Technology and Equipment Committee
Agency Report
Adjusted Need Petition for
One Unit of Shared Fixed Cardiac Catheterization Equipment in Harnett County
Proposed 2016 State Medical Facilities Plan

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Request:
Harnett Health requests an adjusted need determination for one unit of shared fixed cardiac catheterization equipment for Harnett County for the *North Carolina 2016 State Medical Facilities Plan* (SMFP).

Background Information:
The *Proposed 2016 SMFP* provides two standard need determination methodologies for cardiac catheterization equipment. Methodology One is the standard methodology for determining need for additional fixed cardiac catheterization equipment and Methodology Two is the need determination methodology for shared fixed cardiac catheterization equipment. Application of these methodologies to utilization data in the *Proposed 2016 SMFP* does not generate a need determination for fixed or shared fixed cardiac catheterization equipment in Harnett County.

Shared fixed cardiac catheterization equipment is defined in the *SMFP* as "fixed equipment that is used to perform both cardiac catheterization procedures and angiography procedures." Methodology Two for the shared fixed cardiac catheterization equipment in the *Proposed 2016 SMFP* is as follows:

For cardiac catheterization equipment service areas in which a unit of fixed cardiac catheterization equipment is not located, need exists for one shared fixed cardiac catheterization equipment (i.e., fixed equipment that is used to perform both cardiac catheterization procedures and angiography procedures) when:

a. The number of cardiac catheterization procedures as defined in 10A NCAC 14C .1601(5) performed at any mobile site in the cardiac catheterization equipment service area exceeds 240 (300 procedures x 80 percent) procedures per year for each eight hours per week the mobile equipment is operated at that site during the 12-month period reflected in the "2015 Hospital License Renewal Application" or the "2015 Registration and Inventory of Medical Equipment Form" for Cardiac Catheterization equipment on file with the North Carolina Division of Health Service Regulation; and

b. No other fixed or mobile cardiac catheterization service is provided within the same cardiac catheterization equipment service area.

Chapter Two of the *Proposed 2016 SMFP* allows persons to petition for an adjusted need determination in consideration of "unique or special attributes of a particular geographic area or institution…," if they believe their needs are not addressed by the standard methodology. Harnett Health has submitted a petition to adjust the need determination for one unit of shared fixed cardiac catheterization equipment to bring cardiac catheterization services closer to persons in Harnett County in need of these services.

Analysis/Implications:

Methodology One, as it is written, does not apply to Harnett County as it only addresses facilities that have a cardiac catheterization laboratory. Methodology Two provides for the opportunity for a service area that has no fixed laboratory, but instead utilizes a mobile laboratory. Need exists for one unit of shared fixed cardiac catheterization equipment when the number of cardiac catheterization procedures performed at a mobile site exceeds 240 procedures per year.

The petition indicates that Harnett Health has not utilized a mobile cardiac catheterization laboratory as required to generate a need through Methodology Two, but transfers cardiac patients to other facilities in neighboring counties.

Table 1 below details the drive time and distance to both Harnett Health facilities, Betsy Johnson in Dunn and Central Harnett Health in Lillington. The closest facility to either is Johnston Health at 24.5 miles (≈37 minutes). The nearest facility affiliated with Harnett Health, Cape Fear Valley Medical Center, is approximately 30 miles (≈40 minutes). These drive times and distances are important when looking at optimal patient care.

Table 1: Drive Times and Distances from Harnett Health Facilities to Hospitals in Contiguous* Counties

		Betsy Johnson, Dunn		Central Harnett Health, Lillington	
County	**Facility**	**Drive Time**	**Miles**	**Drive Time**	**Miles**
Cumberland	Cape Fear Valley Medical Center	39 Minutes	30.7	44 Minutes	31.2
Wake	Duke Raleigh	43 Minutes	44.4	48 Minutes	39.2
	Rex Hospital	50 Minutes	50.0	45 Minutes	35.3
	Wake Med- Cary	51 Minutes	50.5	37 Minutes	26.4
	Wake Med- Raleigh	43 Minutes	41.4	49 Minutes	40.6
Lee	Central Carolina Hospital	50 Minutes	37.3	33 Minutes	24.5
Moore	First Health Moore	71 Minutes	56.3	59 Minutes	48.7
Johnston	Johnston Health	31 Minutes	25.8	44 Minutes	33.3

Source: Google Maps; Utilized fastest route.

*Five of six contiguous counties only; Sampson County does not have cardiac catheterization services

Standard clinical treatment for ST-Elevation Myocardial Infarction [STEMI] is reperfusion, a procedure performed in the cardiac catheterization laboratory. The *2013 ACCF/AHA Guideline for Management of ST-Elevation Myocardial Infarction* is the most comprehensive resource on the treatment of patients with the diagnosis of this type of myocardial infarction. The report endorses goals that includes time frames for patient treatment. Of these recommendations, 3.4.1 Class I number 5, is probably the most pertinent to this discussion. It reads, "EMS transport directly to a PCI [percutaneous coronary intervention]-capable hospital for primary PCI is the recommended triage strategy for patients with STEMI, with an ideal FMC [first medical contact]-to-device time system goal of 90 minutes or less." The data in Table 1 demonstrates that, in most instances, transport of patients from Harnett Health to a hospital that offers interventional cardiac catheterization procedures would require from a third to more than half of the time allotted in the 90 minute treatment window. Furthermore, the NC Office of EMS's *STEMI: EMS Triage and Destination Plan* includes a decision point for transport of patients to the nearest PCI Capable Hospital at 30 minutes transport time.

Distance to care is an important component of this discussion, but the volume of patients is another factor to consider. It should be noted that patient origin data for cardiac catheterization equipment utilization is not collected by the Division of Health Service Regulation nor do the SMFP's standard cardiac catheterization methodologies consider patient origin to determine need for individual service areas. Therefore, the agency utilized the data provided in the petition in considering estimated procedure counts.

Per the petitioner, Truven data was analyzed to total all Harnett County residents in all counties that underwent a cardiac catheterization procedure. Due to the complexity of cardiac catheterizations being both inpatient and outpatient, this total was derived using a "bridge methodology to match up outpatient CPT codes and inpatient ICD-9 codes". (pg. 21) Table 2 below summarizes the calculated procedures for Harnett County in 2013 and 2014.

Table 2: Harnett County Cardiac Catheterization Procedures, 2013-2014

	2013	2014
Total Procedures	1,786	2,114

Source: Truven

Data submitted in the petition states 67% of cardiac catheterization procedures for Harnett County residents are diagnostic. Comparatively, the statewide percentage as calculated using data in the *Proposed 2106 SMFP* is 57% [(61,271-26,109)/61,271]. Table 3 below provides estimates of the number of procedures based on both the Harnett County and statewide percentages.

Table 3: Estimated Number of Diagnostic Procedures in Harnett County, 2013-2014

	Total Procedures	Diagnostic Procedures (County 67%)	Estimate of Diagnostic Procedures*	Diagnostic Procedures (Statewide 57%)	Estimate of Diagnostic Procedures*
2013	1,786	1,197	599	1,018	509
2014	2,114	1,418	709	1,206	603

Source: Truven; Proposed 2016 SMFP

*Estimate of the potential total number of diagnostic procedures in Harnett County assuming 50% out migration.

Assuming 50% out migration and using the lower statewide calculation, in the most recent data year of 2014, the minimum estimated diagnostic procedures of 603 is more than double the 240 threshold.

Agency Recommendation:

Based on the above discussion, the estimated volume of procedures that would be performed in Harnett County is well above the 240 mobile procedures required to generate a need for a unit of shared fixed cardiac catheterization using Methodology Two. In addition, the travel time from Harnett County to contiguous counties for emergent cardiac patients is not optimal for patient care. Given available information submitted by the August 14, 2015 deadline date for comments on petitions and comments, and in consideration of factors discussed above, the agency recommends approval of this petition.

[1] O'Gara PT, Kushner FG, Ascheim DD, Casey Jr DE, Chung MK, de Lemos JA, Ettinger SM, Fang JC, Fesmire FM, Franklin BA, Granger CB, Krumholz HM, Linderbaum JA, Morrow DA, Newby LK, Ornato JP, Ou N, Radford MJ, Tamis-Holland JE, Tommaso CL, Tracy CM, Woo YJ, Zhao DX. 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation.* 2013;127:e362–e425.