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**Comments on County of Catawba d/b/a Catawba Valley Medical Center's
Replacement Linear Accelerator Application**

Submitted by

Frye Regional Medical Center

In accordance with N.C. GEN. STAT. §131E-185(a1)(1), Frye Regional Medical Center, Inc. ("Frye") submits the following comments related to County of Catawba d/b/a Catawba Valley Medical Center's ("CVMC") application to replace one of its existing linear accelerators ("LINAC"). Frye's comments include "discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with the relevant review criteria, plans and standards." See N.C. GEN. STAT. §131E-185(a1)(1)(c). As such, Frye's comments are organized by the general CON statutory review criteria as they relate to the following application: County of Catawba d/b/a Catawba Valley Medical Center, Linear Accelerator replacement, Project I.D. # E-8603-10.

Because the proposed expenditure for this project is over \$2 million, N.C. Gen. Stat §131E-176(22a) and the rules contained in 10A NCAC 14C .0303 regarding replacement equipment do not apply. However, an applicant must still demonstrate a need by the community to be served for any additional services they propose to perform on the replacement equipment. CVMC fails to demonstrate such a need, for the reasons discussed herein.

(3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

CVMC fails to demonstrate the need the population has for the proposed project, based on the following:

- The utilization numbers for CVMC's existing LINACs provided on page 40 of the Application show a decrease in procedures over the past year.

The number of cancer patients treated on LINACs has decreased each year since FY 2008. See the following chart, provided by CVMC:

	FY 2008	FY 2009	FY 2010
Procedures	15,530	16,455	14,134
ESTVs	14,405	15,522	12,930
Cancer Patients Treated on LINACs	677	640	542

Source: CVMC Application, page 40

- CVMC attributes its decrease in both patients and procedures to 4 main causes:
 - Frye’s acquisition of a LINAC.
 - Patients increasingly leaving Catawba County for treatment – CVMC attributes this fact to a lack of SRT in Catawba County but provides no evidence to support this assertion. There are references to inpatient data supplied by the “Patient Data System” (CON Application, pp. 18, 40), but there is no explanation of what that Patient Data System is, and no data is supplied.
 - A decrease in Catawba County oncologists – CVMC states that Northwest Oncology lost an oncologist in March 2010, (a new cardiologist was scheduled to start in October 2010 and they are in the process of recruiting an additional physician as well).
 - Improvement in treatment techniques has led to a decrease in the number of treatments patients typically need.
- It is important to note that while CVMC lists several reasons why their numbers have decreased, deficiencies in their current equipment is not listed as one of those reasons. If the numbers are not decreasing because of old equipment, it is unreasonable to believe that purchasing new equipment will cause the numbers to increase.
- The number of procedures performed on LINACs has decreased statewide, and every LINAC service area now shows a surplus in machines. Area 5

(where CVMC is located) has the largest surplus in the state. Given such an overall decrease in radiation oncology statewide, CVMC has failed to show why its general radiation oncology procedures will increase with the replacement of its current LINAC.

- CVMC also fails to demonstrate a need for SRT. On page 42 of the Application, CVMC projects to perform 65 SRT procedures per year, with no increase from FY 2012 to FY 2014. CVMC provides no historical or other basis for this projection. The application states on page 42 that the SRT projections are based on “an internal analysis of CVMC’s cancer patients and discussions with the CVMC Radiation Therapy Department.” However, CVMC does not provide any such “internal analysis” and none of the letters of support attached to the application project any number of SRT procedures.
- Additionally, CVMC fails to demonstrate the need for SRT because it fails to demonstrate that it has the physicians capable and willing to perform SRT procedures. Please see discussion under (7).
- On page 39 of its application, CVMC implies that the replacement LINAC requested in the application is crucial to providing the residents of Catawba County with local access to radiation therapy services. However, as discussed above, the application does not propose to increase the number of LINACs in the service area, nor does it demonstrate the need for the one new service proposed, SRT.

(4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CVMC fails to demonstrate that it has proposed the least costly or most effective alternative. The CVMC Application proposes equipment that is not comparable to the equipment that it is replacing because it will be used to provide additional services

not currently offered at CVMC. This service requires additional equipment and software, so therefore it is not the least costly alternative. It also is not the most effective alternative, because CVMC has failed to demonstrate a need for the additional services proposed.

(5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

CVMC fails to demonstrate that its utilization projections are based on sound and reasonable assumptions; therefore the immediate and long-term financial feasibility of the project is questionable. Please see the discussion under Criterion 3.

(6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

CVMC fails to demonstrate that the proposed project will not result in unnecessary duplication of existing health services. See the discussion under (3).

(7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

CVMC does not provide adequate documentation/evidence that it has properly prepared to offer SRT services with the new Linear Accelerator proposed in its CON application. On page 88 of the Application, CVMC states that “staffing for the proposed replacement LINAC is not expected to change from current levels.” Additionally, CVMC states on page 89 that “Existing staff already possesses the required education, experience, and appropriate licensure/certifications to provide administrative and support services for the proposed radiation therapy equipment.”

SRT requires a neurosurgeon to be present for the procedure’s beam-on time and also requires that a neurosurgeon draws the contours on the CT scan during the planning phase for the treatment plan. The CVMC Application fails to identify any neurosurgeon interest or support. Such support would also have to indicate appropriate training and skills to utilize SRT. It is our understanding that the only two neurosurgeons on the CVMC medical staff are Dr. Scott McCloskey and Dr. Peter Miller. Neither wrote a letter of support for the CVMC project.

The CVMC Application fails to demonstrate its proposed population’s need for the additional services and capacity of the new proposed LINAC, fails to demonstrate that CVMC’s decrease in LINAC market share will be remedied by a new “replacement” machine, fails to demonstrate that its proposal is the least costly and most effective alternative, and fails to demonstrate that CVMC has properly anticipated the staffing requirements to perform the new services it proposes to provide. For the above-mentioned reasons, the CVMC Application cannot be found conforming with N.C. GEN. STAT. §131E-183(a) and must be denied by the Agency.