**COMMENTS SUBMITTED BY HOPE-A WOMEN'S CANCER CENTER
IN OPPOSITION TO
PROJECT I.D. NO. B-8542-10
MISSION HOSPITAL REPLACEMENT LINEAR ACCELERATOR
JULY 15, 2010**

Hope-A Women's Cancer Center (Hope) is a physician practice located at 100 Ridgefield Court in Asheville, North Carolina 28806. Hope treats women who have gynecologic and breast health problems. Many of these patients come to Hope for cancer treatment. Hope has previously sought permission from the North Carolina Department of Health and Human Services, Division of Health Service Regulation to offer linear accelerator services at its Asheville facility. Mission Hospital (Mission) vigorously opposed Hope's request, and the Department denied Hope's request. Hope's request is now pending review at the North Carolina Supreme Court. Mission also vigorously opposed Asheville Hematology's efforts to have radiation therapy in Asheville That litigation lasted several years.

Now Mission has filed a CON application seeking to replace one of its three linear accelerators. This linear accelerator will be located in Mission's Regional Cancer Center (Project I.D. No. B-7986-07) which is currently under construction. For the reasons stated below, Mission's CON application should be denied because it does not meet the CON criteria.

I. MISSION HAS FAILED TO DEMONSTRATE THE NEED FOR THE PROJECT AND IS THEREFORE NON-CONFORMING UNDER CRITERION 3.

On page 18 of its application, Mission states that "[t]his project only requires prior CON approval because the cost of the replacement linear accelerator exceeds $2 million." This statement is incorrect; there are several reasons why the project requires CON approval.

According to N.C. Gen. Stat. § 131E-176(16), Mission's project is a "new institutional health service" that requires a CON because:

- It involves a capital expenditure of more than $2 million to develop or expand a health service or health service facility. *See* N.C. Gen. Stat. § 131E-176(16)b.;
- It is a change in a previously-approved project that has not yet been completed. *See* N.C. Gen. Stat. § 131E-176(16)e.; and
- It proposes the acquisition of a linear accelerator. *See* N.C. Gen. Stat. § 131E-176(16)f1.5a.

Moreover, to the extent Mission's statement implied that that the filing of this CON application was "just a formality," Mission is wrong.[1] All CON applications have to demonstrate the need for the projects they propose, and all CON applications must receive the same rigorous analysis. The burden is on Mission to show the need to replace this linear accelerator, and as explained below, Mission has failed meet its burden.

The first question the Agency should ask in reviewing Mission's replacement equipment application is whether the linear accelerator actually needs to be replaced. Yet the Mission application is utterly silent on this point. Other than the brand (Siemens Primus) and its age (currently 9 years), the reader is not told anything about the linear accelerator, such as its useful life, its condition and its capabilities. Rather, the CON Section is simply asked to assume that because the equipment will be 11 years old by the time the Regional Cancer Center opens in 2012, it must be replaced. There is, however, simply no basis for making this

[1]As Exhibit 29 shows, the list price of an Elekta Infinity is more than $6 million. Mission is receiving a substantial discount, but the machine is still quite expensive. Since the fundamental purpose of the CON Law is cost control, *see* N.C. Gen. Stat. § 131E-175, the applicant must provide facts demonstrating why it needs to spend this money.

assumption. The useful life of a Siemens Primus linear accelerator is not a matter of common knowledge. The applicant is required to give the CON Section factual information to document why the machine needs to be replaced. It was incumbent upon Mission to substantiate the need for the replacement with facts and it has failed to do so. *See* N.C. Gen. Stat. § 131E-183(a)(3).

Mission was obviously well aware when it filed the Regional Cancer Center application in 2007 that the Siemens Primus linear accelerator would be 11 years old by the time the Regional Cancer Center opened in 2012. Yet in 2007, Mission did not ask permission to replace Siemens Primus. Instead, Mission asked to replace another linear accelerator, the Siemens MD-2. From this, one can reasonably infer that Mission expected that the Siemens Primus would be suitable for installation in the Regional Cancer Center; otherwise, it would have asked to replace that machine as well.[2] Therefore, age of the machine was not a barrier to its continued use at the Regional Cancer Center. If something happened to the Siemens Primus between 2007 and 2010 that warrants the machine's replacement, the reader is only left to wonder. If there were a real need to replace this machine, one would expect that the physicians who use it on a daily basis might offer some information about their experience with the machine and why they think it needs to be replaced. Yet the physician letters in Exhibit 10 say absolutely nothing about why this machine needs to be replaced. Likewise, the administrative letters in Exhibit 10 are silent on this topic.

[2]Mission's application refers to an "extended appeal" for the Cancer Center. *See* application, page 30. Yet the application also contains the projections for the Cancer Center application which run through 2013. *See* application, page 43. This means the applicant was planning on using the Primus at least through 2013, when the Primus will be 12 years old, so the applicant had to have considered the age and condition of the Primus at the time it filed the Cancer Center application.

On page 30 of the application, Mission refers to the fact that the machine will be fully depreciated in 2012. Depreciation is not the equivalent of obsolescence. Mission also refers to the advancement of linear accelerator technology, yet provides no information to demonstrate that the Siemens Primus is technologically outmoded. Given that Mission proposes to use the machine at least until the day the new Regional Cancer Center opens in 2012, the Siemens Primus must still be viable. Further, Siemens still makes the Primus, so it does not appear that Siemens thinks the Primus is outmoded. *See* www.medical.siemens.com.[3] There is no information in the application to suggest that Siemens Primus is incapable of being upgraded, through software or otherwise, if upgrades are needed to keep pace with technology.

In Section III of the application, Mission talks about growth in procedures, growth in cancer cases and growth in population. However, Mission has failed to link this information with the fundamental question: why does this machine need to be replaced? It would be wrong to assume that a growth in procedures or cancer cases means that the linear accelerator needs to be replaced. There is no information in the application to suggest that the Siemens Primus is incapable of handling future volumes projected in the application.

The burden is always on the applicant to demonstrate the need for the project. The CON Section cannot assume, speculate, fill in the blanks for the applicant or ignore obvious gaps in information. It is too late for Mission to try to plug these holes now, as that would constitute an impermissible amendment to the application. *See* 10A NCAC 14C.0204.

On page 18 of the application, Mission states "it is more cost effective to purchase two replacement linear accelerators concurrently, and installation costs are significantly lower when

[3]By contrast, Siemens no longer makes the MD-2, which was approved for replacement in the Cancer Center application.

the second linear accelerators is replaced and installed before the new Cancer Center is substantially complete in the fall of 2011." No factual support is offered for these statements. Logically, it cannot be more "cost effective" to spend an additional $2.1 million when originally this expense was not supposed to be incurred at all.

Another major flaw is the fact that Mission did not answer the special rules applicable to linear accelerator applications. These are found at 10A NCAC 14C.1901 *et seq.* These rules apply when an applicant is proposing to acquire a linear accelerator, which is obviously the case here. Responding to these rules is mandatory. The rules play an important part in the analysis of whether the project is needed. The rules make no exception for applicants who are proposing to replace existing linear accelerators. Since it did not answer the rules, the CON Section cannot tell, for example, whether each of Mission's existing linear accelerators performed at least 6,750 ESTVs or served at least 250 patients in the twelve months preceding the application. *See* 10A NCAC 14C .1903(a)(1). This includes Mission's CyberKnife, which is a type of linear accelerator. As the table on page 38 of the application shows, this unit appears to be underutilized. Similarly, since the applicant did not answer the special rules, it is impossible to tell whether each linear accelerator will meet the performance standards in 10A NCAC 14C.1902(a)(2) and (a)(3). The applicant's need projections in Section III of the application are useless in this regard because they show *averages*. The rules do not ask for averages – they ask for the performance of *each* machine.

Again, it is the applicant's burden to answer these rules and provide the information. The Agency should not take it upon itself to try to answer these questions for the applicant.

As part of the Cancer Center application, Mission was approved to replace one of its existing linear accelerators with an Elekta Infinity linear accelerator. In this application,

Mission proposes to buy a second Elekta Infinity linear accelerator. The applicant does not explain why it needs two of the exact same linear accelerators. The applicant also does not explain whether the Elekta Infinity has capabilities that the Siemens Primus does not. The fact that the applicant proposes to acquire two of the exact same machines (at a substantial discount) suggests that it was offered a better deal if it bought two machines rather than one. Yet the fact that a manufacturer offers special pricing for volume purchases does not mean that the project is needed.

II. CAPITAL COSTS ARE UNDERSTATED; THEREFORE, THE APPLICATION IS NON-CONFORMING WITH CRITERION 5.

Since the applicant is proposing to replace the Siemens Primus, the applicant must remove and dispose of the Primus when the Elekta is installed. There will be a cost associated with the removal and disposal of the linear accelerator, but the applicant does not account for this cost in Section VIII of the application. The funding letter in Exhibit 26 is for the exact amount of the machine; no disposal cost is included. No contingency has been included.[4] The Elekta equipment quote says nothing about disposing of the Primus. Again, it is too late for Mission to come back now and tell the Agency what the disposal cost is and how it will pay for the disposal cost. Since the application must include all costs, the application should be disapproved for failure to include this essential cost. *See* N.C. Gen. Stat. § 131E-183(a)(5).

CONCLUSION

All applicants must be treated the same. All applicants must demonstrate the need for the projects they propose. Mission's failure to answer a basic foundational question (why

[4]Footnote 30 in the application states "includes contingency," but the amount in Section VIII is $2,159,279.50, which is the exact amount of the Infinity System #2 in the vendor quote in Exhibit 29. Thus, no contingency was included and Footnote 30 appears to be a mistake. The CON application for the Regional Cancer Center did not propose replacement of the Siemens Primus, so removal and disposal costs were not included in that application. The architect's letter in Exhibit 6 says nothing about disposal costs.

does Siemens Primus need to be replaced?), failure to respond to the applicable administrative rules and failure to include all required costs makes this application unapprovable.

Hope appreciates the Agency's review and consideration of these comments and asks that it be informed of the decision on this application.