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N.C. Rules Review Commission  
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**Re: 10A NCAC 13J.1110- Supervision and Competency of In-Home Aides or Other In-Home Caregivers**

Dear Members of the Commission:

I request that the above rule be reviewed by the Rules Review Commission and that the Commission finds that the revised rule is not clear, for the reasons set forth below.

For over 30 years, Pentec Health, Inc. ("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 of various origins. Pentec is currently licensed as a Home Care Agency in North Carolina and provides Specialty Infusion services to one hundred eight (108) North Carolina residents with a team of licensed and specially-trained registered nurses ("RNs").

The revisions to the supervision requirements in 10A N.C. Admin. Code 13J.1110 are unclear in that the revised language could not rationally apply to Pentec and similarly-situated Home Care Agencies, yet the revisions to the language accomplish this result. Pentec expressed these concerns in its comment and testimony to the North Carolina Department of Health and Human Services ("DHHS"). The current version of the rule is rational in that it offers protection to North Carolina residents, because it requires a supervisor to perform quarterly visits to supervise *non-licensed* "in-home aides or other allied health personnel." In contrast, the new rule proposes that "the health care practitioner"<sup>1</sup> (definition includes a *licensed* RN) "shall supervise an in-home caregiver"<sup>2</sup> (definition includes care by a *licensed* RN and infusion nursing services) "by making a supervisory visit to each client's place of residence quarterly with or without the in-home caregiver's presence, and annually, while the in-home caregiver is providing care to each client." Therefore, if read literally, the new rule would require Pentec and similar organizations to have a trained and licensed RN make a supervisory

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<sup>1</sup> See N.C. Gen. Stat. Ann. § 90-640 (defining "health care practitioner" as "an individual who is licensed, certified, or registered to engage in the practice of... nursing").

<sup>2</sup> See proposed 10A N.C. Admin. Code 13J.0901(14) (defining "in-home caregiver" as "any individual who provides home care services as enumerated in G.S. 131E-136"); N.C. Gen. Stat. Ann. § 131E-136(3) (defining "home care services" as including "nursing care provided by or under the supervision of a registered nurse" and "infusion nursing services"); see also 10A N.C. Admin. Code 13J.0901(13) (defining "infusion nursing services" as "those services... [administered] under the supervision of a registered nurse").

visit five (5) times to each of the one hundred eight (108) patients, for the purpose of supervising another specially-trained and licensed RN. The DHHS could not have intended this result with the language written in the new rule. Without clarification, the proposed changes would cause the unintended result of creating a significant burden for Pentec and similarly-situated Home Care Agencies that would outweigh the benefit, if any, to residents.

Additionally, Pentec argued at the hearing and in its comment that the revisions to 10A N.C. Admin. Code 13J.1110 are illogical in that the new rule does not require the "supervisor" RN to have more skills than the in-home caregiver RN. At Pentec, each RN undergoes individual specialized training in the treatment of intrathecal pump patients. This 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 (or greater, considering his or her proximity to the patient) to any "supervisor" RN. Each of Pentec's one hundred eight (108) North Carolina patients is visited by a licensed RN on an interval provided in a physician-approved plan of treatment (generally every thirty to sixty days), where such RN performs an evaluation of the patient, in addition to adjustment and refilling of the intrathecal pump, that is reported back to the patient's physician. The licensed RN performing the in-home care is familiar with each individual client he or she serves, and is in frequent contact with the treating physician. The addition of five (5) supervisory visits per patient by an RN to another RN would provide no material benefit to the patients, while simultaneously causing a significant increase in Pentec's costs of operating in North Carolina. It is possible that, if 10A NCAC 13J.1110 is interpreted to reach this illogical result, Pentec's specialty in-home services could become too costly to be offered in North Carolina.

Pentec suggested, as an alternative, that the DHHS clarify the rule in one of the following ways:

1. Include in 10A N.C. Admin. Code 13J.1110 a provision that Paragraph (c) should only apply to in-home caregivers not subject to occupational licensing laws (i.e., make Paragraph (c) applicable only to in-home caregivers described in Paragraph (b), not Paragraph (a));
2. Add an exclusion in 10A N.C. Admin. Code 13J.1110 for in-home caregivers that are also health care practitioners (or, at a minimum, exclude them from the supervisory requirements in Paragraph (c));
3. Modify the definition of "in-home caregiver" in 10A N.C. Admin. Code 13J.0901 to exclude a "health care practitioner"; or
4. Make no changes to Paragraph (a) and Paragraph (c) in the existing 10A N.C. Admin. Code 13J.1110.

The DHHS did not address Pentec's concerns when the DHHS responded that the supervisory visit every three (3) months has always been a requirement, and that the term "Health Care practitioner" is language that is consistent in current standards of practice and terminology used across the health care spectrum. However, for the reasons stated above, Pentec had argued the rule expands the supervision requirement to require supervision of "in-home caregivers," and this would require an illogical result for Pentec and similar Home Care Agencies. The "Health Care practitioner" term that the DHHS focused on in its response is not the issue, because it would make sense for a Health Care practitioner, as a licensed RN, to make a supervisory visit to a non-licensed "in-home aide." However, by deleting "in-home aide," the rule must then be clarified to prevent the scenario of requiring a licensed RN to make a supervisory visit to another licensed RN who is acting as the "in-home caregiver."

It is not clear whether the changes to 10A N.C. Admin. Code 13J.1110 would apply to Pentec and similarly-situated Home Care Agencies that already have procedures in place to provide safe and high quality care by licensed professionals, as the result would be irrational. The DHHS could not have intended the proposed regulation to have the negative impact that could result for Home Care Agencies and residents of North Carolina. For these reasons, and on behalf of Pentec and the North Carolina residents it serves, I ask the



Commission to review the rule and determine that the DHHS must clarify the supervisory requirement language.

Thank you for your consideration.

Sincerely,

A handwritten signature in cursive script that reads "Kate Spencer".

Kate Spencer, BSN, RN  
Nurse Director

Karen McHenry, MSN, RN  
Senior Vice President, Nursing Services

cc: North Carolina Department of Health and Human Services  
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