August 15, 2014

Ms. Nadine Pfeiffer, Branch Manager
North Carolina Division of Health Service Regulation
Medical Facilities Planning Branch
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

Re: Comment re: Proposed 2015 SMFP

Dear Ms. Pfeiffer:

NCHA wishes to comment on the following petitions submitted during the public comment period for adjusted need determinations to the Proposed 2015 SMFP.

**Acute Care Services Committee:**

NCHA opposes the petition submitted by The Blue Ridge Bone & Joint Clinic to be added to the Single Specialty Ambulatory Surgery Facility Demonstration Project.

- The Demonstration Project, established in the 2010 SMFP, was a decision to locate three single specialty ambulatory surgery centers in the three largest urban areas of the state. As part of the project, the SHCC established definitive measures to meet the three Basic Principles of Safety/Quality, Access and Value, as described in the North Carolina 2010 State Medical Facilities Plan. The success of the centers would be based on criteria established in Table 6D of that SMFP. While the demonstration projects are now in operation, only one year of evaluation has passed and no conclusions have been discussed regarding their success. NCHA does not support expansion of the Single Specialty Ambulatory Surgery Facility Demonstration Project before the SHCC has had the opportunity to evaluate the success of the current facilities in the Project.

NCHA opposes the petition filed by Wilmington Health requesting that need be established for two operating rooms in New Hanover County in the 2015 State Medical Facilities Plan.

- The petition includes data showing that operating room utilization has remained relatively stable during the past five years.

- While the Proposed 2015 SMFP indicates a deficit of .45 operating rooms in the service area, the deficit is based on an occupancy level of 80%. The petitioner overstates the need to establish a need determination in the 2015 State Medical Facilities Plan.

- Wilmington Health was recently approved by the DHSR to establish a multi-specialty surgery center in a facility designed with three procedure rooms. It has not, however, demonstrated a need to supersede the operating room need methodology, nor has it
demonstrated the need to add a second operating room to the need determination.

**Technology and Equipment Committee**

NCHA supports the addition of Policy TE-1 to the State Medical Facilities Plan. Comments opposing Policy TE-1 have been filed by Alliance Imaging, the sole provider of mobile PET services in North Carolina. Comments and a petition in support of the Policy have been filed by Carolinas HealthCare System and by Novant Health/MedQuest.

- NCHA disagrees with Alliance assertion that Policy TE-1 conflicts with the Certificate of Need law finding of fact on proliferation of unnecessary health service facilities. NCHA supports Policy TE-1 because it provides an opportunity to increase access to mobile PET services without adding new PET equipment to the inventory. Alliance Imaging controls both of the mobile PET Scanners in North Carolina, which provided 2,933 and 2,858 procedures each during the last year. These two mobile scanners each provided more procedures than any single fixed PET scanner in the state (average).

Policy TE-1 would allow for conversion of existing fixed equipment to serve hospitals in North Carolina. New capacity would not be added to the inventory of PET equipment while hospitals seeking additional mobile PET time can better meet the needs of their patients.

**Long Term and Behavioral Health Committee:**

NCHA opposes the petition from Triangle Orthopaedic Associates, PA. for need for one Medicare-certified home health agency to be located in either Wake, Durham or Orange County as part of a demonstration project to serve orthopedic surgery patients. NCHA believes the Long Term Care & Behavioral Health Committee and the SHCC should carefully consider the following.

- The home health need methodology is based on need for an agency within a single county. The petitioner has not established a county where the proposed agency would be located.

- At the public hearing in Raleigh a concern was voiced that organizing a certified home health agency as part of a specialty physicians practice could invoke the risk of self referral by referring physicians within the practice. Updates found at CMS’ [Physician Self Referral](https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Patient-Referral-Handbook.html) page “prohibit a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship....” This prohibition should be carefully considered because the patient referrals to the proposed agency would be patients of the practice physicians with orthopedic needs.

- The petition proposes to create a fully certified home health agency with a limited set of services that would be available to only a limited set of patients (orthopedics). The licensure of such an agency could also affect the caseloads of existing full service home health agencies that serve orthopedics patients, and on the accuracy of the planning methodology, which seeks to identify need for full service home health agencies.
• The petitioner has not demonstrated that arrangements to provide home health could not be made with an existing Agency, or that, under the proposed BPCI initiative, a certified Medicare Home Health Agency is required to provide the proposed set of services to patients through the Bundled Payments for Care Improvement Initiative (BPCI).

Thank you for the opportunity to comment. Please feel free to contact me at 919.677.4233 if you have questions.

Sincerely,

Mike Vicario
Vice-President of Regulatory Affairs