

10A NCAC 13F Licensing of Homes for the Aged and Infirm/10A NCAC 13G Licensing of Family Care Homes
 Medication packaging for leave of absence - Public Comments

**Agency Response to Public
 Comments (Adult Care Homes &
 Family Care Homes Rules)**

Comment Period 10/15/14 – 12/15/14

Exhibit D/4

Commenter	Rule	Comment Summary	Agency Response
<p>Carillon Assisted Living, Mary Ann Drummond</p>		<p>They have not identified difficulties obtaining required medications when residents prepare for leave of absences and never adopted a practice of sending all the resident's medications with the resident or responsible party. The specific reasons driving the need for this specific rule change are unclear.</p> <p>The proposed amendment will add multiple steps to the preparation of medications for the leave of absence, therefore will have a negative effect on the resident safety overall with regards to medication administration on the leave of absence.</p>	<p>Adult care facilities differ not only in capacity and staffing but in residents' care needs or services. The agency has received multiple calls from providers over the years regarding the release of medications to residents, even when the resident is with the family or responsible parties. The concerns or calls were due to residents not returning with the medications released upon returning to facility. Residents would be without medications and most facilities would not obtain or unable to obtain an additional supply of medications; therefore, the resident would go without medications prescribed.</p> <p>In addition, the agency received a concern from a family member who was provided all of his parents' medications. Not only were there multiple medications prescribed, there were multiple packages for each medication. The quantity and manner the facility provided the medications for the leave of absence was a safety concern.</p> <p>Any additional tasks with medication administration may increase the incidence of errors. With medications released for leave of absence, there are safety issues that have to be considered with every manner or method of providing a resident's medications. The</p>

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		<p>Long-term care pharmacies are not a solution for filling requests for leave of absences because: a) there is no payer source for out of cycle fill requests; b) Most pharmacies will not prepare labels for medications they have not personally packaged for safety reasons; c) the industry's person centered care component would be lost in this initiative as it would take at least 24-48 hrs to turn around requests, thus spontaneous requests to leave would not be possible.</p> <p>Recommendation of keeping the rule as is and removing recommended changes. Deleting the language from (f) would remove a component of integrity from the medication administration process. The process would be replaced by individuals, likely CNAs, and while have been checked off by licensed practitioners as competent to administer medications, they are not capable of performing at the level of a pharmacist.</p>	<p>provide leave of absence medications and pharmacies should not provide labels for the facility to use. The provision of the pharmacy label may misrepresent the medication was prepared and dispensed by a pharmacist and the pharmacist could be responsible for medications released without any knowledge of medications prepared. There is no requirement in the proposed regulations to hinder the person centered care component. The proposed rules offer another option for providing leave of absence medications if needed for safety reasons.</p> <p>The proposed rules do not require the facility to have staff packaged the resident's medications for leave of absence. For facilities that elect to package medications for leave of absence will need to ensure qualified medication staff are trained on the facility's procedures and able to implement the facility's policies and procedures. The task of the medication staff, if performed, would be to remove the supply of resident's medication already dispensed by the pharmacy. The performing level of a pharmacist would not be expected or necessary since the medications have already been dispensed by the pharmacy for the resident. This is the same as with medication administration, there is no expectation that the performing level of medication aides be at the level of a registered nurse.</p>
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		<p>The information in (a) 1-10 is the basic information we all find and enjoy on our prescription labels. It is clearly typed and easily accessed. To think a Medication Aide would be able to duplicate all of this information with the accuracy required to ensure safe and effective medication administration is unlikely in our industry due to handwriting and transcription errors. It is feasible to assume error rates would be higher than that of licensed staff. Any form of repackaging increases the risk for error regardless of who performs the function.</p>	<p>If a supply of medication provided is not in the original package labeled by the pharmacy, the information required on the container is only the resident's name, medication name and strength. This is to ensure medications are not released without any identification of the medications and the person it is intended for. Written and verbal instructions of the other information such as directions and cautionary information would be provided but not required on the label. There are safety issues that have to be considered with every manner or method of providing a resident's leave of absence medications.</p>
<p>Kerr Health, Long-Term Pharmacy Lisa Russell</p>	<p>10A NCAC 13F 10A NCAC 13G</p>	<p>It is a violation of the NC Pharmacy Practice Act, G.S 90-85.40. Filling or refilling drug containers with prescription drugs for subsequent use by a patient and providing quantities of unit dose prescription drugs for subsequent administration is "dispensing."</p> <p>The G.S states that a pharmacist is only person that can dispense medications or they must be a pharmacy technician, or a pharmacy student enrolled in a school of pharmacy approved by the Board and working under the supervision of a pharmacist.</p>	<p>The agency has had communication with the Board of Pharmacy. Communication with the Executive Director of the NC Board of Pharmacy revealed the proposed rules would not be considered in violation of the Pharmacy Practice Act.</p> <p>Two other states, Maine in 2008 and Ohio in 2010, allow non-licensed staff to package leave of absence medications for residents in assisted living and nursing homes.</p>
<p>Kerr Health, Long-Term Pharmacy Lisa Russell</p>	<p>10A NCAC 13F 10A NCAC 13G</p>	<p>There are several safety concerns by allowing medication aides to repackage medications: insufficient staff education level and training; medications in non-spill proof containers can be mixed with other medications; readability of handwriting on package; no standardized containers may be</p>	<p>There are safety issues to be considered with every manner or method of providing a resident's leave of absence medications. If a facility has medication staff to prepare medications for leave of absence, the facility would be responsible for policies and procedures to ensure safe practices, which</p>

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		<p>used present risk to children and others; pill identification compromised once removed from package; incorrect or incorrect label transcription; auxiliary labels may not be transcribed; unsure what to do with unused medication whether the facility can administer or not; and time constraints on staff will lead to possible errors and/or mixing or mislabeling medications.</p>	<p>should address these concerns identified in the comment summary. The facility's infection control policies and procedures should address prevention and cross contamination regarding the packaging and the container used. Current packaging used by most long term care pharmacies is not child proof. The proposed amendment states policies and procedures shall facilitate safe administration and enable the resident/responsible person to identify medication, dosage and administration time for each medication. The use of containers that are not spill proof containers and illegible information on the container would not facilitate safe administration and enable the resident or others to identify the medication. The facility should have established policies about medications returned to the facility as with medications brought into the facility by family or upon admission.</p>
<p>NC Assisted Living Association Frances Messer</p>	<p>10A NCAC 13F & G .1003 10A NCAC 13F & G .1010</p>	<p>Believe the proposed amendments to the current medication rules require unlicensed persons to dispense medication and conflict with three NCGS under Article 4A. NC Pharmacy Practice Act. (90-85.2, 90-85.3 and 90-85.40). These citations refer to the mandatory licensure or anyone engaged in the practice of pharmacy, the definition of "dispensing" and a pharmacist is only person that can dispense medications or they must be a pharmacy technician, or a pharmacy student enrolled in a school of pharmacy approved by the Board and working under the supervision of a pharmacist or violation of this act is a Class 1 misdemeanor.</p>	<p>The agency has had communication with the NC Board of Pharmacy. Communication with the Executive Director of the NC Board of Pharmacy revealed the proposed rules would not be considered in violation of the Pharmacy Practice Act.</p> <p>Two other states, Maine in 2008 and Ohio in 2010, allow non-licensed staff to package leave of absence medications for residents in assisted living and nursing homes.</p>

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		<p>NCALA disagrees that 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. The amended rule creates significantly more health and safety concerns. The opportunity for human error is greater. Medication errors are the #1 reason for citations of non-compliance with transcription errors the most common cause. These errors will become higher if unlicensed people remove unit dose medications to another container which has to be properly labeled for administration.</p> <p>No fiscal note required but there are costs associated with the change by Medicaid, Part D Medicare, and the private pay resident. Medicaid will pay for only 1 dispensing fee when the order is filled. Additional costs are to be incurred if an LOA supply in advance is left. If the resident is on leave, has only the medications for that time period and decides to stay longer, there are additional costs and logistics to provide the medication. If the resident does not take all the repackaged medication while on leave and returns early, those medications will have to be wasted. There is no way to return loose medications to a unit dose pack.</p>	<p>There are safety issues to be considered with every manner or method of providing a resident's leave of absence medications. The proposed rules do not require prohibit current practices that facilitate safe administration of leave of absence medications. The proposed rules allow another option for leave of absence medications if determined needed.</p> <p>The issue of a resident not having enough medication due to the leave of absence being extended could occur with the current regulations and releasing all of the resident's medications. The quantity of medication to be provided is based on the expected time the resident will be away from the facility and if any question with the length of time the resident may be away from the facility, a sufficient supply should be provided to cover the anticipated time for the leave of absence. The facility's policy and procedures would address the return of medications and communicated with the resident/responsible person. The concern with releasing all of a resident's medications is the medications may not be returned by the resident/responsible person and the resident may go without medication.</p>
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		<p>It may be unsafe to send all medications with the resident, but that is not the policy of NCALA communities, they only send the necessary quantity to meet the needs while on LOA. The rules should not be amended. They contain sufficient language as written and provide the best protections of health, safety and welfare of the resident.</p> <p>If the Commission moves forward with rule amendment, suggest including 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.</p> <p>Enforcing a regulation that is already in place is better than amending the regulation because a few providers have not fully complied with the current rule.</p>	<p>Revisions to the proposed rules have been made based on this comment. The proposed rules do not prohibit current safe practices but allow another option to provide a resident's leave of absence medications if determined necessary for the health, safety and welfare of the resident.</p> <p>We are unable to comment due to not understanding the adult care facility and contracting pharmacy liability of the resident/responsible party's failure to comply.</p> <p>The proposed regulations strengthen the current regulations for leave of absence medications based on the requirement of communication with the resident/responsible person related to the medications and the administration during the leave of absence. The proposed regulations do not prohibit any current safe procedures in place for leave of absence medications. The proposed regulations allow another option for leave of absence medications if needed for the health, safety and welfare of a resident.</p>
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