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March 17, 2021

Christopher G. Ullrich, MD, Chair North Carolina State Health Coordinating Council c/o Healthcare Planning and Certificate of Need Section Division of Health Service Regulation, NC DHHS 2704 Mail Service Center Raleigh, NC 27699-2704

Re: Comments on Petition Filed by Novant and MedQuest

Dear Dr. Ullrich:

Please find attached comments from Cone Health regarding the petition filed by Novant Health, Inc. and MedQuest Associates, Inc. regarding existing and approved specialized breast MRI scanners. Please let me know if you have any questions regarding these comments.

Sincerely,

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Melissa K. Shearer Executive Director, Strategy and Planning Cone Health

Enclosure

<u>Comments on Petition Submitted by Novant Health, Inc. and MedQuest</u> <u>Associates, Inc. Regarding Existing and Approved Specialized Breast MRI</u> <u>Scanners</u>

Cone Health submits these comments in opposition to the petition filed by Novant Health, Inc. ("Novant") and MedQuest Associates, Inc. ("MedQuest") (collectively, "Petitioners") that proposes to move the two dedicated breast MRI scanners currently shown in Table 17E-2 of the 2021 State Medical Facilities Plan ("SMFP") to Table 17E-1 of the SMFP and be included in the general MRI inventory.

Breast Clinic MRI, LLC received approval in 2006 to add a dedicated Breast MRI scanner pursuant to an adjusted need determination. As Table 17E-2 of the 2021 SMFP shows, there are 10 specialized MRI scanner in the state, excluded from the planning inventory. A note below the table states "These scanners shall be used only for the purposes indicated above. They shall not be used for general clinical purposes." These scanners were approved under the assumption that they would be specialized and used only for the indicated purposes.

Additionally, Condition 2 of the CON for the dedicated breast MRI, as presented in the petition, states "The Breast Clinic MRI, LLC shall not use the dedicated breast MRI scanner for non-breast related general diagnostic purposes." As the Petitioners note, on p. 3 of their Petition, the scanner can only be used for breast imaging. If Novant is proposing to violate the conditions of the CON, it should be required to relinquish the CON for failing to materially comply with the conditions imposed upon it by the Agency. Novant should not be allowed to circumvent the standard process by taking advantage of a special need determination that was intended for a specific patient population.

In their petition, the Petitioners state that, of their own volition, they acquired a general purpose MRI scanner with breast coils and that the majority of their breast scans are now performed on that piece of equipment, rendering their specialized breast MRI scanner obsolete and duplicative. Petitioners now seek to remove the restrictions from the specialized breast scanner. However, Novant could have purchased a general-purpose MRI scanner without breast coils for general use, and replaced the dedicated Breast MRI with a general-purpose scanner with breast coils, thereby preserving the dedicated Breast MRI without violating the conditions of their approval.

Moreover, the Petitioners state that the equipment has not been in use since 2017, but now they wish to incur the capital cost of replacing the equipment and placing it into unrestricted service, even though the standard need methodology has not identified a need for an additional MRI scanner in Forsyth County. This request is inconsistent with the basic principles as identified in Chapter 1 of the SMFP. The Value Basic Principle states that, "[m]aximizing the health benefit for the entire population of North Carolina that is achieved by expenditures for services regulated by the State Medical Facilities Plan will be a key principle in the formulation and implementation of the SHCC recommendations for the Plan." Allowing a scanner, that by the Petitioners' own admission has not been needed for the past four (4) years, to be replaced at a cost of greater than \$2 million would violate this principle.

Later in their petition, the Petitioners state that there is no need determination in the 2021 SMFP for any additional fixed MRI scanners in Forsyth County and "Petitioners do not project that there will be a need determination for an additional fixed MRI in Forsyth County in the 2022 or 2023 SMFPs, even with counting the Breast MRI Scanner in the State inventory." The lack of a need determination in the 2021 SMFP in Forsyth County without the scanner in question being in service indicates that Forsyth County is already well served with regard to general MRI services. Beyond 2021, in projecting need in the 2022 and 2023 SMFPs, the need for additional MRI scanners would be artificially depressed by adding an additional MRI scanner to the inventory without allowing any other providers to apply for the opportunity to provide the service. As stated in the footnote to Table 17E-3, "[a]ny person can apply to meet the need, not just the health service facility or facilities that generated the need." Approval of this petition would potentially remove this ability by allowing a general MRI scanner into the inventory without identified need.

Cone Health supports the standard need methodology for MRI scanners as it exists in the 2021 SMFP, which shows that the residents of Forsyth County are currently well served by the existing complement of general purpose MRI scanners. For the foregoing reasons, the petition should be denied.