



North Carolina Department of Health and Human Services  
Division of Health Service Regulation  
Certificate of Need Section

2704 Mail Service Center • Raleigh, North Carolina 27699-2704  
<http://www.ncdhhs.gov/dhsr/>

Drexdal Pratt, Director

Beverly Eaves Perdue, Governor  
Albert A. Delia, Acting Secretary

Craig R. Smith, Section Chief  
Phone: (919) 855-3873  
Fax: (919) 733-8139

March 19, 2012

Jeff Shovelin  
Director, Strategic Development  
Vidant Health  
PO Box 6028  
Greenville, North Carolina 27835-6028

RE: No Review / Vidant Medical Center / Use of a Decommissioned Operating Room as a Non-regulated Procedure Room in an Acute Care Hospital / Pitt County  
FID #933410

Dear Mr. Shovelin:

The Certificate of Need (CON) Section received your letter of March 8, 2012 regarding the development of a procedure room in an existing licensed facility. Based on the CON law in effect on the date of this response to your request, the CON Section has determined that the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need, as long as the capital cost does not exceed \$2 million. However, please note that if the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective. The CON Section's determination is based on the following conclusions and assumptions:

1. The procedure room will not be constructed or developed to meet minimum licensure requirements for operating rooms under either the hospital or ambulatory surgical facility licensure rules.
2. The procedure room will not be used for gastrointestinal endoscopy procedures.
3. The procedure room will not be reported in any Hospital License Renewal Application form as an operating room.

Please be advised the Division of Health Service Regulation has determined it is the responsibility of the health care provider to research, evaluate and identify the most appropriate environment that procedures should be performed in accordance with acceptable standards of practice. Acceptable standards of practice include guidelines governing procedures, including locations where they should be performed, as well as, any standards and recommendations promoted by or established by nationally recognized professional organizations (e.g., the American Medical Association, American College of Surgeons, Association of Operating Room Nurses, Association for Professionals in Infection Control and Epidemiology, etc.).

In determining which procedures are appropriate to be performed in a procedure room, of paramount importance is patient safety, which should always dictate and guide where procedures should be performed in all health care facilities. Those procedures, which standards of care dictate should be performed in an operating room, should always, with the exception of emergency situations, be performed in an operating



room. For purposes of this document, “emergency situations” mean circumstances in which time is of the essence and life-saving measures must be implemented immediately and there may not be sufficient time to prepare and transport the patient to an operating room.

A number of state licensing and federal regulations that address quality of care, safety and the appropriateness of care and treatment are provided below. Questions pertaining to these requirements should be directed to Ms. Azzie Conley with the Acute and Home Care Licensure and Certification Section, DHSR. Ms. Conley can be reached at (919) 855-4620.

#### N.C. Hospital Licensing Rules - 10A NCAC 13B

- Section .3300 – Patient’s Bill of Rights.

10A NCAC 13B .3302 Minimum Provisions of Patient’s Bill of Rights

*(7) A patient has the right to good quality care and high professional standards that are continually maintained and reviewed.*

- Section .4600 – Surgical and Anesthesia Services

10A NCAC 13B .4602 Director of Surgical Services

*(b) The medical staff shall establish and maintain a system for monitoring and evaluating the quality and appropriateness of the care and treatment of surgical patients, and for monitoring the clinical performance of all individuals with clinical privileges.*

#### Federal Regulations Governing Hospitals 42 § CFR Part 482 – Medicare Conditions of Participation

- §482.12 Governing Body

Condition of Participation - *The hospital must have an effective governing body legally responsible for the conduct of the hospital as an institution. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body.*

- §482.12(A)(5) - *Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients;*

- §482.13 Patients’ Rights

§482.13(c)(2) - *The patient has the right to receive care in a safe setting.*

- §482.21 Quality Assessment and Performance Improvement

§482.21(e) Standard: Executive Responsibilities

*The hospital’s governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following:*

*§482.21(e)(2) - That the hospital-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety and that all improvement actions are evaluated.*

*§482.21(E)(3) – That clear expectations for safety are established.*

The Division of Health Service Regulation discourages providers from shifting procedures typically performed in an operating room environment to a procedure room without clear evidence the procedure can be performed safely and without risk of compromising patient outcomes, particularly in the areas of infection

March 19, 2012

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control, use of anesthesia or any other indices of safe and appropriate patient care. It is ultimately up to the facility to ensure procedures are performed in the most safe and appropriately equipped environment.

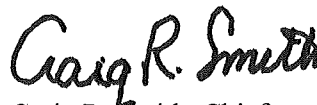
It should be noted that the determination made by the CON Section is binding only for the facts represented in your correspondence. Consequently, if changes are made in the project or in the facts provided in your correspondence, a new determination as to whether a certificate of need is required would need to be made by the Certificate of Need Section. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the original cost estimate; (3) modifications in the construction or design of the project; (4) change in location; (5) any increase in the number of square feet to be constructed, and (6) change in use of the procedure room.

If you have questions concerning this matter, please do not hesitate to contact this office.

Sincerely,

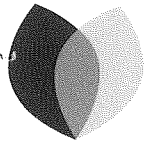


Jane Rhoe-Jones  
Project Analyst



Craig R. Smith, Chief  
Certificate of Need Section

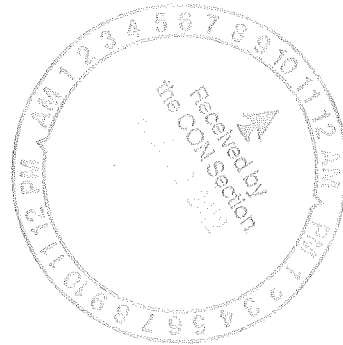
c: Construction Section, DHSR  
Medical Facilities Planning Section, DHSR  
Acute and Home Care Licensure and Certification Section, DHSR



# VIDANT HEALTH™

March 8, 2012

Jane Roe-Jones, Project Analyst  
Certificate of Need Section, Department of  
Health Service Regulation  
NC Depart. of Health and Human Services  
2704 Mail Service Center  
Raleigh, NC 27699-2704



**RE: Request for "No Review" for Use of A Decommissioned Operating Room as a Non-regulated Procedure Room.**

Dear Ms. Jane Roe-Jones,

Pitt County Memorial Hospital, now doing business as Vidant Medical Center (VMC) proposes to utilize a decommissioned operating room as a non-regulated procedure room. The primary reason for this request is to facilitate relocation of cholangiopancreatography (ERCP) services from our interventional radiology procedure rooms to an operating room decommissioned as part of a certificate of need application filed on June 15, 2004, ID #Q7075-4. VMC believes the proposed project is not subject to review under North Carolina's Certificate of Need (CON) laws.

As part of this decommissioning, operating room lights were removed and medical gases capped. As ERCP frequently requires heavy sedation or general anesthesia, VMC would propose to restore medical gas service to this procedure room. VMC would test and certify all mechanical and electrical systems to ensure the room was appropriate for patient care as a non-regulated procedure room. No re-installation of surgical lighting is proposed. Further, this room would be designated as a procedure room with appropriate signage, check lists, and used solely for ERCP, central line placement, and other types of procedures typically performed outside of an operating room or endoscopy suite. Any procedures done in this room would be billed to the patient appropriately for procedure room time.

Vidant Medical Center  
2100 Stantonsburg Road  
Greenville, NC 27834-2818  
PO Box 6028  
Greenville, NC 27835-6028  
252.847.4100  
VidantHealth.com

Letter of No Review  
3/3/12

VMC believes the proposed project is not subject to review under North Carolina's Certificate of Need (CON) laws for the following reasons:

- 1 – VMC is proposing to only perform cases that can be completed in a non-regulated procedure room and does not propose to increase the number of Operating Rooms or Endoscopy Suites.
- 2 – The proposed project has a total capital budget of \$106,000.

Finally, we believe efficiency and patient safety will be enhanced through the location of this procedure room.

If you need any additional information or clarification, please feel free to contact me at 252-847-3631.

Sincerely,



Jeff Shovelin, Director, Strategic Development

Vidant Health System

Cc:

Carmen Vincent, VP Corporate Accreditation and Regulatory Compliance

Tim McDonnell, Chief Design and Construction Officer

Jay Walton, VP, Design and Construction

Steve Butler, AVP Operative Services, Vidant Medical Center