

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

MINUTES OF PUBLIC HEARING

August 9, 2017

10:00 A.M.

Division Staff Present:

Nadine Pfeiffer, Rule-making Coordinator
Diana Barbry, Assistant to Rule Coordinator
Clarence Ervin, Assistant Chief, Acute and Home Care Licensure Section
Nancy Joyce, Acute and Home Care Licensure Section

Others Present:

Kate Spencer, RN BSN, Pentec Health
Stacy Crowder, Pentec Health
Kathie Smith, Association of Home Health and Hospice of North Carolina
Shelli Norris, Amedisys Home Health
Glenda Artis, Division of Aging and Adult Services
Richard Rutherford, Sembra Care
Brooke Baragone, Sembra Care
Ari Medoff, Nurse Care of NC

1. Purpose of Hearing

The purpose of this public hearing was to solicit verbal and/or written comments from the public on the proposed re-adoption of 8 rules for the Licensing of Home Care Agencies rules, specifically 10A NCAC 13J .0901, .1004, .1007, .1107, .1110, .1202, .1402, and .1502.

2. Hearing Summary

The Public Hearing was opened by Nadine Pfeiffer at 10:00 a.m. Attending were representatives from the provider community and advocacy organizations. A total of six oral comments were recorded.

A summary of these comments is as follows:

OFFICE OF THE DIRECTOR

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AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER



1. **Kate Spencer with Pentec Health** read from written comments and stated that for over 30 years, Pentec has been an industry leader in providing in-home Specialty infusion services. The proposed language in the 13J .1110 would create a significant burden for Home Care Agencies and this burden would outweigh any benefit to patients. The current version of the rule makes sense, that a supervisor would perform quarterly visits of in-home aides or other allied health personnel, because in-home aides and similar personnel are not licensed. The new rule would require an RN to make a supervisory visit quarterly and annually to the client for the purpose of supervising another Pentec RN. The financial impact would be significant and would require a significant increase in staff that would pass on to patients. It would not benefit patients. The proposed rule does not afford greater protection for NC residents. The proposed rule changes to the supervisory requirements offer no greater patient protection while simultaneously providing a significant cost to Home Health agencies like Pentec. Please revise the proposed rule to reflect our concerns. Suggested ways to revise the rule, include:

- Paragraph (c) should only apply to the in-home care providers not subject to occupational licensing laws (only apply to in-home care providers described in Paragraph (b), not Paragraph (a));
- Add as an exclusion for in-home care providers that are also health care providers from 10A NCAC 13J .1110 (or, at a minimum, exclude them from the supervisory requirements;
- Modify the definition of “in-home care provider” in 10A NCAC 13J .0901 to exclude a “health care practitioner”; or
- Leave Paragraph (a) and Paragraph (c) in 10A NCAC 13J .1110 as they were in the original rule. (Written Statement Attached)

2. **Stacy Crowder with Pentec Health** spoke in support to the statement that was given by Kate Spencer.

3. **Kathie Smith with AAHC of NC** read written comments for two specific proposed rule changes: 10A NCAC 13J .1107 and .1202. The Association for Home & Hospice Care of North Carolina (AHHC) is a nonprofit trade association representing providers of home health, hospice, palliative care, personal care, private duty nursing and companion/sitter services.

- 13J .1107: (Paragraph a): Wants to validate referencing the aide plan of care for a client left in the patient's home and not the physician's plan of care for skilled services. Physician's plans of care change often with changes in skilled care. It's cost prohibitive to drive to the patient's home to leave an updated copy of a physician's plan with each skilled orders change. Under the home health CMS Conditions of Participation, agencies only verbally notify the patient of changes in skilled services and obtain signatures on federal beneficiary notices when changes meet federal requirements rather than driving to the patient's home with physician's plan of care changes.

Electronic health records are more widely utilized in home care and the trend will continue; will a signed electronic Plan of Care, signed by the RN and client or

designee, meet the requirement for leaving a copy of the aide plan of care in the home. Aide plans of care changes are infrequent and often coincide with a supervision visit by the RN unlike skilled plans of care.

- (Paragraph d & e): The federal Home Health Conditions of Participation (COP) allow therapists (PT, ST, OT) in therapy only cases to conduct the initial assessment in the patient's home and complete assignment/plan of care for home health aides. Suggest that the language in (d) and (e) be changed to coincide with what is allowed under federal Home Health regulations: therapists listed above be allowed to provide the initial assessment visit and complete the aide plan of care and oversee the aide when only therapy services have been ordered by a physician.

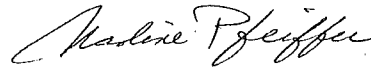
"Medicare certified agencies must meet the requirement for licensure, but are regulated by federal regulations". Concern for Medicare Certified Home Health agencies whom by federal law are allowed to have therapy develop the Home Health aide plan of care for therapy only cases will be out of compliance with the DHR Home Care Licensure rules, even though they would be compliant with federal COP language.

Requiring certified home health agencies send an RN to complete the aide plan of care when nursing has not been ordered adds significant financial burden to home health agencies, creates a further workforce burden due to the growing shortage of RNs, especially in rural areas. There is no payment source for the RN visit because only therapy has been ordered, not nursing. The financial implications of this proposed rule were not included in the fiscal impact statement, therefore with the additional financial burden in mind, a rule re-write was requested to allow the therapists (as listed above) to perform this task when only therapy is ordered. This is allowed under their scope of therapy practice and in the case of assigning range of motion exercises or assisting with acquiring independent skills in bathing and dressing, a therapist may be the most appropriate professional discipline to assign and oversee the tasks.

- (Paragraph f): In therapy only cases, and in accordance with the CMS Home Health COP, therapists are allowed to provide aide oversight. It would create a financial burden to the agencies to require a nurse to provide this service when nursing has not been ordered and create a further crisis in the RN shortage that NC is experiencing.
 - 13J .1202: Paragraph (a): In many aide only cases physician orders are not necessary. Suggestion: Keep wording: "If physician orders are needed for the services," as many private pay services are initiated by family caregivers and no physician has been involved in the agency aide services to the client.
4. **Shelli Norris with Amedisys Home Health** spoke about the requirement for a signed and dated copy in 10A NCAC 13J .1107 (a) stating that with most agency assessments being done by electronic means it may be difficult to leave a copy of the assessment in the home.
 5. **Richard Rutherford with Sembra Care** stated that changes made to definitions in: 10A NCAC 13J .0901 - may not match the need by the patient. In rule 10A NCAC 13J .1107 – the use of the word designee is not legally precise and the definition needs to be a precise legal term. In 10A NCAC 13J .1110 – the standards of supervision has been loosened by eliminating words such as continuously onsite, when a person is not permitted to be available to others during that time frame. We don't want to allow someone to have a beeper and respond while working elsewhere.

6. **Ari Medoff with Nurse Care of NC** stated that in rule 10A NCAC 13J .1110 (g) a supervision rollback would be detrimental to patient care. For rule 10A NCAC 13J .1107 (c)(3) it is not realistic to expect some patients to be able to dispense their own medications especially if they have dementia. He believes that the nurse aide should be more involved in the dispensing of medications even if it means that they need additional training as a medication aide.

Respectfully Submitted,



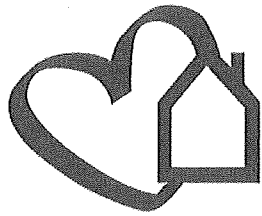
Nadine Pfeiffer, Rule-making Coordinator
August 9, 2017

Public Hearing Attendance
 The Licensing of Home Care Agencies Readoption Rules
 10A NCAC 13J
 .0901, .1004, .1007, .1107, .1110, .1202, .1402, .1502.

August 9, 2017 10:00 a.m.

Please print information below:

Name	Representing	E-mail Address	Speaking Yes(Y)No(N)
Kate Spence	Pentec Health	kspence@pentechealth.com	Y
Stacy Crowder	Pentec Health	stcrowder@pentechealth.com	Y
Kathie Smith	Assin Home and Hospice Care (Attend)	kathie@ahcnc.org	Y
Shelli Norris	Amedisys Home Health	shell.norris@amedisys.com	Y
Glenda Oates	DHHS	Glenda.AOates@dhs.nc.gov	N
Larrea Ferris	DHHS	larrea.ferris@dhs.nc.gov	N
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Richard R. Menford	Sembra Care	RRUTHERFORD@sembra.com	Y
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August 9, 2017

Re: Public Comments to the Proposed Readoption of the Licensing of Home Care Agency Rules 10A NCAC 13J.

The Association for Home & Hospice Care of North Carolina (AHHC) is a nonprofit trade association established in 1972 representing providers of home health, hospice, palliative care, personal care, private duty nursing, and companion/sitter services.

We appreciate the opportunity to provide comments on the Proposed Readoption of The Licensing of Home Care Agencies Rules – 10A NCAC 13J.

As stated in the background text of the Fiscal Impact Analysis of Permanent Rule Readoption, there are 1505 licensed Home Care agencies. Of that number 1292 are non-certified Home Care agencies and 213 are Medicare Certified Home Health agencies that provide Home Health Services. The Medicare Certified Agencies must meet the requirements for licensure, but are regulated by federal regulations as well.

Proposed Changes by DHSR noted in In Rule .1107 – In-Home Aide Services Rule as noted in the fiscal impact analysis are:

Paragraph (c), Healthcare practitioner was deleted. The change clarifies that registered nurse writes the plan of care for hands on care. The change is reflective of current practice for in-home aide services.

Added Paragraph (d), to clarify for agencies providing in-home aide services where the initial assessment should be done and by whom. In addition, it clarifies the components of the initial assessment.

Added Paragraph (e), to clarify that the initial assessment must be signed, dated, and when it should be conducted. This will help ensure the plan of care addresses the clients' needs. This has been and continues to be a standard practice. Agencies are currently required to have a registered nurse available for the provision of In-Home Aide services for supervision and consultation. In-home aide services are hands-on service and nurses are required for the provision of hands-on care.

AHHC offers the following comments related to the proposed Readoption of the rule 10A NCAC 13J.1107 In-Home Aide Services:

The Proposed rules in section (d) and (e) in the paragraph above specifies that the initial assessment shall be conducted in the client's home by the registered nurse.

AHHC comments- The federal Home Health Conditions of Participation allow therapists (Physical, Speech and Occupational licensed therapists) in therapy only cases to conduct the initial assessment in the patient's home and complete the aide assignment/plan of care for home health aides. We suggest that the language in section (d) and (e) be changed to coincide with what is allowed under federal Home Health regulations. That is, that therapists listed above be allowed to provide the initial assessment visit and complete the aide plan of care and oversee the aide when only therapy services have been ordered by a physician.

As noted in the background text provided on the rules readoption "Medicare certified agencies must meet the requirement for licensure, but are regulated by federal regulations". We are concerned that for Medicare Certified Home Health agencies whom by federal law are allowed to have therapy develop the Home Health aide plan of care for therapy only cases that these agencies will be out of compliance with the DHSR Home Care Licensure rules, even though they would be compliant with federal COP language for Medicare Certified Home Health agencies.

To require that certified home health agencies send a Registered Nurse to complete the aide plan of care for such activities as bathing, dressing and range of motion exercises when nursing has not been ordered by a physician adds significant financial burden to home health agencies and creates a further workforce burden due to the growing shortage of Registered Nurses – especially in our rural areas. Because registered nursing services have not been ordered, there is no payment source for this visit when only therapy has been ordered. Since the financial implications of this proposed rule have not been included in the fiscal impact statement with this additional financial burden in mind we respectfully ask that the proposed rule be re-written to allow the therapists (as listed above) to perform this task when only therapy is ordered. This is certainly allowed under their scope of therapy practice and in the case of assigning range of motion exercises or assisting with acquiring independent skills in bathing and dressing, a therapist may be the most appropriate professional discipline to assign and oversee the tasks.

Proposed rules section- (f) Agencies providing in-home aide services shall provide availability of the registered nurse for supervision and consultation.

AHHC comments- In therapy only cases, and in accordance with the federal Home Health Conditions of Participation, as similar to the issue above, therapists are allowed to provide the oversight for the aides. Additionally requiring a nurse to provide this service when nursing has not been ordered would again financially burden the agencies and create a further crisis in the shortage of registered nurses that NC is experiencing and is well documented.

AHHC offers the following comments related to the proposed Readoption of the rule -10A NCAC 13J .1202 Case Review and Plan of Care:

Proposed rules section- (a) If the client record is thinned, the original and updated authorization or orders for care as appropriate shall be maintained in the client's current record. All records shall be readily available to Department staff for review if requested. ~~*If physician orders are needed for the services, home care health professional*~~ The health care practitioner shall notify the physician of any changes in the client's condition that indicates the need for

altering the plan of care or for terminating services. (The italics and underlined sections are removed from the proposed rule language).

AHHC comments- In many aide only cases physician orders are not necessary, as an example, for bathing a patient. We recommend that the sentence "If physician orders are needed for the services," be left intact as many private pay services are initiated by family caregivers and no physician has been involved in the agency aide services to the client.

We appreciate the consideration of these comments and are very happy to work with DHSR if anything further is needed. We appreciate the hard work of the DHSR staff.

Sincerely,



Kathie Smith

Kathie Smith, RN, Vice President of State Relations, Home & Community Based Care Association for Home & Hospice Care of NC

NC PUBLIC HEARING

1) Introduction

- My name is Kate Spencer, and I am a Nurse Director for Pentec Health, Inc. with management responsibility for the State of North Carolina.
- For over 30 years, Pentec has been an industry leader in providing in-home Specialty Infusion services, which are limited to patients who depend on a surgically-implanted intrathecal pump to obtain relief from chronic intractable pain or spasticity.
- Pentec is currently licensed as a Home Care Agency in North Carolina and provides Specialty Infusion services to 108 North Carolina residents with a team of specially-trained registered nurses.
- We appreciate the opportunity to comment on the proposed readoption of “The Licensing of Home Care Agencies Rules” on behalf of Pentec.
- We appreciate the Department of Health and Human Services’ updates to the rules to reflect greater protection for our patients.
 - However, we believe there is an instance where the Department may have overlooked the serious negative consequences of the revised language, for Pentec and similarly operated Home Care Agencies.
 - The proposed language in the supervision requirements of 10A NCAC 13J.1110 would create a significant burden for Home Care Agencies like Pentec, and this burden would outweigh any benefit to patients.

2) Discussion of 10A NCAC 13J.1110: Supervision and Competency of In-Home Aides or Other In-Home Care Providers

- The revisions to 10A NCAC 13J.1110 propose that “the health care practitioner” (definition includes a registered nurse) “shall supervise an in-home care provider” (definition also includes a registered nurse) “by making a supervisory visit to each client’s place of residence quarterly with or without the in-home care provider’s presence, and annually, while the in-home care provider is providing care to each client”.

- The current version of the rule provides that a supervisor would perform quarterly visits of “in-home aides or other allied health personnel”.
- The current version of the rule makes sense, because in-home aides and similar personnel are not licensed.
- In contrast, the new rule would require Pentec to have an RN make a supervisory visit quarterly and annually to the client for the purpose of supervising another Pentec RN.
- The financial impact on Pentec in year one would be significant.
 - Supervisory visits performed 5 times a year for each of Pentec’s 108 clients would require a significant increase in Pentec’s staff.
 - In the worst-case scenario, this may cause Pentec’s in-home services to be too expensive to be offered in North Carolina.
 - [Other financial impact data.]
- Equally important is the fact that the proposed rule does not afford greater protection for NC residents.
 - Each Pentec RN undergoes individual specialized training in the treatment of intrathecal pump patients.
 - Pentec’s nurse training program is unique in the United States and has been certified by the American Nurses Association.
 - The Pentec RN performing the services would have a high level of knowledge equivalent to any “supervisor” RN.
 - Pentec has 108 patients visited by an RN every 30-60 days performing a standard evaluation, in addition to intrathecal pump adjustment and refilling, that gets reported back to a physician.

3) Conclusion

- We believe that the proposed changes to the supervisory requirements offer no greater patient protection while simultaneously providing a significant cost to Home Health Agencies that operate like Pentec.

- We do not believe that the Department intended the proposed regulation to have the negative impact that could result for certain Home Care Agencies in the provision of in-home care services to North Carolina residents.
- We ask the Department to please revise the proposed rule to reflect our concerns.
- We also are preparing written comments to be submitted to you this week.
- On behalf of Pentec and the patients we serve, we thank you for your time and consideration.

Other Notes

Suggested ways to revise the rule, to address Pentec's concerns:

1. Include in 10A NCAC 13J.1110 that Paragraph (c) should only apply to the in-home care providers not subject to occupational licensing laws (only apply to in-home care providers described in Paragraph (b), not Paragraph (a));
2. Add an exclusion for in-home care providers that are also health care providers from 10A NCAC 13J.1110 (or, at a minimum, exclude them from the supervisory requirements);
3. Modify the definition of "in-home care provider" in 10A NCAC 13J.0901 to exclude a "health care practitioner"; or
4. Leave Paragraph (a) and Paragraph (c) in 10A NCAC 13J.1110 as they were in the original rule.