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October 12, 2016

Ms. Nadine Pfeiffer, DHSR Rules Coordinator
NC Division of Health Service Regulation
2701 Mail Service Center
Raleigh, NC 27699-2701

Ms. Martha Frisone, Assistant Chief
NC Division of Health Service Regulation - CON Section
2704 Mail Service Center
Raleigh, NC 27699-2704

Dear Ms. Pfeiffer and Ms. Frisone:

I am pleased to advise you the North Carolina Radiological Society fully supports the proposal of the North Carolina Hospital Association with respect to the proposed removal of Certificate of Need Criteria and Standards for "Diagnostic Centers" and "Major Medical Equipment," effective December 1, 2016 and the changes to Rules 14C.1804(2-4) as set forth in the NCHA Memorandum dated September 30, 2016, a copy of which is attached hereto.

The North Carolina Radiological Society represents more than 700 radiologists practicing medicine in North Carolina and teaching medicine at all of our medical schools.

We thank you for the time and effort involved in making Health Care work effectively for the people of North Carolina.

Sincerely,

Sheryl Jordan, M.D. cds

Sheryl Jordan, MD, RCC
President

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North Carolina Hospital Association
Serving North Carolina's Hospitals & Health Systems

MEMORANDUM

TO: Ms. Nadine Pfeiffer, DHSR Rules Coordinator
Ms. Martha Frisone, Assistant Chief, CON Section

FROM: Mike Vicario, Vice President of Regulatory Affairs
919-677-4233 (mvicario@ncha.org)

DATE: September 30, 2016

SUBJECT: Diagnostic Center Rules

The Division of Health Service Regulation is proposing to remove Certificate of Need Criteria and Standards for "Diagnostic Centers" and "Major Medical Equipment," effective December 1, 2016. According to the NC Register, obtaining the information needed to conform to the rules places an impossible burden on applicants for a certificate of need.

NCHA agrees that the requirement to identify and document other providers' current and future performance in 14C .1804(1) can be problematic, and supports the Departments proposal to remove that requirement. However, rules in 14C .1804(2-4) require the applicant to document that *its own* existing and proposed diagnostic center equipment will be utilized at "80% of the maximum number of procedures that the equipment is capable of performing by the fourth quarter of the third year of operation following initiation of diagnostic services." The applicant is provided with the opportunity to describe how the equipment's capacity was determined in the CON application form.

NCHA supports retention of those rules, as drafted below, as these reports and projections would clearly be available to the applicant. Further, these rules help to document the level of need the community has for the proposed services, and the data required for those rules would represent a basic component of any applicant's business plan. Retaining the rules as drafted below represents a more reasonable approach to demonstrating need.

SECTION .1800 - CRITERIA AND STANDARDS FOR DIAGNOSTIC CENTERS

10A NCAC 14C .1801 PURPOSE AND SCOPE

The rules set forth in this Section shall apply to applications for diagnostic centers for which specific criteria and standards have not otherwise been promulgated in 10A NCAC 14C.

10A NCAC 14C .1802 DEFINITIONS

The following definitions shall apply to all rules in this Section:

(1) ~~"Approved diagnostic center" means a diagnostic center that was not operational prior to the beginning of the review period but that had been issued a certificate of need or had been developed prior to March 18, 1993 in accordance with 1993 N.C. Sess. Laws c. 7, s. 12.~~

(~~2~~) "Diagnostic center" shall have the same meaning as defined in G.S. 131E-176(7a).

(2)(~~3~~) "Diagnostic center service area" means the geographic area, as defined by the applicant, for which the proposed diagnostic center will provide services.

(3) (~~4~~) "Diagnostic procedure" means a discrete diagnostic procedure with a distinct CPT code or ICD-9-CM procedure code performed on one patient during one visit to a diagnostic suite.

(4)(~~5~~) "Diagnostic suite" means a single room or group of rooms in a diagnostic center, which is used for the purpose of conducting diagnostic procedures.

(5)(~~6~~) "Essential" means those items which are indispensable, the absence of which renders the equipment useless.

~~(7) "Existing diagnostic center" means a diagnostic center in operation prior to the beginning of the review period.~~

~~(8) "Freestanding diagnostic center" means a diagnostic center that is not operated as a part of another health service facility but rather as a discrete business entity. A freestanding diagnostic center may be owned by another health service facility and may be located on the campus of another health service facility.~~

(6)(~~9~~) "Medical diagnostic equipment" means a single piece of diagnostic equipment or a single component of a multi-component diagnostic system which costs ten thousand dollars ($10,000) or more, or whose fair market value is ten thousand dollars ($10,000) or more.

(7)(~~10~~) "Mobile medical diagnostic equipment" means medical diagnostic equipment and transporting equipment, which is moved to provide services at two or more host facilities.

(8)(~~11~~) "Mobile diagnostic program" means the provision of diagnostic services using mobile medical diagnostic equipment and transporting equipment at two or more host facilities.

(9)(~~12~~) "Radiologic technologist or X-Ray technician" means a person who, under the supervision of a physician radiologist, operates radiologic equipment and assists radiologists and other health professionals, and whose competence has been tested and approved by the American Registry of Radiologic Technologists.

10A NCAC 14C .1804 PERFORMANCE STANDARDS

An applicant proposing to establish a new diagnostic center or to expand an existing diagnostic center shall provide:

(1) ~~documentation that all existing health service facilities providing similar medical diagnostic equipment and services as proposed in the CON application in the defined diagnostic center service area were operating at 80% of the maximum number of procedures that the equipment is capable of performing for the twelve month period immediately preceding the submittal of the application~~;
(~~2~~) documentation that ~~all~~ the applicant's existing and approved medical diagnostic equipment ~~and~~ providing services of the type proposed in the CON application and the proposed medical diagnostic equipment are projected to be utilized at 80% of the maximum number of procedures that the equipment is capable of performing by the fourth quarter of the third year of operation following initiation of diagnostic services;

(~~3~~)(2) documentation that the applicant's utilization projections are based on the experience of the provider and on epidemiological studies; and

(~~4~~) (3) all the assumptions and data supporting the methodologies used for the projections in this Rule.