The Licensing of Home Care Agencies Readoption Rules Public Comments
10A NCAC 13J .0901, .1004, .1007, .1107, .1110, .1202, .1402 and .1502
Comment Period 6/15/17 – 08/14/17

Introduction:

There were 11 individual comments received during the public comment period on the readoption of Rules 10A NCAC 13J .0901, .1004, .1107, .1110, .1202 and .1402. In addition, six individuals made statements during the public hearing conducted on August 9, 2017. These comments were submitted by representatives from Homewatch CareGivers of the Triangle; Association for Home & Hospice Care of NC; Pentec Health, Inc.; SembraCare; Division of Aging and Adult Services; Rainbow 66 Storehouse, Inc.; ACTS Home Health; Bayada Home Health Care; Amedisys, Inc., Amedisys Home Health, and Nurse Care of NC, and one individual: Terri Sullivan. All of the comments received on these rules are summarized below:

1) Listing of Comments Received and Agency's Consideration of Comments for Readoption Rule 13J .0901 - Definitions:

Commenter	Comment Summary
1) SembraCare (written comments)	The effects of the changes to the definition of "Extensive Assistance" is that more clients would qualify as having "extensive" needs with an Activity of Daily Living and require a nurse aide listed on the Registry because the definition has been broadened. "Dependent" and "hands on assistance" includes more situations than "totally dependent" and "weight bearing support." This will increase costs by requiring home care agencies to hire, train, supply more CNAs that are in short supply and face competition from the community care spectrum. The fiscal analysis fails to discuss this change or address these added costs. The change will have a substantial adverse economic impact and should not be adopted.
2) SembraCare (public hearing comments)	Changes made to definitions in: 10A NCAC 13J .0901 – may not match the need by the patient.
3) Division of Aging and Adult Services	The Social Worker definition is now defined as the same as G.S. 90B3-(8): A person certified, licensed, or associate licensed by this Chapter or otherwise exempt under G.S. 90B-10. Does 90B 10 and 90B 16 cover an individual who is performing the duties of a social worker and may be called a social worker in an agency that may operate under the auspices of a county but is not county run? Example, does this definition cover a Council on Aging agency that may contract with county government to provide home management only in home aide services and who have social workers who provide assessments and supervision for in home management services? Does it cover an agency that is providing home management only if it is a nonprofit entity?
4) Bayada Home Health Care	Extensive Assistance: Support the language change but the re-numbering Item reference is incorrect and should remain as current rule has referenced. Health Care Practitioner: If the definition is all encompassing, why does the rule include specific definitions with related status reference, this may be unnecessary. Suggest: if this does not add value, eliminate it. Instrumental Activities of Daily Living: Concerned that providing a definitive list excludes other IADL activities falling outside the named tasks. Suggest: add "for example" and/or "etc." to imply other tasks could apply.

Commenter	Comment Summary
	In-home Care Provider: Need clarifying language. "Provider" often refers to the agency holding the license, not caregiver. Suggest: Change to "In-home Caregiver."

Agency Response to Comments Above:
As a result of comments received the strike through from the word "totally" in item 7 line 23 in .0901 has been removed. Totally will remain in the rule. Also, all clients who need extensive or total assistance with ADL's may not need weight bearing support, consequently, no changes will be made regarding this comment. Hands on assistance allows greater flexibility to the provider in assessing the extensive or total care needs of the client. In addition, DHSR has no authority to define scope of practice for "social worker" as this is under the auspices of the licensing board. The agency agrees that the reference to Item 20 should be item 19 instead. The reference was changed to remain as "item 19" instead of "item 20". Regarding the social work comment, DHSR has no authority to define scope of practice for "social worker" as this is under the auspices of the licensing board. The term "Health Care Practitioner" is language that is consistent in current standards of practice and accepted across the health care spectrum. The definition of Instrumental Activities of Daily Living (IADL) in Rule .0901 Item #15 is inclusive of the activities and tasks beyond basic self-care that are necessary for management of the household. "In-Home Care Provider" has been changed to "In-Home Caregiver" in Rules .0901 item #14; .1110 and .1202 (c) #3.

2) Listing of Comments Received and Agency's Consideration of Comments for Readoption Rule 13J .1004 – Evaluation:

Commenter	Comment Summary
Bayada Home Health Care	Paragraphs (a) – (e): Revising the text can provide more meaningful changes in care delivery. Currently the section is a byproduct of the Medicare Conditions of Participation (COP). In 2018, Medicare is eliminating their "evaluation" section and requiring a Quality Assessment Performance Improvement Program (QAPI) for home health providers. National accrediting providers are following suit. CMS recently eliminated the requirement for the annual evaluation and professional advisory committee for home health providers to align with hospitals and SNFs. The evaluation can be eliminated and captured in a QAPI program, and be in line with federal regulations. Suggest: delete "Evaluation" section and incorporate a robust QAPI program, allowing time for providers to develop, transition, and implement a new program and provide extensive education for providers and surveyors on the new requirement. Paragraph (d): Deletion of "service is satisfactory and appropriate" and new wording of "service meets the client's needs." Rules address care delivery regardless of payor source. Concerned wording change may be beyond provider's ability to determine and/or action-ize. Care is implemented as ordered by the physician per payor approval. Providers may not have control whether services meets the client's needs. Providers do not determine the state or payor's assessment and cannot predict what a physician would deem appropriate for care. We can recommend but cannot be held responsible for not meeting the client's overall needs. Suggest: See comment for replacing with QAPI to focus on outcomes rather than chart audits. If not, retain original language.

Agency Response to Comments Above:
The Quality Assessment Performance Improvement Program (QAPI) request is beyond the scope of the readoptions and will be considered at the next phase of the Home Care Rule Adoptions.

Also, through the quarterly evaluation of the client's records the agency should be able to determine if the service is meeting the client's needs. No changes will be made to this rule.

3) Listing of Comments Received and Agency's Consideration of Comments for Readoption Rule 13J .1007 – Client Rights and Responsibilities:

Commenter	Comment Summary
Bayada Home Health Care	The rule added 2 provisions, HC rights and policies, it did not materially change how providers operate and communicate client rights and responsibilities with clients.

Agency Response to Comments Above:
This change included all 15 rights/responsibilities identified in the General Statute 131E-144.3. Providers are expected to be compliant with the provisions of the statute. There was no change to the way providers operate and communicate client rights and responsibilities.

4) Listing of Comments Received and Agency's Consideration of Comments for Readoption Rule 13J .1107 – In-Home Aide Services:

Commenter	Comment Summary
1) Homewatch CareGivers of the Triangle	Paragraph (a): (new language to this paragraph) They do not have paper copies of the care plan available at the assessment, but has electronic copies documented following the assessment. The client may be unable to sign and a designee may not be available. At a follow up visit, when care plans are modified, these tasks may take place after hours or during a time period when a designee may not be available and the client is unable to sign. A lot of business is conducted electronically or telephonically because the designee may live apart from the client. Care plans can also be modified at any time due to changing client needs, with some weeks being changed 2-3 times. It's not always feasible to have a client representative sign off on these changes. Suggested Changes: - Leave as is currently and do not add new rule language OR - Include documentation in the service agreement that indicates "both parties agree to the care plan, it can be modified per the Registered Nurse upon discretion/caregiver report/request by the client or designee until severance of working relationship" OR - Modify to state "the care plan shall be signed/dated by RN" alone. This can be done electronically.
2) Association for Home & Hospice Care of NC (from public hearing)	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

Commenter	Comment Summary
	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 (c) 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 DHSR 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.
3) Association for Home & Hospice Care of NC	Paragraph (a):

Commenter	Comment Summary
(written comments, same as from public hearing)	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 (c) 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 DHSR 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):

Commenter	Comment Summary
	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.
4) SembraCare (written comments)	Paragraph (a): The plan of care is the most important care-related document in the client's possession and key element to providing person centered services. The term "designee" is not a defined term nor are the circumstances under which a client's signature is unneeded made clear. The rule should not be adopted unless a precise legal term is used to describe who can sign a plan of care, and unless limits are added on having a designee sign in cases when the client is unable to or is not competent to sign.
5) SembraCare (public hearing comments)	The use of the word designee is not legally precise and the definition needs to be a precise legal term.
6) Division of Aging and Adult Services	Line 35 (g) discusses the Home and Community Care Block Grant and the Social Services Block Grant rules regarding levels and following those rules. What is confusing is that the last line that says that all other agencies have to comply with (a)-(f). If the agency is licensed and receiving these funds for providing personal care services, wouldn't these agencies still have to comply with (a)-(f)? Perhaps it would be less confusing and to provide more clarity if this section is referring to personal care if the last line was restated or deleted. If the intent is to reference the levels that Aging and DSS network use, perhaps it would be helpful to add that these agencies still need to meet a-f if providing personal care.
7) Terri Sullivan	The only place in the rules giving definition of respite services and non-hands on care and giving direction as how to handle a client in need of respite services is in rule 10A NCAC 13J .1501. There are situations where home care companies provide respite care to clients who are need of both hands on and non-hands on care. Suggestion: include the terminology of respite care also within the body of 10A NCAC 13J .1107 because for those situations the Health Care Practitioner and RN is required to provide the assessment and write the plan of care for the client. Due to current wording of the Rule, home care companies may interpret that clients in need of respite care do not require an assessment/plan of care by an RN.
8) Bayada Home Health Care	Paragraph (a): Adds an additional client signature on the initial visit. This adds administrative burden to the provider and no value to the client. Under Medicare, a PT or ST is allowed to open a case, therefore licensure is more stringent than the COP. Requiring a nurse to sign a therapy only case will add an extra, unreimbursed and unnecessary visit. Suggest: Delete additional client signature on the POC and/or revert back to the original language. Paragraph (c): Limits signature to the RN, excludes oversight of licensed therapist. Be consistent with language in rules and allow HCP to sign. Rule .1110 also mentions and allows HCP. Suggest: Revert back to HCP language as to who can sign the POC or add clarifying language to allow signatures from other authorizing health care practitioners (PT); add "or Therapist" in line 26.

Commenter	Comment Summary
9) Amedysis, Inc.	Paragraph (a): Providers with EMR would be challenged to comply with paper-based process. Paper-based would be cumbersome. Obtaining new signatures each time the aide plan is updated/revised would increase the burden to providers. Consider the process for tracking and obtaining signatures when the POA/legal rep does not reside with the client, lives out of state or is not readily available. Paragraph (b): Request more information on the intent of this section. Paragraph (c): Questions whether this implies that only the RN can complete an aide care plan or if this is applicable to PCS or licensed only HHA's. Federal COP's for HHA's allow therapists to complete the aide care plan when skilled nursing was not ordered by the physician. Paragraph (d): Consider comments for Paragraph (c) if this includes Medicare-certified HHA's. Paragraph (f): Is this only applicable to PCS/licensed-only home care agencies or does it include Medicare-certified HHA's. Medicare-certified HHA's have specific standards related to home health aide services.
10) Association for Home & Hospice Care of NC	Seeking clarification in relation to Medicare certified COP's. In (d) and (e), a Medicare certified agency will be surveyed on the HH COP's that allow the therapist to provide the assessment and supervision for therapy only cases. In (a), will the Medicare agency be surveyed on the COP's that apply to them regarding the plan of care? In a Medicare certified facility, an RN supervisor does the over POC but the patient does not sign it. The POC changes frequently based on MD orders. There would be no practical and cost efficient way to achieve the licensure rule for a home health agency. The HH COP's say the aide is assigned with written instructions and the COP's allow other disciplines than an RN to assign aide tasks. We don't want a conflict between the licensure rules and the COPs.
11) Amedisys Home Health (public hearing comments)	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.
12) Nurse Care of NC (public hearing comments)	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.

Agency Response to Comments Above:
All patients have a right to a copy of their care plan. The plan of care identifies the services the patients should receive and thus allows the patient the ability to determine if services are not being provided according to the plan of care. When a client is unable to sign or a designee is not available it should be

documented that the client is unable to sign and that there is no other person available to sign. Care plan changes should be made with the involvement of the client or designee. Also the changes in this rule are applicable to agencies providing In-Home Aide Services according to 10A NCAC 13J .1107. The term designee is not being used outside of its' established definition and is used when a client is unable to sign. The client can designate a person of their choosing to sign. No changes will be made this area. The last sentence in this rule, in addition, "All other agencies providing in-home aide services shall comply with the provisions in paragraphs (a) through (f) of this rule" was removed.

Also, this rule is not requiring a copy of the assessment be left in the home. It is requiring a copy of the signed, dated plan of care be left in the home.

In regards to medication aides, the NC Board of Nursing establishes the scope of practice for medication aides. Finally, the comment regarding services and non-hands-on-care and giving direction as how to handle a client in need of respite services in rule 10A NCAC 13J .1501 is outside the scope of the these readoptions and will be considered during the next phase of rule adoptions.

5) Listing of Comments Received and Agency's Consideration of Comments for Readoption Rule 13J .1110 – Supervision and Competency of In-Home Care Providers:

Commenter	Comment Summary
1) Pentec Health, Inc. (written comments)	Changes create a significant problem for Pentec and similar Home Care Agencies. DHHS may have overlooked the serious negative consequences of the revised language. Proposed language would create a significant burden for Home Care Agencies, outweighing benefit to clients. The new rule would require organizations to have a trained and licensed RN make supervisory visits quarterly and annually to clients for the purpose of supervising another specially-trained licensed RN. The revisions afford a minimal increase in protection to NC residents, as it does not require the supervisor to have more skills than the in-home care provider RN. At Pentec, the RN is highly trained and would have a level of knowledge equal to any supervisor RN. Currently each Pentec client is visited by an RN according to the physician plan of care (30-60 days), is evaluated by the RN, and the RN is familiar with the patient and is in frequent contact with the physician. Adding 5 supervisory visits by an equally trained RN would be futile and costly. The financial impact would be substantial to agencies, requiring hiring of additional RN's. This could cause the in-home services to be too costly for the client. Suggestion for revisions to the rule: 1) make Paragraph (c) only apply to in-home care providers not subject to occupational licensing laws; 2) add an exclusion for in-home providers that are also home care providers or exclude them from supervisory visits; 3) modify definition of "in-home care provider" to exclude "health care practitioner;" or 4) make no changes to Paragraph (a) and (c).
2) Pentec Health, Inc. (public hearing comments)	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

Commenter	Comment Summary
	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.
3) Pentec Health, Inc. (public hearing comments)	Spoke in support to the statement that was given by other Pentec Health, Inc. representative.
4) SembraCare (written comments)	Paragraph (g): By removing the requirements that the RN be available "continuously" and the reference to "on-site" supervision where it is necessary, the rule is weakened substantially. Too many agencies have RN's truly available for supervision or are free to go to a home if needed. The rule change will enable compliance by an RN receiving a text, email or beeper message and responding during a break or after a shift at another job, rather than being truly available. This rule change should not be adopted.
5) SembraCare (public hearing comments)	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) Rainbow 66 Storehouse, Inc.	With the change "and annually, while the in-home care provider is providing care to each client." Does this mean that the RN does not have to see the aide every 6 months anymore?
7) ACTS Home Health	Changing "in-home aides" to "in-home provider," does this mean we can't use in-home aides?
8) Bayada Home Health Care	Title: The title change makes the rule confusing. The term "provider" is typically used for a licensed agency/organization, not an individual. Suggest: Replace "Provider" with "Caregiver" to refer to an individual. Paragraph (c): Adding "every quarter" offers unintended flexibility that does not align with best practices. It could be misinterpreted to be done anytime within the quarter or done every quarter. Suggest: change to every 90-day or revert back to every three months.
9) Amedysis, Inc.	Paragraph (c): Does this imply each home health supervisory visit must include a physical assessment of the patient or does this pertain specifically to Personal Care or licensed-only HHAs?

Agency Response to Comments Above:

The requirement for supervisory visits every three months with or without the in-home care giver presence, and annually while the in-home care giver is providing care to each client has always been a requirement for in-home aide providers providing services under 10A NCAC 13J .1107. The term "Health Care practitioner" is language that is consistent in current standards of practice and terminology used across the health care spectrum.

Regarding the request to remove the strikethrough from "on site where services are provided when necessary," it is the agency's responsibility to ensure RN's are available for supervision and consultation and to ensure health care practitioners are available for supervision. DHSR does not have the authority to define secondary work requirements.

The agency made no changes regarding the use of in-home aide. However, In-Home Aide Provider was changed to In-Home Caregiver and the term quarterly was changed to every 90 days.

6) Listing of Comments Received and Agency's Consideration of Comments for Readoption Rule 13J .1202 – Case Review and Plan of Care:

Commenter	Comment Summary
1) Homewatch CareGivers of the Triangle	Paragraph (a): They are not required to have a physician's order for care. It does not make sense to inform a physician each time there is a change or for client discharge. Suggested Changes: - Leave as is currently. The portion "If physicians orders are needed for the services", a [health care practitioner] shall notify the physician…is sufficient. This was marked through unnecessarily and needs to remain in the document.
2) Association for Home & Hospice Care of NC (from public hearing)	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.
3) Association for Home & Hospice Care of NC (written comments, same as from public hearing)	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.

Agency Response to Comments Above:
Agency agrees with the request to restore the language "if physician orders are needed for the services." The rule has been changed to reflect the change.

7) Listing of Comments Received and Agency's Consideration of Comments for Readoption Rule 13J .1402 – Content of Record:

Commenter	Comment Summary
Rainbow 66 Storehouse, Inc.	The rule states, "If the client is diagnosed as not competent the approval of the client's responsible party shall be recorded". Can we just continue to document this in the file or is this saying we should get a copy of the guardianship papers?

Agency Response to Comments Above:
No, this change doesn't require agencies to get a copy of the guardianship papers. Agencies should follow their established policies.