

1 10A NCAC 14C .1902 is proposed as a temporary rule as follows:

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3 **10A NCAC 14C .1902 INFORMATION REQUIRED OF APPLICANT**

4 (a) An applicant proposing to acquire radiation therapy equipment shall use the Acute Care Facility/Medical
5 Equipment application form.

6 (b) An applicant proposing to acquire radiation therapy equipment shall also provide the following additional
7 information:

- 8 (1) a list of all the radiation therapy equipment to be acquired and documentation of the capabilities
9 and capacities of each item of equipment;
- 10 (2) documentation of the purchase price and fair market value of each piece of radiation therapy
11 equipment, each simulator, and any other related equipment proposed to be acquired;
- 12 (3) the projected number of patient treatments by ~~county and by~~ intensity modulated (IMRT),
13 stereotactic radiosurgery, simple, intermediate and complex radiation treatments to be performed
14 on each piece of radiation therapy equipment for each of the first three years of operation
15 following the completion of the proposed project and documentation of all assumptions by which
16 utilization is projected;
- 17 (4) documentation that the proposed radiation therapy equipment shall be operational at least seven
18 hours per day, five days a week;
- 19 (5) documentation that no more than one simulator is available for every two linear accelerators in the
20 applicant's facility, except that an applicant that has only one linear accelerator may have one
21 simulator;
- 22 (6) documentation that the services shall be offered in a physical environment that conforms to the
23 requirements of federal, state, and local regulatory bodies; ~~and~~
- 24 (7) the projected total number of radiation treatment patients that will be treated by county in the
25 facility in each of the first three years of operation following completion of the proposed ~~project.~~
26 project;
- 27 (8) the projected number of radiation treatment patients that will be treated for palliation in each of the
28 first three years of operation following completion of the proposed project; and
- 29 (9) the projected number of radiation treatment patients that will be treated for cure in each of the first
30 three years of operation following completion of the proposed project.

31 (c) An applicant proposing to acquire a linear accelerator for development of a multidisciplinary prostate health
32 center pursuant to a need determination for a demonstration project in the State Medical Facilities Plan shall provide
33 the following additional information:

- 34 (1) description of all services to be provided by the proposed multidisciplinary prostate health center,
35 including a description of each of the following services:
 - 36 (A) urology services,
 - 37 (B) medical oncology services,

- 1 (C) biofeedback therapy,
- 2 (D) chemotherapy,
- 3 (E) brachytherapy, and
- 4 (F) living skills counseling and therapy;
- 5 (2) documentation that urology services, medical and radiation oncology services, biofeedback
- 6 therapy, brachytherapy and post-treatment living skills counseling and therapy will be provided in
- 7 the same building;
- 8 (3) description of any services that will be provided by other facilities or in different buildings;
- 9 (4) demographics of the population in the county in which the proposed multidisciplinary prostate
- 10 health center will be located, including:
- 11 (A) percentage of the population in the county that is African American,
- 12 (B) the percentage of the population in the county that is male,
- 13 (C) the percentage of the population in the county that is African American male,
- 14 (D) the incidence of prostate cancer for the African American male population in the county,
- 15 and
- 16 (E) the mortality rate from prostate cancer for the African American male population in the
- 17 county;
- 18 (5) documentation that the proposed center is located within walking distance of an established bus
- 19 route and within five miles of a minority community;
- 20 (6) documentation that the multiple medical disciplines in the center will collaborate to create and
- 21 maintain a single or common medical record for each patient and conduct multidisciplinary
- 22 conferences regarding each patient's treatment and follow-up care;
- 23 (7) documentation that the center will establish its own prostate/urological cancer tumor board for
- 24 review of cases;
- 25 (8) copy of the center's written policies that prohibit the exclusion of services to any patient on the
- 26 basis of age, race, religion, disability or the patient's ability to pay;
- 27 (9) copy of written strategies and activities the center will follow to assure its services will be
- 28 accessible by patients without regard to their ability to pay;
- 29 (10) description of the center's outreach activities and the manner in which they complement existing
- 30 outreach initiatives;
- 31 (11) documentation of number and type of clinics to be conducted to screen patients at risk for prostate
- 32 cancer;
- 33 (12) written description of patient selection criteria, including referral arrangements for high-risk
- 34 patients;
- 35 (13) commitment to prepare an annual report at the end of each of the first three operating years, to be
- 36 submitted to the Medical Facilities Planning Section and the Certificate of Need Section, that shall
- 37 include:

- (A) the total number of patients treated;
- (B) the number of African American persons treated;
- (C) the number of persons in other minority populations treated; and
- (D) the number of insured, underinsured and uninsured patients served by type of payment category;

(14) documentation of arrangements made with a third party researcher to evaluate, during the fourth operating year of the center, the efficacy of the clinical and outreach initiatives on prostate and urological cancer treatment, and develop recommendations regarding the advantages and disadvantages of replicating the project in other areas of the State. The results of the evaluation and recommendations shall be submitted in a report to the Medical Facilities Planning Section and Certificate of Need Section in the first quarter of the fifth operating year of the demonstration project; and

(15) if the third party researcher is not a historically black university, document the reasons for using a different researcher for the project.

History Note: Authority G.S. 131E-177(1); 131E-183;
Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Eff. January 4, 1994;
Amended Eff. November 1, 1996;
Temporary Amendment Eff. January 1, 1999;
Temporary Amendment Eff. January 1, 1999 Expired on October 12, 1999;
Temporary Amendment Eff. January 1, 2000;
Temporary Amendment effective January 1, 2000 amends and replaces a permanent rulemaking originally proposed to be effective August 2000;
Amended Eff. April 1, 2001;
Temporary Amendment Eff. January 1, 2005;
Amended Eff. November 1, 2005;
Temporary Amendment Eff. February 1, 2009;
Amended Eff. November 1, 2009;
Temporary Amendment Eff. February 1, 2010.