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

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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.