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December 14, 2015

Via email (DHSR.RulesCoordinator@ddhs.nc.gov)
Via US Mail

Nadine Pfeiffer
NC Department of Health and Human Services
2701 Mail Service Center
Raleigh, NC 27699-2701

Re: Notice of Intent to Repeal Rules

Dear Ms. Pfeiffer:

Thank you for the opportunity to submit comments on the proposed repeal of certain rules pertaining to 10A NCAC 14C, Certificate of Need ("CON"). This letter responds to the Notice of Intent to Repeal Rules as published in the October 15, 2015 edition of the *North Carolina Register*.

The Carolinas Center for Hospice and End of Life Care ("The Carolinas Center") is the only state association exclusively focused on serving hospice and palliative care providers in North Carolina and South Carolina. The Carolinas Center represents an extensive network of hospice providers who collectively provided care to more than 80,000 patients in 2014. The Carolinas Center's members are diverse, representing large and small, urban and rural and for-profit and nonprofit hospice programs. Our goal is to assist providers with fulfilling their missions of delivering exceptional care to patients facing the end of life, as well as to the patients' caregivers.

The Carolinas Center appreciates the intent of the Department of Health and Human Services ("DHHS" or "Department") in its efforts to streamline rules that it has determined to be unnecessary. We concur with the proposal to repeal the following rules related to Hospice Home Care: 10A NCAC 14C .1504 (Support Services) and 10A NCAC 14C .1505 (Staffing and Staff Training) as well as the following related to Hospice Inpatient Facilities: 10A NCAC 14C .4004 (Support Services), 10A NCAC 14C .4005 (Staffing and Staff Training) and 10A NCAC 14C .4006 (Facility).

We do, however, have concerns about the proposed repeal of hospice rules 10A NCAC 14C .1502 and .4002, both of which would eliminate the Information Required of Applicants for hospice home care and hospice inpatient facilities, respectively. The rules related to Information Required of Applicants for hospice services are the only rules that inform what is presently in the two types of CON applications for hospices. Their repeal could have unintended consequences on future applicant submissions and review.



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In G.S. § 131E-177(5), the DHHS is granted the power and duty to “implement, by rule, criteria for project review.” G.S. § 131E-182 also provides that:

(b) An application for a certificate of need shall be made on forms provided by the Department. *The application forms, which may vary according to the type of proposal, shall require such information as the Department, by its rules deems necessary to conduct the review.* An applicant shall be required to furnish only that information necessary to determine whether the proposed new institutional health service is consistent with the review criteria implemented under G.S. 131E-183 and with duly adopted standards, plans and criteria. [*emphasis added*]

Since the Applications for Hospice Home Care and for Hospice Inpatient Facilities generally follow these rules, and since the content of the applications is determined by rule, The Carolinas Center believes these rules are necessary rules. These rules are within the authority granted to DHHS and are reasonably necessary to implement G.S. § 131E-177(5) and G.S. § 131E-182(b).

Hospice services (both home care and inpatient) are highly specialized forms of healthcare, subject to stringent federal statutory, regulatory and state licensing requirements. The current NC hospice rules related to Information Required of Applicants outline specific criteria for hospice programs to demonstrate when applying for a CON, thus drawing out important contextual information about applicants. If the Information Required of Applicants rules were to be repealed, there would be no hospice-specific review criteria in the rules. The Carolinas Center believes that the rules should determine what is required to be in the applications and that it is important that the rules contain hospice-specific requirements for the applications.

We believe it is good policy to have clear rules for what is required of applicants so that existing and future providers of hospice services can understand what is required. As provided for in G.S. § 131E-175 (7), the Department is required to evaluate proposed projects on a range of general criteria including need, cost of service, accessibility to services, quality of care, feasibility, and other criteria.

We have additional concerns about repealing the rules related to Information Required of Applicants. While we appreciate the apparent desire to have flexibility to update or change the applications without going through the rule-making process, we do not agree that the rulemaking process relating to the information required to be in an application should be abandoned. Without rules informing the development of the application as required by G.S. § 131E-182(b), the Department can apparently act quickly to update or change the required CON applications and potentially can do so without a required process for public notice and opportunity for comment. While we do not expect the current Administration or its staff to leave stakeholders out of this important review process, we are not aware of any requirement that the public be provided with notice and an opportunity to comment on proposed changes to applications with proposed effective dates for those changes. By contrast, the rulemaking process is set up to be thoughtful and deliberative, providing opportunities for public comment and one that has appropriate checks and balances.

The Carolinas Center believes that the current CON applications are fair and adequately capture what is needed for the state to make a fair assessment of applicants. Without the force of any rule behind the application, there is concern that the application could

materially change without an opportunity for public comment on the changes.

The proposed repeal of the Information Required of Applicants also results in the loss of the following:

10A NCAC 14C .1502 (c) An applicant proposing to develop a hospice shall commit that it shall comply with all certification requirements for participation in the Medicare program within one year after issuance of the certificate of need.

Medicare is the primary payer for hospice services in North Carolina. There is concern that some healthcare providers are marketing 'hospice' or 'hospice-like' services without a license or CON. The Medicare certification requirement ensures that all hospices in North Carolina are providing the full range of services required under federal law and state licensing requirements. We believe that 10A NCAC 14C .1502(c) is necessary and should not be repealed.

Recommendation:

We ask the Department to reconsider its proposed repeal of 10A NCAC 14C .1502 and .4002 until it can

1. Promulgate revised final rules related to project review criteria and the development of the applications; and
2. Update the applications to conform to the requirements of those final rules.

Thank you for your consideration of our comments. Representatives of our association are available to discuss these comments further at your convenience.

Sincerely,



Carol B. Meyer
President and CEO