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COMMENT

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

COMMENTER

Rex Healthcare
4420 Lake Boone Trail
Raleigh, NC 27607

Steve Burriss
Chief Operating Officer
919-784-3181
Steve.Burriss@rexhealth.com

Rex Healthcare ("Rex") appreciates the opportunity to comment on the petition filed by Duke Raleigh Hospital ("Duke") for an additional linear accelerator ("linac") 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 linac is warranted in Service Area 20 at the present time. 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. Since 2007, three additional linacs have been approved or otherwise added to the inventory in Service Area 20, which is more than any other service area in the state.
2. Duke's linac volume (ESTV's) actually declined from the *2010 SMFP* to the *Proposed 2013 SMFP*, indicating no basis of need for additional equipment.
3. The surplus of linacs in Service Area 20 has increased over the past several years.

Each of these issues is discussed in detail below.

Additional Linacs in Service Area 20 Currently Under Development

First, the SHCC should be aware that the capacity of linacs in Service Area 20 has increased significantly since 2007. In addition to the 2007 CON-approval of a linac at Cancer Centers of North Carolina (CCNC), as cited in the petition, the linac in Franklin County (which has been operational since 2006) has recently become officially recognized in the *SMFP*, and a third linac was approved for Cary Urology to develop in a prostate health center in Raleigh. Both the CCNC and Cary Urology linacs represent new, unused capacity in the service area that will become available in the near future.

Duke's petition refers to the delay in the development of CCNC's approved linac as a basis for the need for another linac in the service area. Rex believes contrarily that the fact that an approved linac has yet to be developed in the service area is a reason not to allocate yet another linac. As is common practice in the various need methodologies in

the *SMFP*, a placeholder for the approved linac is used to prevent the continual re-allocation of another unit of equipment until the approved equipment can be made operational. According to CCNC's project development schedule included in Duke's petition, the linac can be made operational in fewer than six months from the ordering of the equipment. If the SHCC were to ignore this approved equipment and approve Duke's petition, the linac at CCNC could be developed before the CON review was even scheduled. Given that the approval of Duke's petition would not prevent this approved linac 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 linac in Franklin County, which has low utilization compared to the average in the service area. Although this linac has been operating since 2006, it only recently became recognized in the *SMFP*. Prior to its inclusion in the official inventory, two additional linacs received CON-approval in Wake County—one at CCNC and one at Cary Urology. Particularly now that the Franklin County linac is also part of the inventory, its existence—and available capacity—should be considered, as the *SMFP* methodology correctly does.

As a final point on this issue, Duke states that it believes the Cary Urology scanner will not "alleviate the demand on the existing high-volume accelerators in the service area" because of its "dedicated-use" status. While the linac is dedicated to be used as part of the demonstration project, the SHCC should be aware that the Cary Urology linac is in no way limited as to the types of cancers or patients it can treat. As stated in Table 9J of the *Proposed 2013 SMFP*, the linac is part of a "prostate health center *focused* on the treatment of prostate cancer," but not limited as such (emphasis added). Further, the conditions of Cary Urology's Certificate of Need do not limit it to only prostate cases, as Mr. Mike McKillip, CON Project Analyst testified in the contested case hearing on Cary Urology's project:

> *87*
> *Q Let me know when you're there. Are those the--is the boldface type--on pages 755 and 756 is the boldface type the conditions that the CON Section placed upon the approval of the Cary Urology application?*
> *A Yes.*
> *Q Okay. Now, you're not aware of anything in those conditions on 755 or 756 of the agency file that would prevent Cary Urology from providing linac services to anyone who might be referred to the linac approved here; is that fair?*
> *A Yes.*
> *Q And also you're not aware of any of these conditions preventing Cary Urology's linac services through*
> *88*
> *this prostate health center from being provided to cancer patients other than prostate cancer patients; correct?*

A Correct.
Q And you're not aware of anything in these conditions that prevents Cary Urology's linac services from being provided to patients other than African-American males; correct?
A Correct.
Q And you're not aware of any of these conditions limiting the percentage or numbers of non-prostate cancer patients served on Cary Urology's linac; correct?
A Correct.
Q And you're not aware of any of these conditions setting the maximum percentage or number of patients that Cary Urology could serve on its linac that would not be African-American males; correct?
A Correct.

Please see Attachment 1 for the caption pages and excerpt of the hearing transcript quoted above.

Thus, there are no conditions on the Cary Urology CON that prevent it from serving any and all patients and types of cancers, just like the other existing and approved linacs in Service Area 20. Moreover, even if the Cary Urology linac were limited to prostate cases only, these cases represent a significant portion of the current demand for linac procedures; as such, the new linac would be able to serve a substantial portion of the procedures already being performed in the service area.

Based on these factors, the SHCC should consider that two additional linacs have been approved for Service Area 20 with a third being newly-recognized; therefore, no additional capacity is needed at this time.

Duke's Linac Volume Has Not Increased for Several Historical Reporting Periods

Duke's own linac volume has been rather flat since 2007, as shown on page 3 of its petition, and actually declined overall from 2007 to 2011. Only in the most recent year has the volume of ESTV's increased substantially; however, the accuracy of these data is uncertain. First, the data for 2011-2012 appear beside the other years, which are apparently the reporting periods for Hospital License Renewal Applications and *SMFP*s: federal fiscal years. Yet, the 2011-2012 federal fiscal year is not yet complete; thus, Duke must have either annualized its data or provided data for another, unidentified timeframe. In either case, the SHCC should not rely on this data to find a special need for another linac in the service area, given the potential that the data is erroneous or anomalous. Even if the data are accurate, and Duke's ESTV volume has increased as shown, that level of utilization in itself is not sufficient to warrant the allocation of yet another linac in Service Area 20. Table 9G of the *Proposed 2013 SMFP* shows several providers with similar or higher per-linac utilization than what Duke shows for 2012, and many providers with higher volume than what Duke has historically performed.

While higher utilization can sometimes be problematic for a provider to sustain over a long period, Duke has not sufficiently substantiated its 2012 volume nor demonstrated that its volume can realistically be expected to continue to grow.

It appears that Duke may be asking the SHCC to ignore the service area methodology in favor of a facility-specific methodology that would allocate additional linacs regardless of the average utilization in the service area. If the SHCC chooses to make such a change in the methodology, the spring would be a more appropriate time to consider a facility-based methodology.

Service Area 20 Linac Capacity Surplus Continues to Grow

As shown in the tables in the linac portion of the *SMFPs*, Service Area 20 has had a surplus of linac capacity for several years. Using the *2010* and *Proposed 2013 SMFPs*, the same timeframe provided in the Duke petition, Table 9F of the *2010 SMFP* shows a surplus of 1.77 linacs in Service Area 20; the corresponding table in the *Proposed 2013 SMFP*, Table 9H, shows a surplus of 2.41 linacs. Thus, even with increasing total utilization in the service area, the additional capacity of the already approved linacs has expanded the surplus, indicating the need for additional linacs is decreasing.

The petition fails to truly consider negative impact of another linac in the service area. The growth in the surplus of linacs in the service area, which has persisted over the last several years will continue to increase. A growing surplus means that the average per-linac volume of existing providers is continuing to decline—the approval of another linac will further erode the utilization of existing providers in the service area. This is in direct opposition to the intent of the health planning process and the CON law, which states at § 131E-175 (4) and (6):

> *"That the proliferation of unnecessary health service facilities results in costly duplication and underuse of facilities, with the availability of excess capacity leading to unnecessary use of expensive resources and overutilization of health care services....That excess capacity of health service facilities places an enormous economic burden on the public who pay for the construction and operation of these facilities as patients, health insurance subscribers, health plan contributors, and taxpayers."* (emphasis added)

Given that the surplus of linacs has continued to increase, the growth in linac procedures has not exceeded the growth of available capacity represented by the existing and approved linacs in the service area. If the SHCC were to approve Duke's petition because its recent one-year volume—and not that of the service area as a whole—has demonstrated a need for additional capacity, then the surplus of linacs will increase in Service Area 20, meaning volume may shift among providers, but no significant increase in the average utilization of linacs will occur.

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.

Attachment 1

STATE OF NORTH CAROLINA COUNTY OF WAKE	IN THE OFFICE OF ADMINISTRATIVE HEARINGS
REX HOSPITAL, INC. d/b/a REX HEALTHCARE, Petitioner, and UNIVERSITY OF NORTH CAROLINA HOSPITALS AT CHAPEL HILL and WAKE RADIOLOGY ONCOLOGY SERVICES, PLLC, Petitioner-Intervenors, v. NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIVISION OF HEALTH SERVICE REGULATION, CERTIFICATE OF NEED SECTION, Respondent, and PARKWAY UROLOGY, P.A., d/b/a CARY UROLOGY, P.A., Respondent-Intervenor.	No. 09-DHR-5769 TRANSCRIPT OF HEARING BEFORE HONORABLE BEECHER R. GRAY ADMINISTRATIVE LAW JUDGE TUESDAY, JUNE 1, 2010
UNIVERSITY OF NORTH CAROLINA HOSPITALS AT CHAPEL HILL, Petitioner, and REX HOSPITAL, INC., d/b/a REX HEALTHCARE, and WAKE RADIOLOGY ONCOLOGY SERVICES, PLLC, Petitioner-Intervenors,	Courtroom A Office of Administrative Hearings 1711 New Hope Road Raleigh, North Carolina 9:00 a.m. VOLUME PAGES 1 THROUGH 223

v.	)	No. 09-DHR-5770
	)	
NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIVISION OF HEALTH SERVICE REGULATION, CERTIFICATE OF NEED SECTION,	)	
	)	
Respondent,	)	
	)	
and	)	
	)	
PARKWAY UROLOGY, P.A., d/b/a CARY UROLOGY, P.A.,	)	
	)	
Respondent-Intervenor.	)	
WAKE RADIOLOGY ONCOLOGY SERVICES, PLLC,	)	
	)	
Petitioner,	)	
	)	
and	)	
	)	
UNIVERSITY OF NORTH CAROLINA HOSPITALS AT CHAPEL HILL and REX HOSPITAL, INC. d/b/a REX HEALTHCARE,	)	
	)	
Petitioner-Intervenors,	)	
	)	
v.	)	No. 09-DHR-5785
	)	
NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIVISION OF HEALTH SERVICE REGULATION, CERTIFICATE OF NEED SECTION,	)	
	)	
Respondent,	)	
	)	
and	)	
	)	
PARKWAY UROLOGY, P.A., d/b/a CARY UROLOGY, P.A.,	)	
	)	
Respondent-Intervenor.	)	

with the first one anyway, but we'll come back after lunch and pick it up.

Mr. Qualls: Your Honor, our first witness is going to be Mike McKillip from the Agency, whom we are calling adversely. And under the rules of evidence, I would ask if we could ask leading questions because he will be a hostile witness, being an opposition witness.

The Court: All right.

The Reporter: Mr. Qualls, may I ask if this witness is a witness for all three petitioners?

Mr. Hollowell: Yes, Your Honor.

Mr. Kirschbaum: Yes.

(Whereupon,

MICHAEL McKILLIP

was called as a witness, duly sworn, and testified as follows:)

D I R E C T E X A M I N A T I O N 11:16 a.m.

By Mr. Qualls:

Q Good morning, Mr. McKillip.

A Good morning.

Q As you know, my name is Gary Qualls and I represent UNC. I'll be asking you some questions today. If you'll turn to the agency file, which should be in front of you, and I'll ask you to turn to the first page and ask if you can identify that? And that should be in--within the

A Yes.

Q If the Cary Urology application had indicated that they did not propose to provide medical oncology services, it's your view that they would have--that Cary Urology's application would have been nonconforming with Criterion (1); is that fair?

A I think so.

Q Now, if you look at--let's look in the findings at pages 755 and 756, which is toward the very end, I believe. Actually, it's the last two pages.

(Witness complies.)

A Okay.

Q Let me know when you're there. Are those the--is the boldface type--on pages 755 and 756 is the boldface type the conditions that the CON Section placed upon the approval of the Cary Urology application?

A Yes.

Q Okay. Now, you're not aware of anything in those conditions on 755 or 756 of the agency file that would prevent Cary Urology from providing linac services to anyone who might be referred to the linac approved here; is that fair?

A Yes.

Q And also you're not aware of any of these conditions preventing Cary Urology's linac services through

this prostate health center from being provided to cancer patients other than prostate cancer patients; correct?

A Correct.

Q And you're not aware of anything in these conditions that prevents Cary Urology's linac services from being provided to patients other than African-American males; correct?

A Correct.

Q And you're not aware of any of these conditions limiting the percentage or numbers of non-prostate cancer patients served on Cary Urology's linac; correct?

A Correct.

Q And you're not aware of any of these conditions setting the maximum percentage or number of patients that Cary Urology could serve on its linac that would not be African-American males; correct?

A Correct.

Q Now, the conditions, I believe, talk in terms of a report. And if you look at--look at condition 7. Well, actually, look at condition 6 first. And condition 6 on page 755 talks in terms of an annual report at the end of each of the first three years. Do you see that?

A Yes.

Q Okay. And it talks about specific items that are to be included in that report. Do you see that?