

PETITION

Petition for Change to Cardiac Catheterization Need Determination Methodology

PETITIONER

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STATEMENT OF THE PROPOSED CHANGE

Rex Healthcare (Rex) respectfully petitions the State Health Coordinating Council (SHCC) to change the Cardiac Catheterization Need Determination Methodology in *2015 State Medical Facilities Plan (2015 SMFP)*. Specifically, Rex requests that the threshold for additional cardiac catheterization equipment be applied to each hospital, or in the case of hospitals under common ownership in the same service area, to each group of hospitals. Need determinations would be granted once equipment is appropriately utilized irrespective of the utilization of other hospitals in the same service area. Rex proposes the following changes to Chapter 9: Cardiac Catheterization Need Determination Methodology, Methodology 1:

Step 5: ~~Sum the number of units of fixed cardiac catheterization equipment required for all facilities in the same cardiac catheterization equipment service area as calculated in Step 4. (NOTE: The sum is rounded to the nearest whole number.)~~

Subtract the total planning inventory for each facility from the number of units of fixed cardiac catheterization equipment required as calculated in Step 4. The difference is the surplus or deficit of units of fixed cardiac catheterization equipment. *(Note: Deficits will appear as positive numbers; surpluses, as negative numbers.)*

Step 6: ~~Subtract the number of units of fixed cardiac catheterization equipment required in each cardiac catheterization equipment service area from the total planning inventory for each cardiac catheterization equipment service area. The difference is the number of units of fixed cardiac catheterization equipment needed.~~

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The number of units of fixed cardiac catheterization equipment needed in a service area is determined as follows:

- a) The threshold for a need determination for additional units of fixed cardiac catheterization equipment is a projected deficit of 0.1 or more units as calculated in Step 5.
- b) The threshold is applied individually to each hospital, and a need determination is generated irrespective of surpluses at other hospitals in the service area, unless there are other hospitals in the service area under common ownership.
- c) If two or more hospitals in the same service area are under common ownership, the surpluses and deficits for those hospitals are totaled as calculated in Step 5. The threshold for a need determination for hospitals under common ownership in the same service area is a total projected deficit of 0.1 or more.
- d) The projected need determinations of all facilities and owners in the service area will be summed to determine the total number of units of fixed cardiac catheterization equipment needed in the service area.

Qualified Applicants

Any qualified applicant may apply for a certificate of need to acquire needed cardiac catheterization capacity. An applicant is a qualified if it is an existing hospital without fixed cardiac catheterization equipment, or if its existing cardiac catheterization equipment is operating at an average of 1,200 weighted procedures per unit of fixed cardiac catheterization equipment as reported in the current State Medical Facilities Plan under which the application is being reviewed.

Based on Rex's review of the 2014 Hospital License Renewal Applications and Inventory of Medical Equipment Forms, the proposed change will result in an additional need determination in Wake County for the 2015 *SMFP*. Please see Attachment 1 for detailed tables comparing the results of the current methodology and the proposed methodology. As discussed below, Rex believes the proposed change is needed in order to provide access to cardiac catheterization services, that it will not have adverse effects on providers or consumers, will not result in unnecessary duplication, and is consistent with the Basic Principles of the *SMFP*.

BACKGROUND

The various methodologies in the *SMFP* generally consider need based either on the entire service area or each individual provider. The current cardiac catheterization methodology determines need based on the entire service area, and as a result, individual providers may have a significant deficit, but no need is determined to exist in the area because of the surplus at other providers. The idea of ensuring that additional capacity is not prematurely allocated is central to the goal of suppressing unnecessary duplication, a central tenet of the CON statute. This approach may be reasonable for certain services, particularly those for which the service is merely one adjunct to the overall diagnostic process and treatment plan. For example, a patient needing an MRI scan to support a diagnosis may choose an MRI provider separate from his physician or hospital, without it negatively impacting his diagnosis or treatment, particularly on an outpatient basis, as the vast majority of MRI scans are provided. Other services, however, are much more central to the overall process of diagnosis and treatment, require a physician present to perform the procedure, and may be performed more often on an inpatient basis than other procedures. Such is the case for cardiac catheterization services. The cardiologist is central to the diagnosis and treatment, as he or she is directly involved with performing the procedure on the patient. Since that physician has been chosen by the patient to provide his or her care, the notion of the physician referring the patient to a physician at another facility, just because there may be more capacity available there, is extraordinarily unlikely. Although cardiologists may be privileged at multiple hospitals, they typically choose a single facility at which to perform most of their procedural work. The utilization of a particular facility is thus driven primarily by physician and patient preference, not the deficit or surplus at a facility. Therefore, a facility-specific methodology for cardiac catheterization is more appropriate than a service area-based methodology.

As noted above, other methodologies within the *SMFP* use a facility-specific approach, consistent with the proposed change, including the methodologies for acute care beds and PET scanners. In contrast, the existing fixed cardiac catheterization need determination methodology calculates projected need based on the aggregate need within each service area. However, since cardiac catheterization services are limited to hospital providers, and since most service areas include only one hospital, the vast majority of facilities have a need methodology that is, in essence, facility-based. Specifically, in the 39 cardiac catheterization service areas, all but seven (7) of them have only one fixed cardiac catheterization provider. In each of these service areas, the need methodology bases its calculation on the utilization of a single facility, and so the methodology is effectively facility-specific for the majority of state. In the remaining seven service areas in which there are two or more providers of fixed cardiac catheterization services, the need methodology calculates projected need based on the aggregate need of all providers in the service area. As such, the utilization of a single facility is subordinate to overall utilization. Please note, however, that the Durham/Caswell Service Area includes two hospitals under the common ownership of Duke University Health System; thus, as a result, the proposed methodology will have

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no impact on this service area.¹ Therefore, only six (6) service areas will be affected by the proposed change in the methodology.

Rex believes that for services such as cardiac catheterization, a service area-based methodology can perpetuate imbalances between highly utilized and underutilized providers. Underutilized equipment offsets the need expressed by well-utilized equipment and prevents the creation of additional need determinations which would allow high utilization providers to acquire more capacity and operate at more appropriate utilization levels. Even some methodologies which determine need on a service area basis attempt to mitigate this imbalance by excluding chronically underutilized facilities. In order to ensure that underutilized providers cannot diminish the need of overutilized providers, Rex proposes that only providers operating their fixed cardiac catheterization equipment at appropriate utilization levels be qualified applicants for additional fixed capacity. By failing to adjust the methodology as proposed, well-utilized facilities may be forced to operate above appropriate utilization levels and may not be able to deliver optimal care consistent with the Basic Principles of the *SMFP*, as discussed below.

Similar to other methodologies, the cardiac catheterization need methodology considers the units of equipment needed by dividing the number of weighted procedures by some percentage of the total capacity of the equipment—in this case, 80 percent. For cardiac catheterization, the capacity is defined as 1,500 diagnostic-equivalent procedures, so 80 percent is 1,200 diagnostic-equivalent procedures. The cardiac catheterization methodology differs somewhat from other need methodologies for other types of services as it currently requires the number of units of equipment needed to be rounded to the nearest whole number. In other words, the need for a second unit of cardiac catheterization equipment is not generated until a need for 1.5 units is shown. Therefore, to trigger a need determination, the existing cardiac catheterization equipment in a county must actually perform 600 procedures over the stated threshold (1,200 procedures) (e.g., a need for at least 0.5 units of equipment is required to generate a need determination for one additional unit of equipment; $0.5 \times 1,200$ procedures = 600 procedures). As a result of this step, providers located in counties with only one piece of cardiac catheterization equipment are forced to perform 1,800 procedures per year, or 120 percent of defined capacity, before a need is triggered for additional equipment. Under the proposed facility-based methodology, each provider will be evaluated on its own and will be required to perform above capacity in order to generate a need. This burden on providers is due to the lack of a “tiering” approach for facilities/counties with less total capacity in the cardiac catheterization methodology, unlike the “tiered” approaches used in the acute care bed, operating room and MRI methodologies. As noted above, cardiac catheterization is a much different service than most of the other regulated services in the *SMFP* in that it is often used for emergency procedures. Most

¹ Under the proposed methodology change, if two or more hospitals in the same service area are under common ownership, their surplus or deficit of equipment is totaled and then evaluated against the threshold for a need determination. Please see the revised Step 6.c above for the specific language.

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other equipment-based services, including MRI, PET, lithotripsy, gamma knife and linear accelerator treatments, are rarely, if ever used for emergency cases. Thus, with those services, when equipment reaches or exceeds capacity, patients may be inconvenienced, but rarely is emergency treatment potentially delayed as a result. Given these factors, Rex proposes that a need determination be generated when a provider reaches the capacity of its current equipment. In order to avoid potential issues related to rounding, as experienced relative to the home health methodology in recent years, Rex proposes that the threshold for a need determination for additional units of fixed cardiac catheterization equipment be defined as a projected deficit of 0.1 or more units.

Although Rex believes the proposed change is important, and though it will change the methodology statewide, it does not believe it will have a far-reaching impact. As the SHCC is aware, since 2003, cardiac catheterization volume has decreased statewide, although it does appear to have stabilized in recent years. Given this trend, it is unlikely that many providers will generate a need in the near future. However, Rex believes the methodology should evolve to reflect changes in healthcare, including the increasing alignment between physicians and hospitals in single systems of care, which has led to substantial shifts of patients among providers. Notably, Rex has experienced a substantial increase in its cardiac catheterization volume recently (more than 20 percent increase in weighted procedures in each of the last two years) due to its increased alignment with its cardiologists. In this context, the cardiac catheterization methodology must be more flexible in responding to the needs of specific facilities and the patients and physicians who choose to utilize them.

REASON FOR THE REQUESTED ADJUSTMENT

Rex believes that the cardiac catheterization methodology should determine need on a facility-specific basis, which would provide an equitable approach and only impact a minority of the hospitals across the state. Highly utilized providers would be able to generate need determinations, regardless of underutilized providers in the same service area. Underutilized providers would be prevented from applying for any need determinations as they would not be qualified applicants. It should be noted any need determination generated under the proposed change would still be subject to Certificate of Need review, whereby any qualified provider could apply for, and demonstrate the need to acquire, additional cardiac catheterization equipment. Finally, the threshold for a need determination should be lowered so that in order to ensure that need determinations are generated when providers reach capacity (especially given the use of cardiac catheterization equipment for patients on an emergency basis).

The proposed change will further the efforts of those healthcare systems that are working to improve their quality and continuity of care. As noted above, patients and physicians generally do not wish to utilize a site of care under the control of a different provider. Under the proposed change, systems will have a process to acquire needed cardiac catheterization equipment.

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Rex also believes this change would be consistent with other recent recommendations from the SHCC. Specifically, the 2014 SMFP includes an adjusted need determination for a linear accelerator in Service Area 20 resulting from a petition from Duke Raleigh Hospital (DRH). The SHCC concluded that even with a significant surplus of linear accelerator capacity in the service area, the need shown by the utilization at DRH was not mitigated by the surplus capacity of other providers in the service area or the pending implementation of two additional linear accelerators. One of the central themes of the DRH petition was that the available capacity at other providers was “not available as a practical matter to alleviate demand” on its unit. Rex believes that to the degree this notion motivated the SHCC to allocate another linear accelerator in the service area, the same rationale should lead to the approval of this proposed change in the cardiac catheterization methodology.

Additionally, the 2013 SMFP included an adjusted need determination for one additional unit of fixed cardiac catheterization equipment in Robeson County resulting from a petition from Southeastern Regional Medical Center (SRMC). The SHCC concluded that SRMC’s utilization of its one existing fixed cardiac catheterization unit demonstrated the need for additional equipment as it exceeded 100 percent of defined capacity, yet did not generate a need determination due to the rounding factor in the methodology. Rex believes that its proposed changes to the rounding rules for cardiac catheterization equipment will alleviate this issue for the future.

The approval of this methodology change will provide a clear and consistent path for highly utilized providers to generate need determinations and thus prevent potentially repetitive special need adjustment requests from the facilities in the service areas that are inequitably treated in the current methodology.

ADVERSE EFFECTS IF PETITION IS NOT APPROVED

As noted above, the current fixed cardiac catheterization need determination methodology can perpetuate imbalances between highly utilized and underutilized providers in the same service area. An underutilized provider diminishes the need demonstrated by a highly utilized provider. A provider could operate above the utilization standards indefinitely and not be able to acquire additional capacity, if another provider in its community was sufficiently underutilized. Physicians and patients are increasingly reluctant to shift to another site of care under the control of a different healthcare system for their care as this can lead to disruptions in the continuity and quality of care. There is no remedy for the patients, physicians, and providers in such a situation for cardiac catheterization services outside of a methodology change, as proposed, or a special need adjustment.

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ALTERNATIVES CONSIDERED

File a Petition for a Special Need Adjustment

As noted above, the current cardiac catheterization methodology is inequitable and perpetuates imbalances between providers. A petition in the summer for a special need adjustment would, at best, result in a one-time allocation and would fail to address the problematic aspects of the current methodology. While Rex believes a special need determination can remedy the growing issues for cardiac catheterization capacity in Wake County, it would not address potential issues in other counties or issues that arise in future years. For these reasons, Rex has chosen to file a methodology change petition. However, if the SHCC determines that this methodology change is not desirable and would prefer a special need adjustment request to remedy these issues, Rex respectfully requests that the SHCC express this preference during its deliberations on this proposal.

Exclude Chronically Underutilized Facilities

The operating room methodology excludes chronically underutilized facilities in order to remedy the imbalances between highly utilized and underutilized providers. Rex does not believe this approach is appropriate for the cardiac catheterization methodology for several reasons. First, there is no consensus around an appropriate definition of a chronically underutilized cardiac catheterization provider. Such a definition would need to account for the emergency, life-saving nature of the service and its subsequent vital importance in many communities, regardless of utilization. More importantly, the majority of the state is already treated with a facility-specific methodology, effectively, and an extension of that approach to the remainder of the state would provide the needed remedy. Finally, the number of cardiac catheterization units in each service area is much lower than the number of operating rooms, and most providers have at least modest utilization levels. Thus, the exclusion of chronically underutilized facilities would not be as useful for this methodology. However, Rex does propose that only appropriately utilized facilities be qualified applicants for additional cardiac catheterization equipment.

UNNECESSARY DUPLICATION

Rex does not believe the proposed change will result in unnecessary duplication of health resources. The current acute care bed and PET methodologies use facility-specific methodologies consistent with the change proposed by Rex for cardiac catheterization. Need determinations for acute care beds and PET scanners are generated by facilities regardless of the utilization of other facilities within the same service area. Based on its adoption of these methodologies, it is clear that the SHCC understands that this approach to healthcare planning does not result in the unnecessary duplication of health resources. In fact, as discussed above, this approach provides a more specific and flexible methodology for allocating healthcare resources, as needed, across the state.

BASIC PRINCIPLES

Safety and Quality

The proposed methodology change will provide a process for facilities to generate cardiac catheterization capacity regardless of the utilization of other providers. Without this methodology change, a provider could indefinitely operate its cardiac catheterization equipment at high levels of utilization without any possibility of acquiring additional capacity through the current methodology. In such a situation, a facility may not be able to provide optimal safety and quality of care. Cardiac catheterization services must be available immediately for patients who present to a hospital with certain cardiology issues. These emergency situations inevitably delay scheduled patients or cause rescheduling. If the demand for cardiac catheterization services at a facility exceeds its reasonable capacity, then these delays and reschedules result in patients beginning their procedures late in the day, thus requiring a more expensive and inconvenient overnight stay, or waiting until a later scheduled time. Scheduled procedures, while not emergency cases, are needed to improve the health of these patients and the delays that may result from overcapacity equipment results in delays in their recovery and return to normal life. Increased utilization also causes stress on the cardiac catheterization equipment leading to increased maintenance issues. The downtime needed to address these maintenance issues can cause additional delays in treatment and further exacerbates the overutilization of the equipment. If patients and physicians are forced to access care at another facility which has available capacity, they may encounter disruptions in the continuity of care. Physicians and providers work every day to improve the systems of care which leverage information technology, multidisciplinary teams, and processes of care to deliver the right care at the right time to the right person. A facility under the control of another healthcare system cannot provide that same system of care to an unfamiliar physician and patient. As a result, safety and quality may be reduced without the proposed change in the methodology.

Access

The proposed change will enable the development of additional access to cardiac catheterization equipment, as needed throughout the state. Seven service areas are inequitably treated under the current methodology. Any potential need within these service areas could be indefinitely suppressed by underutilization, for whatever reason, at another provider in the same service area. In these areas, access to care for patients of all types is impacted.

Value

The proposed change will enable providers throughout the state to provide greater healthcare value. As noted above, facilities that have a process to add capacity as needed will be able to provide safer and higher quality services than if forced to operate overcapacity. Delays in needed treatment or unanticipated overnight stays at the

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hospital add to healthcare expenditures. Overutilized equipment requires greater maintenance which creates additional expenses.

CONCLUSION

In conclusion, Rex requests that the SHCC approve the petition to change the cardiac catheterization need determination methodology. The proposed change would extend the facility-specific approach to cardiac catheterization need determinations to the entire state, rather than just to the majority of providers, and ensure the a need determination is generated when additional capacity is needed. As such, the methodology will become more specific and flexible to the changing needs of the citizens of North Carolina.

Thank you for your consideration.

Attachment 1

Cardiac Catheterization Equipment Service Areas	Facility	Total Planning Inventory	2013 Procedures (Weighted Totals)	Machines Required Based on 80% Utilization	Total No. of Additional Machines Required by Facility	No. of Machines Needed
Catawba	Catawba Valley Medical Center	1	658	0.55	0	
	Frye Regional Medical Center	4	4,408	3.67	0	
	TOTAL	5		4		0
Forsyth	N.C. Baptist Hospital	5	3,606	3.00	0	
	Novant Health Forsyth Medical Center	8	4,612	3.84	0	
	TOTAL	13		7		0
Guilford	Cardiovascular Diagnostic Center	1	830	0.69	0	
	Cone Health	7	5,245	4.37	0	
	High Point Regional Health System	4	3,973	3.31	0	
	TOTAL	12		8		0
Iredell	Davis Regional Medical Center	1	441	0.37	0	
	Iredell Memorial Hospital	1	1,194	1.00	0	
	Lake Norman Regional Medical Center	1	53	0.04	0	
	TOTAL	3		1		0
Mecklenburg	Carolinas Medical Center (CMC)	7	6,804	5.67	0	
	CMC Mercy-Pineville	4	3,552	2.96	0	
	CMC-University	1	39	0.03	0	
	Novant Health Matthews Medical Center	1	765	0.64	0	
	Novant Health Presbyterian Medical Center	4	3,447	2.87	0	
	TOTAL	17		12		0
Wake	WakeMed	9	8,570	7.14	0	
	WakeMed Cary	1	222	0.19	0	
	Duke Raleigh Hospital	3	447	0.37	0	
	Rex Hospital	4	5,029	4.19	0	
	TOTAL	17		12		0

