

COMMENT

**Comment on Petition for Special Need Adjustment
for Linear Accelerator in Service Area 20**

COMMENTER

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Rex Healthcare ("Rex") appreciates the opportunity to comment on the petition filed by Duke Raleigh Hospital ("Duke") for an additional linear accelerator ("linear accelerator") in Service Area 20. While Rex understands the need for providers to petition for adjustments to the standard need determination when they believe special circumstances exist, Rex does not believe an additional linear accelerator is warranted in Service Area 20 at the present time. First, it should be noted that Duke's petition is similar in rationale and identical in request to its 2012 petition. Rex believes that the circumstances in the service area that led the Technology and Equipment Committee and the SHCC to deny Duke's petition last year have not changed in such a way to warrant approval of the petition this year. In fact, as described in detail below, Rex believes Duke's rationale is even less compelling than it was in 2012, and the petition should again be denied. The following discussion will provide detail as to Rex's concerns about the allocation of another linear accelerator in the service area, based on the following primary reasons:

1. Additional linear accelerator capacity is under development or has recently been developed in the service area.
2. Duke's utilization trend does not demonstrate the need for another linear accelerator.
3. Approval of the *Proposed 2014 SMFP* will add another linear accelerator to the area.

Each of these issues is discussed in detail below.

Additional Linear Accelerator Capacity Available

Duke's petition refers to the delay in the development of CCNC's approved linear accelerator as a basis for the need for another linear accelerator in the service area. Rex believes contrarily that the fact that an approved linear accelerator has yet to be developed in the service area is a reason not to allocate yet another linear accelerator, unless there is a reasonable expectation that the additional unit will not be developed or

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a similarly compelling reason. As is common practice in the various need methodologies in the *SMFP*, a placeholder for the approved linear accelerator is used to prevent the continual re-allocation of another unit of equipment until the approved equipment can be made operational. As noted in the latest progress report from CCNC included in Duke's petition, the schedule for developing CCNC's additional linear accelerator indicates that construction for the project is expected to be complete in 2014, with the additional linear accelerator becoming operational in 2015. If the CON Section believed that CCNC were not developing the linear accelerator in a timely manner, it could withdraw the certificate¹; however, it has not done so, and thus evidently believes that CCNC is proceeding in good faith. If the SHCC were to ignore this approved equipment and approve Duke's petition, it is likely that the linear accelerator at CCNC would be developed long before the linear accelerator in the 2014 *SMFP* could be developed. Given that the approval of Duke's petition would not prevent this approved linear accelerator from being developed, the SHCC should not ignore the fact that CCNC has received a CON and will add capacity to the service area in the future.

Duke also refers to the linear accelerator in Franklin County, which has low utilization compared to the average in the service area. Although other methodologies, such as the operating room methodology, include exclusions for "chronically underutilized" facilities, the current linear accelerator methodology does not. While Duke attempts to describe this linear accelerator as operating outside of the "effective capacity" of the service area, such a definition does not currently exist in the methodology for linear accelerators and the capacity does, in fact, exist in the service area.

In addition, Duke completely ignores the recently-developed Cary Urology linear accelerator, which, as noted in the comments filed by that provider, began operating only a few months ago. While this provider is focused on prostate patients, there are no conditions on its certificate of need that prevent it from serving any and all patients and types of cancers, just like the other existing and approved linear accelerators in Service Area 20. Moreover, even if the Cary Urology linear accelerator were limited to prostate cases only, these cases represent a significant portion of the demand for linear accelerator procedures, given both the prevalence of prostate cancer and the use and higher number of linear accelerator treatments for prostate cancers; as such, the new linear accelerator would be able to serve a substantial portion of the procedures already being performed in the service area.

Finally, Duke fails to consider the additional throughput represented by Rex's approved replacement linear accelerator at its Wakefield campus. In April 2013, Rex received a certificate of need to replace its linear accelerator in northern Wake County. The replacement linear accelerator will provide kilovoltage (KV) imaging, cone beam capabilities, and volumetric modulated arc therapy, which is currently unavailable at Rex Healthcare of Wakefield. These advancements, along with additional upgrades, will improve patient access and throughput in the service area, which should be considered as this linear accelerator is well-utilized.

¹ <http://www.ncdhhs.gov/dhsr/coneed/progressreport.html>.

Based on these factors, Rex believes the SHCC should consider, as it did last year, that an additional linear accelerator has been approved for Service Area 20 with a second being newly-developed, and a third at Rex being approved to be replaced and upgraded; therefore, no additional capacity is needed at this time.

Duke's Data Do Not Demonstrate the Need for its Petition

Based on the utilization information presented in Duke's petition, the hospital does currently appear to exceed the utilization threshold for one linear accelerator. However, the historical data does not demonstrate a sustainable growth trend, but rather a one-year spike in volume. As shown on page 3 of the petition, from the 2010 to the current 2013 SMFP, Duke's volume barely fluctuated, and actually experienced a compound annual growth rate of *negative* 0.4 percent. For the 2012 data in the *Proposed 2014 SMFP*, Duke's volume appears to spike to 9,807 ESTV's, but, in the most recent year (2013), decreases back to 9,154 ESTV's. Thus, the first issue with Duke's data trend is that the 2012 volume appears to be an outlier, not a trend.

Second, the 2013 "outlier" year is based on questionable data. In its 2013 HLRA, Duke states that it provided 11,142 linear accelerator treatments on a total of 8,166 patients in 2012. In comparison, in its 2012 HLRA, Duke reported 8,446 treatments and only 325 patients in 2011. Clearly, Duke did not actually treat over 8,000 patients on its linear accelerator in 2012, and although that number matches the patient origin data in the same document, it is obviously erroneous. The SHCC commonly refrains from determining that need for additional capacity exists when a provider's data is clearly in error, such as for acute care beds; for similar reasons, the SHCC should not award a special need determination based on data that is highly suspect.

Finally, Duke's data issues also extend to the most recent year, reported as 2012-13 and shown in Exhibit C of its petition. As was the case in last year's petition as well, Duke presents data for FY 2013 as a complete year; however, federal fiscal year 2013 is not yet complete. Thus, Duke has either annualized its volume based on an incomplete year, or it is using a different fiscal year for reporting data for 2013. If the data are annualized, then the SHCC should consider that the actual data for the full year may be much different than the annualized total, and may in fact be lower. If the data are for a different fiscal year, then the comparison to previous years is flawed, because they are based on Duke's reported volume in its HLRA, which states that data are to be reported for October 1 to September 30, or federal fiscal years.

Approval of the Proposed 2014 SMFP Will Increase Capacity in the Area

Even if the SHCC believes that additional capacity may be warranted in the area, approval of the *Proposed 2014 SMFP*, as written, will provide that additional capacity. Although Duke's petition mentions the fact that the *Proposed 2014 SMFP* includes the separation of Harnett County out of Service Area 20 and into its own new service area, it does not provide any analysis of the impact of the potential development of that linear

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accelerator on its proposal. In essence, since Harnett County is currently part of Service Area 20, the allocation of a linear accelerator in the newly-created Service Area 21 will add capacity in the currently-defined Service Area 20. Duke failed to adequately analyze this fact, and as such, has failed to demonstrate that approval of its petition would not unnecessarily duplicate the pending approval of the linear accelerator in Harnett County.

In addition, the allocation of a linear accelerator in Harnett County would likely have the greatest impact on Duke, thereby diminishing some of the volume on the Duke linear accelerator. As indicated in the Medical Facilities Planning Branch's database, based on the 2013 Hospital License Renewal Applications and Registration and Inventory of Medical Equipment forms, Duke Raleigh Hospital treated the plurality of patients from Harnett County in 2012 – a total of 75 of the nearly 300 patients² who had linear accelerator treatments from that county; thus, the development of the first linear accelerator in Harnett County would likely decrease the number of patients seeking care at Duke in particular. If each of these patients receives 25 treatments on average³, that represents a total of 1,875 treatments. If just one-half of these patients chose to access care in Harnett County in the future, that would reduce the number of treatments at Duke by over 900, and certainly the potential exists for a much greater impact (decrease) at Duke, even beyond the decrease Duke experienced from 2012 to 2013.

Based on these factors, Rex believes that Duke has failed to demonstrate any compelling reason that patients in Service Area 20 need an additional linear accelerator and believes that the petition should be denied.

² There is a minor discrepancy between the database and the numbers reported on the various forms; however, the difference is immaterial to this analysis, and the number of Harnett County patients treated at Duke Raleigh Hospital is shown as 75 in both locations.

³ Although the number of treatments varies based on site and treatment plan, 25 is a reasonable average to use for planning for most linear accelerators that treat a variety of cancer types.