See attached comments)

3) Keri Medlin with Kerr Health LTC stated that medication aides being allowed to repackage medications generated safety concerns. Several safety concerns were listed and briefly described with examples which included the following: staff having no formal education on the task, the type of container to be used for the medications, transcription errors, pill identification, unused medication use and staff time needed for the task. (See attached comments)

4) Mary Ann Drummond with Carillon Assisted Living stated that they have not found it difficult to obtain medications for residents who go out on leave of absence (LOA). Their common practice was to send the current dose supply. They strongly disagree with the amended rules that claim to make the process of sending medications easier yet assuring accountability for medications and promoting safety of residents. There is great concern the unlicensed med tech would be asked to prepare medications for the resident on LOA and is concern about how the medications would be packaged, especially with the potential for medication mix-up. Individuals preparing, packaging, labeling medications other than pharmacists increase the risk for error. Carillon interpreted the rule amendments as "dispensing." If further security was needed in the rules, a requirement for facilities to send written interpretation of the medication and signature of verification of the information should be added. There is no payer source for out of cycle fill requests, as there are only one month fills for medications, and medications cannot be taken back to facilities. With person-centered care, it is difficult to respond to spontaneous requests for LOA. Carillon recommends the existing rules remain as written with the addition of language as suggested. (See attached comments)

These comments will be taken into consideration by the Agency. The hearing was adjourned at 10:35 a.m.

Respectfully Submitted,

Nadine Pfeiffer

Nadine Pfeiffer, Rule-making Coordinator
December 9, 2014

KERR HEALTH

Long Term Care Pharmacy

Comments Regarding Proposed Amendment of Adult Care Licensure Rules
10A NCAC 13F Licensing of Homes for the Aged and Infirm
10A NCAC 13G Licensing of Family Care Homes

Submitted by:
Lisa Russell, General Manager of Operations
Keri Medlin, PharmD, FASCP, Clinical Coordinator

Comment A:

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.

In our opinion, this is in violation of the North Carolina Pharmacy Practice Act which states that "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.

(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 prescription 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.

Comment B:

By allowing medication aides to repackage the medication there are many patient safety concerns:

- Education level and training of staff being requested to do this is not sufficient
- Medications not put in a spill proof container can be mixed with other medications
- The readability of the handwriting on the package
- The types of containers that may be used will not be standardized and could present risk to medication and to children or other people in the home
- Pill identification would be compromised once removed from the package
- Information from the label not transcribed correctly or completely
- Auxiliary labels may not transcribed- such as "Do Not Crush"
- What will be done with unused medication, will the facility be able to administer from this packaging?
- Time constraints of staff within the facility will lead to possible errors and/or medications being mixed or mislabeled.

Comments Regarding Proposed Amendment of Adult Care Licensure Rules

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

10A NCAC 13G Licensing of Family Care Homes

Submitted by: Mary Ann Drummond, RN

Vice President of Operations, Carillon Assisted Living

Comment A: Reasons for proposed rule amendment.

Upon review of the stated reason for the proposed rule, we find there is a lack of consensus in our industry regarding current practices to support some of the stated reason for change. Specifically, as written in the North Carolina Register Volume 29 Issue 08, 10/15/14, it states:

"The rules have been amended to allow adult care homes (adult care homes of more than six beds and family care comes) 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.***

Carillon Assisted Living serves in excess of 1000 assisted living residents per day in the state of North Carolina. While the numbers have grown since inception in 1997, we have not identified difficulties obtaining required medications when residents prepare for a leave of absence. In addition, we have never adopted a practice of sending all the resident's medications with the resident or the responsible party. In our interpretation, it would be neither prudent nor appropriate to send a full 90 day supply for a one or two week leave of absence.

Upon comparing policies with other providers we have found the current common practice is to issue a supply that is adequate to cover the leave of absence needs, which typically is limited to the current dose pack. Therefore, our first comment is that the specific reasons driving the need for this specific rule change are unclear to us as a provider of Adult Care Services.

It is also stated the amended rule will make the process of sending the needed medications with the resident easier yet assuring accountability for the medications and promoting the safety of the resident. We find this statement to not be applicable to our practice and procedures in that the process as outlined in the proposed rule amendment will add multiple steps to the preparation of medications for leave of absence that presently do not exist, and by staff that are much less qualified to perform those steps than the individuals who currently package and label the medications that are sent with residents who go on a leave of absence. Therefore, we do not believe that the amended rule as such will promote safety but rather have a potential negative impact on resident safety overall in regards to medication administration when on a leave of absence.

Comment B: Individuals preparing/packaging medications and labels other than pharmacists or licensed professionals.

In proposed language under 10A NCAC13F.1010 (d), It states Medications prepared for a resident's temporary leave of absence shall be packaged in a manner that facilitates safe administration and enables the resident or resident's responsible person to identify the correct medication and correct administration time for each medication.

In order to ensure "safe" administration the delivery system must ensure the same safeguards that a pharmacy provides for administration either in the assisted living or home administration settings. To veer from this course, essentially allowing unlicensed individuals to dispense medications, would increase the risk of harm to the residents served by our industry and increase risk to providers. We whole heartedly agree with the initial statement made in the above language of proposed rule, and support efforts to improve medication compliances for leave of absence scenarios, yet feel there has to be a better way to accomplish this than undoing a system that is universally recognized as appropriate in similar care settings in most states presently.

A solution we propose, without changing the existing rules that as an industry we feel continues to protect the overall safety of our residents, would be to add language such as:

The facility will provide written and verbal instructions listing the name, dose, strength, and next dose scheduled for each medication and review the medication regimen with the resident and their responsible person prior to the leave of absence. The resident and/or their responsible person will sign verification that the written review was discussed verbally with a facility staff member. Medications will be released in a quantity sufficient to cover the duration of the planned leave of absence, but shall not exceed a current dose pack/card/container if current container is sufficient for planned absence.

If language such as the above were added to the existing rule, we believe the initial intent of the rule amendment may be met without adding increased risk of harm or injury to residents served and/or increased risk for error to providers.

Comment C: Burden of cost to the resident and concerns regarding person centered care.

It has been stated that perhaps the long term care pharmacies could be the "solution" by filling requests for leave of absence medications, or preparing the labels in advance for communities. This is likely not a solution in that:

a) There is no payer source for out of cycle fill requests. Nearly all residents are either Medicaid, private insurance or Medicare D, all of which will not pay for an out of cycle fill request.
b) Most pharmacies will not prepare a label for a medication they have not personally packaged for safety reasons.
c) While some pharmacies have stated they might be willing to provide the labels, the person centered care component our industry is striving to achieve would be lost in this initiative as it would take at least 24 to 48 hours to turn around such requests. Residents would not be able to execute a "spontaneous" request to leave with a family member should they show up to take them on leave.

Conclusion:

In the interest of the overall welfare of the residents served by our industry as well as the ability of the provider to meet the intent of ensuring safe and effective means of medication administration by the resident and/or their responsible person when on leave of absence, we recommend the existing rules remain as written with the addition of language as referenced in "Comment C" of this document requiring the facility to review the medication regimen both verbally and in writing with the resident and their responsible party and issuing a quantity that is adequate to meet the needs of the planned leave of absence.

By removing 10A NCAC13F.1003 (f) (lines 31-35) from rule as currently proposed, we believe a component of integrity would be removed from the medication administration process. Presently a licensed pharmacist has prepared medications to be administered in appropriate containers with appropriate labels following a meticulous process approved by multiple layers of state and federally controlled rules and regulations in a licensed pharmacy following all relevant checks and protocols.

This process would be replaced and carried out by individuals who are neither pharmacists, nurses, or in many cases, Certified Nursing Assistants. While they have received training on how to administer medications from containers and/or dose packs that have been packaged and labeled by pharmacists, and have passed state exams and have been checked off by Licensed Practitioners as competent to administer medications, these individuals are in no way capable of performing at the level of a pharmacist.

The information as identified in section 10A NCAC 13F.1003 (a) 1-10 is the basic information we all find and enjoy on our prescription labels when we have our medications filled at any local pharmacy including the name of the medication, the name of our doctor that prescribed it, the dose, directions for administration and strength of the medication, any special instructions we should know such as don't take with milk or mix with 6 ounces of water or other auxiliary statements. There is also a name and number of the pharmacist who dispensed should we have questions. It is clearly typed and easily accessed. To think that Medication Aides would be able to duplicate all of this information with the accuracy required to ensure safe and effective medication administration occurs is unlikely in our industry as handwriting deficits alone cause reading errors, and then there will be issues related to the inevitable transcription errors which we know occur between nurses and doctors and are the number one reason for medication errors among licensed staff. I could not find data related to the error rate of unlicensed staff when re-packaging from labels to envelopes and such, as I could not find a relevant setting wherein this practice occurs, but it is feasible to assume the error rates would be higher than that of licensed staff

It is our strong recommendation that the current rules remain in place. If it is felt that it is necessary, they could be amended with an addition as recommended herein to add clarification of the medication regimen and address quantities issued at the time of leave. Any form of repackaging increases the risk for error regardless of who performs the function. That being said, one should remember that the multiple container options a facility might choose should repackaging come to fruition is concerning. What would happen if a child accessed an envelope filled with Coumadin? What if a resident spilled their "look-a-like" pills from a container and mixed them up with another pill, with the result being subsequent miss dosing? The potential risk to resident and provider is much too high with the proposed rule amendment as written, and simply not present in the existing rules.