

May 31, 2018

Jane Rhoe-Jones, Project Analyst
Healthcare Planning & Certificate of Need Section
Division of Health Service Regulation
North Carolina Department of Health and Human Services
809 Ruggles Drive
Raleigh, North Carolina 27626-0530

RE: Comments regarding Vidant Medical Group CON Project I.D. L-11498-18

Dear Ms. Rhoe-Jones:

Enclosed please find comments prepared by Wilson Medical Center, regarding the CON application submitted by Vidant Medical Group, LLC to develop a diagnostic center in Wilson County. We trust that you will take these comments into consideration during the Agency's review of the applications.

Wilson Medical Center is an existing provider of outpatient diagnostic services in Wilson County, and therefore, is an affected party pursuant to N.C. Gen. Stat. §131E-188(c). As an affected party, Wilson Medical Center requests a public hearing pursuant to N.C. Gen. Stat. § 131E-185(a1)(2), which ensures that a public hearing will take place if "a written request for a public hearing is received before the end of the written comment period from an affected party."

If you have any questions about the information presented here, please feel free to contact me at (252) 399-8139.

Sincerely,

#### William Caldwell

William Caldwell, FACHE Chief Executive Officer Wilson Medical Center

## COMMENTS REGARDING VIDANT MEDICAL GROUP CON APPLICATION TO DEVELOP A DIAGNOSTIC CENTER IN WILSON COUNTY PROJECT I.D. L-11498-18

### SUBMITTED BY WILSON MEDICAL CENTER MAY 31, 2018

Vidant Medical Group (VMG) submitted a Certificate of Need (CON) application to develop a diagnostic center in Wilson County. Wilson Medical Center (WMC) is an existing provider of diagnostic services, and thus is well aware of the local healthcare needs. As the leading healthcare provider in Wilson County and a participant in the CON regulatory review process, WMC is supportive of the State of North Carolina's health planning process and endorses the Agency goal of ensuring that all providers fully comply with the requirements of the CON statute. Therefore, in accordance with N.C. Gen. Stat. § 131E-185(a1)(1), WMC submits the following comments regarding VMG's CON application.

WMC's comments include "discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with relevant review criteria, plans, and standards" (N.C. Gen. Stat. § 131E-185(a1)(1)(c)). WMC has identified several statutory and administrative review criteria for which the VMG application appears to be nonconforming. Therefore, the VMG application should not be approved.

<u>Criterion 3</u>: The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

VMG did not adequately demonstrate that the utilization projections for its diagnostic services are based on reasonable and supported assumptions. The utilization projections are founded upon a "build it and they will come" assumption, which is insufficient to satisfy conformity to Criterion (3). Specifically,

• VMG provided <u>no letters of support</u> from physicians who will be located at the healthplex or from physicians who may refer patients to the proposed diagnostic services. Utilization of the proposed diagnostic services is predicated on physician referrals, therefore documentation to support the credibility of VMG's assumptions and methodology to project diagnostic procedures is paramount. Page 25 of VMC's CON application describes that the healthplex will open with eight (8) primary care providers, two (2) cardiologists, one pulmonologist, one gastroenterologist, one dermatologist, and one neurologist. However, on page 83 of the application VMC states "there are no physicians that currently refer or admit patients." "VMG believes that there is enough strong interest that at least two providers at two days per week on average will be

- available at opening." Thus, VMG has not adequately documented that the projected utilization will be supported by any physicians who would be located at the healthplex.
- In Section O, VMG states cardiac exercise stress tests are based on its experience providing stress tests across its four cardiology practices in Pitt County, which results in a ratio of 0.106 cardiac stress tests per cardiology office visit (p.109). Similarly, VMG states nuclear stress tests are based on a ratio of 0.105 nuclear stress tests per cardiology office visit (p.110) and US/ECHO scans are based on a ratio of 0.495 ECHO tests per cardiology office visit (p.111). On page 108, VMG projects cardiology office visits based on the presence of two (2) cardiology providers beginning in November 2018 (FY2019). However, VMG failed to adequately document the availability of two (2) cardiology providers beginning November 2018. Specifically, VMG provided no letters of support from cardiologists. On page 83 of the application VMC states VMG believes that there is enough strong interest that at least two providers at two days per week on average will be available at opening." VMG goes on to state that some of the providers that expressed "strong" interest include ECU pediatric specialists, thoracic surgeons, vascular surgeons, and behavioral health providers. VMG failed to provide any documentation to substantiate the presence of two cardiology providers beginning November 2018. Therefore, the utilization projections for cardiac exercise stress tests, nuclear stress tests, and ECHO scans are unreliable and not supported.
- In Section Q (p. 109), VMG states cardiopulmonary rehab utilization is based on Vidant Medical Center's (VMC) outpatient cardiopulmonary program and a physician clinic that is "closely tied" to that program, which results in a ratio of 0.029 cardiopulmonary rehab patients per cardiology visit. As described previously, VMG failed to provide any documentation to substantiate the presence of two cardiology providers beginning November 2018. Therefore, the utilization projections for cardiopulmonary rehab sessions are unreliable and not supported.
- In Section Q (p. 109), VMG states dermatology procedures are based on the ratio of dermatology visits to procedures for ECU Dermatology in Pitt County. On page 108, VMG projects dermatology office visits based on the presence of one (1) dermatology provider beginning in November 2018 (FY2019). However, VMG failed to adequately document the availability of a dermatologist beginning November 2018. Specifically, VMG provided no letters of support from a dermatologist. On page 83 of the application VMC states VMG believes that there is enough strong interest that at least two providers at two days per week on average will be available at opening." VMG goes on to state that some of the providers who expressed "strong" interest include ECU pediatric specialists, thoracic surgeons, vascular surgeons, and behavioral health providers. VMG failed to provide any documentation to substantiate the presence of a dermatology provider beginning November 2018. Therefore, the utilization projections for dermatology procedures are unreliable and not supported.
- In Section Q (p. 109), VMG states X-ray scans are based on the ratio of office visits to X-ray scans for primary care/urgent care and specialty clinics. This results in a ratio of 0.107 X-rays per office visit. On page 108, VMG projects office visits based on the

presence of 18 total providers. However, VMG failed to adequately document the availability for any of these providers to be located at the healthplex. Specifically, VMG provided no letters of support in its CON application. VMG failed to provide any documentation to substantiate the presence of primary care and specialty providers beginning November 2018. Therefore, VMG's utilization projections for X-ray scans are unreliable and not supported.

- In Section Q (p. 110), VMG states EKG/ECG tests are based on a ratio of 0.424 tests per cardiology office visit and a ratio of 0.027 tests per primary care office visit. As described previously, VMG failed to provide any documentation to substantiate the presence of two cardiology providers and eight (8) primary care providers beginning November 2018. Therefore, the utilization projections for EKG/ECG tests are unreliable and not supported.
- In Section Q (p.110), VMG states EEG and EMG tests are based on the "ratio of EEG test to neurology visits for the provider who was hired for the healthplex's current actual experience in their practice today" and the "ratio of EMG tests to neurology visits for the provider who was hired for the healthplex's current actual experience in their practice today". On page 108, VMG identifies the presence of one (1) neurologist beginning in November 2018 (FY2019). However, VMG failed to adequately document the availability of a neurologist beginning November 2018. VMG did not provide a letter of support from the neurologist who was hired for the healthplex, nor did it provide the historical office visits and EEG or EMG tests for the physician. Therefore, the utilization projections for EEG and EMG tests are unreliable and not supported.
- In Section Q (p.111), VMG states pulmonary tests are based on the experience for one of its practices in Pitt County, which results in a ratio of 0.895 pulmonary tests per pulmonary visit. On page 108, VMG identifies the presence of one (1) pulmonologist. However, VMG did not provide a letter of support for a pulmonologist. Therefore, the utilization projections for pulmonary tests are unreliable and not supported.

North Carolina's CON statute mandates that providers proposing to offer or expand healthcare services reasonably project utilization for the proposed services. However, VMG's application does not adequately demonstrate that the utilization projections for its diagnostic services are based on reasonable and supported assumptions. Consequently, VMG does not demonstrate the need it has to develop the proposed diagnostic center and services and the application is not conforming to Criterion 3.

<u>Criterion 4</u>: Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

VMG does not adequately demonstrate the need the population to be served has for VMG's proposal. See Criterion (3) for facts and discussion. A proposal that is not needed is not the most effective alternative.

Furthermore, the application is not conforming to all applicable statutory and regulatory review criteria, and thus, the application is not approvable. An application that cannot be approved is not an effective alternative.

For these reasons, VMG did not adequately demonstrate that the proposal is the most effective alternative. Consequently, the application is not conforming to this criterion.

<u>Criterion 5</u>: Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

VMG's application has several deficiencies with its financial projections and documentation, including:

- The VMG Board of Managers approved filing a CON application at a capital cost for equipment not to exceed \$900,000. The CON project cost for equipment is listed on pages 70 and 112 as \$917,801, which exceeds the Board of Managers approved amount. Thus, VMG has not demonstrated the availability of funds for capital and operating needs, because the VMG Board of Managers did not specifically authorize a CON application for equipment that totals in excess of \$900,000.
- Vidant Medical Group is the sole CON applicant. The funding letter in Exhibit 10 is from Vidant Health and doesn't specify that the funds will be made available to VMG for the project. Page 71 of the VMG application identifies the source of funds as "assets limited as to use: internally designated for capital improvements" and references page 64 of the Vidant audited financial statements. That referenced page shows that VMG does not specifically have any such funds. Similarly, page 73 of the application identifies the line item "excess of revenues over expense" on page 66 of the audited financial statements. There, the referenced page shows that VMG specifically does not have such funds available. Thus, VMG has not demonstrated the availability of funds for capital and operating needs.
- The PY3 gross revenue on Form F.5B of \$30.6M does not match the PY3 gross revenue of \$12.3M on Form F.4 on page 120.

- The total projected salaries during the interim year are shown as \$4.56M on Form F.3; however, this does not match the total projected salaries for the interim year of \$4.98M as shown on Form H Staffing. Thus, VMG underestimated the working capital expense, and underfunded the project working capital requirement in Section F (p.72) by over \$415K. Thus, VMG has not demonstrated the availability of funds for capital and operating needs.
- All of the vendor equipment quotations included in Exhibit 2 have or will expire prior to the end of the Agency review, with most having expired prior even to submission of the CON application. This presents a question as to the accuracy of the capital cost projection shown in Section F. Therefore, VMG has not demonstrated the availability of funds for capital needs.

Further, VMG does not adequately demonstrate that projected revenues and operating costs are based on reasonable, credible, and supported assumptions regarding projected utilization. See Criterion (3) for discussion regarding projected utilization.

In summary, VMG does not reasonably project the costs of and charges for providing health services. Therefore, VMG does not adequately demonstrate that the financial feasibility of the proposal, and the application is nonconforming to this criterion.

### <u>Criterion 6</u>: The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

VMG does not adequately demonstrate that its proposal would not result in the unnecessary duplication of existing or approved services in Wilson County. VMG did not adequately demonstrate in its application that the diagnostic services it proposes to develop in Wilson County are needed in addition to the existing resources available. See discussion regarding conformity to Criterion (3).

Consequently, the VMG application is not conforming to Criterion (6).

# <u>Criterion 7:</u> The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

VMG's application includes inconsistent and/or incomplete information regarding the availability of health manpower and management personnel. Specifically:

• The VMG application states (on p.83) "there are no physicians that currently refer or admit patients." "VMG believes that there is enough strong interest that at least two

providers at two days per week on average will be available at opening." VMG did not include any letters of support or any indication from any physician of a willingness to refer patients, or to provide service at the proposed diagnostic center. Thus, VMG has not shown evidence of the availability of resources for the provision of services to be proposed.

- The application references Dr. Sunny Darji as the Medical Director for the proposed healthplex. However, the referenced Exhibit 13 includes a CV for Dr. Darji, but no letter of support or documentation from Dr. Darji indicating a willingness to serve as Medical Director. Thus, VMG has not shown evidence of the availability of health manpower for the provision of services to be proposed.
- The clinical staffing levels portrayed on Form H do not change between the interim year and PY3. This raises a question as to whether the proposed clinical staffing totals are sufficient to serve the projected increasing diagnostic testing volumes during the initial three project years. VMG does not provide any narrative or assumptions regarding how it projected the clinical staffing levels, or how it links the clinical staffing levels with the projected medical diagnostic procedures. This is meaningful because VMG projects some of the diagnostic equipment procedures to increase significantly during the initial three project years. Thus, it is questionable as to if VMG has reasonably shown evidence of the availability of health manpower for the provision of services to be proposed.

<u>Criterion 18a:</u> The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

VMG did not reasonably demonstrate the need the population has for the proposed services and did not reasonably project the extent to which the population will utilize the proposed medical diagnostic equipment. Further, VMG did not reasonably project the costs of and charges for providing health services. Therefore, VMG's application is non-conforming to Criterion 18a because VMG did not demonstrate that the proposed project will have a favorable impact on cost effectiveness and access.