

August 11, 2017

VIA EMAIL: DHSR.RulesCoordinator@dhhs.nc.gov

**North Carolina Department of Health and Human Services
Division of Health Service Regulation
2701 Mail Service Center
Raleigh, North Carolina 27699-2701
Attention: Nadine Pfeiffer**

RE: Comment on Proposed Re-adoption of 10A N.C. Admin. Code 13J.1110

This comment, submitted on behalf of Pentec Health, Inc. ("Pentec"), is regarding the proposed re-adoption of North Carolina's rules on "The Licensing of Home Care Agencies,"¹ particularly with respect to the proposed changes to 10A N.C. Admin. Code 13J.1110, "Supervision and Competency of In-Home Aides or Other In-Home Care Providers."² The proposed changes to Section 13J.1110 create a significant problem for Pentec and similarly-situated Home Care Agencies, and we believe the North Carolina Department of Health and Human Services ("DHHS") may have overlooked the serious negative consequences of the revised language. We urge DHHS to carefully consider the undesirable result of the proposed changes.

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 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 proposed language in the supervision requirements of 10A N.C. Admin. Code 13J.1110 would create a significant burden for Home Care Agencies like Pentec, and this burden

¹ 10A N.C. Admin. Code 13J.0901, et seq.

² 31 N.C. Reg. 2446–2447.

would outweigh any benefit to clients. The revisions propose that “the health care practitioner”³ (definition includes a RN) “shall supervise an in-home care provider”⁴ (definition includes care by a RN and infusion nursing services) “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, which requires a supervisor to perform quarterly visits of “in-home aides or other allied health personnel,” offers an additional protection for North Carolina residents, because in-home aides and similar personnel are not licensed. In contrast, the new rule would require Pentec and similar organizations to have a trained and licensed RN make a supervisory visit quarterly and annually to each of the one hundred eight (108) clients, for the purpose of supervising another specially-trained and licensed RN.

The proposed revisions to 10A N.C. Admin. Code 13J.1110 afford a minimal increase in protection for North Carolina residents. The proposed rule does not require the “supervisor” RN to have more skills than the in-home care provider 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 to any “supervisor” RN. Each of Pentec’s one hundred eight (108) North Carolina clients 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

³ 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”).

⁴ See 10A N.C. Admin. Code 13J.0901(16)(defining “in-home care provider” 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”).

addition of five (5) supervisory visits by another licensed and equally trained RN would be futile for North Carolina clients, while simultaneously increasing costs for Pentec.

The financial impact of the proposed changes for Pentec and similar organizations would be substantial. For example, new supervisory visits required to be performed five (5) times a year for each of Pentec's one hundred eight (108) clients in North Carolina would require Pentec to hire additional RNs. In the worst-case scenario, this could cause Pentec's in-home services to become too costly to be offered in North Carolina.

We suggest, as an alternative, that the DHHS revise the proposed 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 care providers not subject to occupational licensing laws (i.e., make Paragraph (c) applicable only to in-home care providers described in Paragraph (b), not Paragraph (a));
2. Add an exclusion in 10A N.C. Admin. Code 13J.1110 for in-home care providers 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 care provider" 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 proposed changes to 10A N.C. Admin. Code 13J.1110 offer a minimal increase in protection to North Carolina citizens, while providing a significant cost to Pentec and similarly-situated Home Care Agencies that already have procedures in place to provide safe and high quality care by licensed professionals. We do not believe that DHHS has intended the proposed regulation to have the negative impact that could result for these Home Care Agencies. For these reasons, we ask DHHS to revise the proposed rule to address our concerns. On behalf of Pentec and the clients we serve, we thank you for your consideration of this request.