

THE STATE OF SOUTH CAROLINA
IN THE COURT OF APPEALS

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SC Court of Appeals

APPEAL FROM THE ADMINISTRATIVE LAW COURT
The Honorable H.W. Funderburk, Jr., Administrative Law Judge

APPELLATE CASE No.: 2019-000358
ADMINISTRATIVE LAW COURT CASE No.: 16-ALJ-07-0386-CC

Trident Medical Center, LLC, d/b/a Trident Medical
Center,.....Respondent,

v.

South Carolina Department of Health and Environmental Control,
and Roper St. Francis Hospital – Berkeley, Inc., d/b/a Roper St.
Francis Hospital – Berkeley,.....Respondents below,

Of Which South Carolina Department of Health and Environmental
Control is a.....Respondent,

And Roper St. Francis Hospital – Berkeley, Inc., d/b/a
Roper St. Francis Hospital – Berkeley is the.....Appellant.

**RECORD ON APPEAL
VOLUME 5 OF 6
Pages R963 – R1124**

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Hospital – Berkeley, Inc., d/b/a Roper St.
Francis Hospital – Berkeley*

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Columbia, SC 29201
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*Attorneys for Respondent, SC Department
of Health & Environmental Control*

January 15, 2020
Columbia, South Carolina

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INVOICE FOR SERVICES

Bureau of Financial Management / Sims/Aycock Building
2600 Bull St, Columbia, South Carolina 29201

Invoice No.

PC18322-8

Invoice To:

ROPER ST. FRANCIS HEALTHCARE
SHANNON CANTWELL, REGULATORY AFFAIRS
SPECIALIST
125 DOUGHTY ST UNIT STE. 760
CHARLESTON, SC 29403

Ship To:

S.C. DHEC
Attention: Bureau of Financial Management
2600 Bull Street
Columbia, South Carolina 29201

Date:
5/11/2016

Terms:
DUE UPON RECEIPT

Department Name
Planning and Programs

Order Filled By:
GERRALN

Description of Services: CERTIFICATE OF NEED FILING FEE

Qty	Unit Description	Loc	Organ.	Fund	Account	Analytical	Unit Price	Amount
1	CERTIFICATE OF NEED FILING FEE (2340)	400	402011	428015	4486701	0000000	\$500.00	\$500.00
Total:								\$500.00

Payment can be made by credit card by completing the below form or by visiting www.scdhec.com and clicking on Invoice Payment under the Quick Links.

Name as it appears on credit card

Telephone Number

Mailing Address

Master Card / Visa / Discover

Type of card (circle one)

Credit Card Number

Expiration Date

Signature

Note: Make checks payable to South Carolina Department of Health and Environmental Control, remit to above address to the Attention of: Bureau of Financial Management

6 NOTICES

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

NOTICE OF GENERAL PUBLIC INTEREST

In accordance with Section 44-7-200(D), Code of Laws of South Carolina, the public is hereby notified that a Certificate of Need application has been accepted for filing and publication May 27, 2016 for the following project(s). After the application is deemed complete, affected persons will be notified that the review cycle has begun. For further information, please contact Vonja Szatkowski, Certificate of Need Program, 2600 Bull Street, Columbia, SC 29201 at (803) 545-3028.

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Establishment of a new Home Health Agency in Lancaster County at a total project cost of \$18,138.

Compassionate Care, LLC d/b/a BrightStar Care of Rock Hill/Fort Mill – Lancaster County

Establishment of a new Specialty Home Health Agency in Lancaster County wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$1,500.

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Affecting Pickens County**AnMed Health d/b/a AnMed Health Clemson – Pickens County**

Construction for the purchase and installation of CT Scanner at a total project cost of \$921,553.

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Affecting Richland County**Palmetto Health d/b/a Palmetto Health Children's Hospital – Richland County**

Renovation to an existing facility for the addition of a new 13 bed Rehabilitation Inpatient Unit at a total project cost of \$1,950,035.

Affecting Saluda County**Amedisys SC, LLC d/b/a Amedisys Home Health of Lexington – Saluda County**

Establishment of a new Home Health Agency in Saluda County at a total Project cost of \$18,138.

Affecting Spartanburg County**Amedisys Home Health, Inc. of South Carolina d/b/a Amedisys Home Health of Clinton – Spartanburg County**

Establishment of a new Home Health Agency in Spartanburg County at a total project cost of \$21,894.

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Brent Brady, R.Ph d/b/a Rock Hill Treatment Specialist – York County

Establishment of a new Narcotic Treatment Program (NTP) in York County at a total project cost of \$141,400.

Compassionate Care, LLC d/b/a Brightstar Care of Rock Hill/Fort Mill – York County

Establishment of a new Trident Medical Center, LLC d/b/a Trident Medical Center Specialty Home Health Agency in York County wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$5,000.

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL**NOTICE OF GENERAL PUBLIC INTEREST**

DHEC-Bureau of Land and Waste Management, File #20352
BC Components (also known as Philips Components) Site

NOTICE OF SETTLEMENT, CONTRIBUTION PROTECTION, AND COMMENT PERIOD

PLEASE TAKE NOTICE that the South Carolina Department of Health and Environmental Control (DHEC) intends to enter into a Cost Recovery Settlement Agreement (CRSA) with General Electric Company (GE) and Philips Electronics North America Corporation (PENAC) with respect to the facility known as the BC Components Site at 6071 Saint Andrews Road in Columbia, in the County of Lexington, South Carolina (Site). The CRSA provides for a payment of \$500,000.00 for reimbursement of DHEC's past response costs through the date of the CRSA. The CRSA also releases GE and PENAC from further liability to DHEC for the matters addressed in the CRSA and confers protection upon GE and PENAC from claims of other potentially liable persons for additional contribution. The CRSA is subject to a thirty-day public comment period, consistent with the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), 42 U.S.C. Section 9622, and the South Carolina Hazardous Waste Management Act (HWMA), S.C. Code Ann. Section 44-56-200 (as amended).

Notice of Settlement, Contribution Protection and Comment Period will be provided to potentially responsible parties. The proposed CRSA is available:

- (1) On-line at www.scdhec.gov/Apps/Environment/PublicNotices; or
- (2) By contacting Ms. Pat L. Vincent at 803-898-0840 or vincenpl@dhec.sc.gov.

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10 NOTICES**Affecting Jasper County****SS&J Associates, LLC d/b/a BrightStar Care Lowcountry - Jasper County**

Establishment of a new Home Health Agency in Jasper County wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$5,000.

Affecting Lancaster County**Amedisys SC, LLC d/b/a Neighbors Care Home Health Agency, an Amedisys Company - Lancaster County**

Establishment of a new Home Health Agency in Lancaster County at a total project cost of \$18,138.

Compassionate Care, LLC d/b/a BrightStar Care of Rock Hill/Fort Mill - Lancaster County

Establishment of a new Specialty Home Health Agency in Lancaster County wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$1,500.

Tri-County Home Health Care & Services, Inc. d/b/a Tri-County Home Health Care and Services, Inc. - Lancaster County

Establishment of a new Home Health Agency in Lancaster County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$8,100.

Affecting Laurens County**Tri-County Home Health Care & Services, Inc. d/b/a Tri-County Home Health Care and Services, Inc. - Laurens County**

Establishment of a new Home Health Agency in Laurens County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$8,100.

Affecting Pickens County**AnMed Health d/b/a AnMed Health Clemson - Pickens County**

Construction for the purchase and installation of CT Scanner at a total project cost of \$921,553.

Tri-County Home Health Care & Services, Inc. d/b/a Tri-County Home Health Care and Services, Inc. - Pickens County

Establishment of a new Home Health Agency in Pickens County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$8,100.

Affecting Richland County**Palmetto Health d/b/a Palmetto Health Children's Hospital - Richland County**

Renovation to an existing facility for the addition of a new 13 bed Rehabilitation Inpatient Unit at a total project cost of \$1,950,035.

Affecting Saluda County**Amedisys SC, LLC d/b/a Amedisys Home Health of Lexington - Saluda County**

Establishment of a new Home Health Agency in Saluda County at a total Project cost of \$18,138.

Affecting Spartanburg County**Amedisys Home Health, Inc. of South Carolina d/b/a Amedisys Home Health of Clinton – Spartanburg County**

Establishment of a new Home Health Agency in Spartanburg County at a total project cost of \$21,894.

The Amendments Group, LLC d/b/a BrightStar Care Upstate – Spartanburg County

Establishment of a new Home Health Agency in Spartanburg County wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$5,000.

Affecting York County**Amedisys SC, LLC d/b/a Neighbors Care Home Health Agency, an Amedisys Company – York County**

Establishment of a new Home Health Agency in York County at a total Project cost of \$21,894.

Brent Brady, R.Ph d/b/a Rock Hill Treatment Specialist – York County

Establishment of a new Narcotic Treatment Program (NTP) in York County at a total project cost of \$141,400.

Compassionate Care, LLC d/b/a Brightstar Care of Rock Hill/Fort Mill – York County

Establishment of a new Trident Medical Center, LLC d/b/a Trident Medical Center Specialty Home Health Agency in York County wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$5,000.

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL**NOTICE OF GENERAL PUBLIC INTEREST**

DHEC-Bureau of Land and Waste Management, File #20352
BC Components (also known as Philips Components) Site

NOTICE OF SETTLEMENT, CONTRIBUTION PROTECTION, AND COMMENT PERIOD

PLEASE TAKE NOTICE that the South Carolina Department of Health and Environmental Control (DHEC) intends to enter into a Cost Recovery Settlement Agreement (CRSA) with General Electric Company (GE) and Philips Electronics North America Corporation (PENAC) with respect to the facility known as the BC Components Site at 6071 Saint Andrews Road in Columbia, in the County of Lexington, South Carolina (Site). The CRSA provides for a payment of \$500,000.00 for reimbursement of DHEC's past response costs through the date of the CRSA. The CRSA also releases GE and PENAC from further liability to DHEC for the matters addressed in the CRSA and confers protection upon GE and PENAC from claims of other potentially liable persons for additional contribution. The CRSA is subject to a thirty-day public comment period, consistent with the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), 42 U.S.C. Section 9622, and the South Carolina Hazardous Waste Management Act (HWMA), S.C. Code Ann. Section 44-56-200 (as amended).

Notice of Settlement, Contribution Protection and Comment Period will be provided to potentially responsible parties. The proposed CRSA is available:

- (1) On-line at www.scdhec.gov/Apps/Environment/PublicNotices; or
- (2) By contacting Ms. Pat L. Vincent at 803-898-0840 or vincenpl@dhec.sc.gov.

Implementation Tab



Article #: 92148969009997901405488353

7/26/2016

VIA CERTIFIED MAIL AND EMAIL

Shannon Cantwell
Regulatory Affairs Specialist
Roper St. Francis Healthcare
125 Doughty Street, Suite 760
Charleston, SC 29403

Re: **Proof of Closure - Roper St. Francis Xavier Cardiac Catheterization Lab**
Upon Certificate of Need Approval of Cardiac Catheterization services to Roper
St. Francis Hospital - Berkeley

Dear Ms. Cantwell:

As you know, the S.C. Department of Health and Environmental Control (Department) granted a Certificate of Need (CON) to Roper St. Francis Hospital - Berkeley for the addition of diagnostic cardiac catheterization services at that hospital's future location. As you also know, Roper St. Francis Healthcare agreed to shutter the operation of its diagnostic cardiac catheterization lab at St. Francis Xavier Hospital upon issuance of that approval by the Department. Pursuant to this matter, please provide evidence of closure of that laboratory to the Department no later than 30 days from the date of this letter. This evidence should include the removal of any advertising, in print or on the web, which may cause any patient to believe that such services are being provided at the Xavier location. Please include, as well, an affidavit signed by the appropriate individual within Roper St. Francis Healthcare which will attest to the closure of the aforementioned cath lab.

Sincerely,

A handwritten signature in black ink, appearing to read 'Louis Eubank', with a horizontal line extending to the right.

Louis Eubank
Director
Certificate of Need Program

cc: Ralph Barbler, Esquire (email)



2095 Henry Tecklenburg Drive, Charleston, SC 29414, Telephone: (843) 402-1006, Fax: (843) 402-1550

August 17, 2016

VIA EMAIL AND US MAIL

EUBANKLW@dhsc.sc.gov

Louis Eubank
Director, Certificate of Need (C.O.N.) Program
South Carolina Department of Health & Environmental Control
301 Gervais Street
Columbia, SC 29201

Re: Proof of Closure – Bon Secours St. Francis Xavier Cardiac Catheterization Lab

Dear Mr. Eubank:

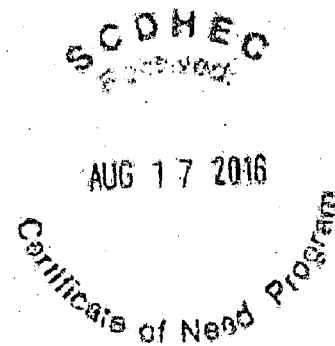
In response to your letter dated July 26, 2016, and in accordance with Roper St. Francis – Berkeley's Certificate of Need application for the addition of the cardiac catheterization service, which was approved by the South Carolina Department of Health and Environmental Control on July 25, 2016, please accept this letter as confirmation that Bon Secours St. Francis Xavier Hospital ("BSSFH") permanently closed its diagnostic cardiac catheterization lab on August 1, 2016. Please note that the area within BSSFH in which the now closed diagnostic catheterization lab was located, is being used to provide other medical services to patients consistent with BSSFH's license.

Please let me know if you have any questions regarding this matter.

Sincerely,

Allen Carroll
Chief Executive Officer
Bon Secours St. Francis Xavier Hospital

cc: Ralph Barbier, Esq. (via email only)





William R. Thomas

Partner

Telephone: 803.253.8658

Direct Fax: 803.255.8017

willthomas@parkerpoe.com

August 9, 2016

Via E-mail (LUCASLM@dhec.sc.gov) & Hand Delivery:

The Honorable Lisa Lucas Longshore

Clerk

SC Board of Health and Environmental Control

2600 Bull Street

Columbia, SC 29201-1708

Re: Request for Final Review

Department decision granting application for a Certificate of Need to Roper St. Francis Hospital - Berkeley for the addition of cardiac catheterization services at a total project cost of \$2,873,366

CON Case No.: 2340

Dear Ms. Longshore:

Pursuant to S.C. Code Ann. § 44-1-60(E); the State Certification of Need and Health Facility Licensure Act (S.C. Code Ann. §§ 44-7-110 *et seq.*) ("CON Act"); S.C. Code Ann. Regs. 61-15 ("CON Regulations"); and Article I, Section 22 of the South Carolina State Constitution; on behalf of our client, Trident Medical Center, LLC, d/b/a Trident Medical Center ("Trident"), I am writing to request that the Department Board conduct a final review conference of the Department's July 25, 2016 decision to approve Roper St. Francis Hospital-Berkeley's¹ ("Roper - Berkeley") Certificate of Need ("CON") application for the addition of diagnostic cardiac catheterization services at a total project cost of \$2,873,366 ("Proposed Project"). **Exhibit A**. Trident respectfully requests that the Department Board reverse the Department's decision to approve the Proposed Project and sets forth its arguments in support of its position herein.

Also, enclosed with this Request for Final Review, please find a check in the amount of \$100.00 as payment of the filing fee.

BACKGROUND

On May 9, 2016, Roper-Berkeley submitted its CON application for its Proposed Project. On May 26, 2016, the CON application was deemed complete. **Exhibit B**. By letter dated, June 24, 2016, Trident notified the Department of its status as an "affected person," as that term

¹ The Department approved this project even though the Roper-Berkeley Hospital is not scheduled to open until the year 2019. Thus, if any provider in the service area were to apply for a CON to add diagnostic services to its facility, Roper-Berkeley could assert that the Department should not approve the CON until such time as Roper-Berkeley's diagnostic catheterization lab is up and running.

PPAB 3340372v1

The Honorable Lisa Lucas Longshore
August 9, 2016
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is defined by the CON Act and the CON Regulations, stated its opposition to the Proposed Project, and requested a Project Review Meeting. Exhibit C. Subsequently, on July 21, 2016, Trident submitted a letter from its consultant, Sullivan Consulting Group, Inc., detailing its reasons for opposing Roper-Berkeley's Proposed Project. Exhibit D. On July 25, 2016, the Department issued its letter to Roper-Berkeley, notifying Roper-Berkeley that its CON application was approved. The Department declined to hold a Project Review Meeting on the basis that Roper-Berkeley's project was subject to the State Health Plan's Chapter II transfer provision, but according to the approval letter, that was not the case. As the approval letter states, the Department reviewed Roper-Berkeley's CON application based on the applicable project review criteria for a new cardiac catheterization lab, rather than an intra-system transfer of a catheterization lab. If Trident knew that the Department was not going to review Roper-Berkeley's CON application using the transfer provision, it would have requested a formal Public Hearing instead of a Project Review Meeting.²

As set forth in detail below and as will be more fully explained at a final review conference held on this matter, Trident respectfully requests that the Board overturn the Department's decision to approve Roper-Berkeley's CON application because it (i) fails to satisfy the criteria set forth in the South Carolina Health Plan enacted August 13, 2015 ("State Health Plan"); (ii) fails to demonstrate community need for the Proposed Project; (iii) is not financially feasible; (iv) will not promote cost containment; and (v) will adversely impact other area providers, including Trident.

ARGUMENTS

Compliance with the State Health Plan

Bon Secours' Non-Existent Diagnostic Cardiac Catheterization Program

Roper-Berkeley's CON application states that upon approval of the application, Bon Secours St. Francis Xavier Hospital ("Bon Secours"), Roper - Berkeley's sister facility, will close its existing diagnostic catheterization lab. See CON Application, § B11. Roper - Berkeley then

² The CON Regulations provide that

[a] public hearing must be requested in writing by an 'affected person' as defined in these regulations within thirty (30) calendar days of the notification of the beginning of a review. Where such a hearing is requested, prior notice of the hearing will be provided to 'affected persons.' The written notification of the hearing shall include the proposed schedule for the review time, date, and place of such hearing. The public hearing shall provide an opportunity for any person to present information relevant to the application.

S.C. Code Ann. Regs. 61-15, § 306. To avoid the complications associated with a public hearing, the Department established the informal Project Review Meeting back in the 1990s. The Project Review Meeting gives the applicant and affected persons the ability to meet with and present its position to the Department's staff in a forum that allows the opposing side to address the Department's staff. The Department's staff also can also question each side and here the opposing party's response. The process is very transparent, and it gives the Department an opportunity to learn more about the application. By denying Trident's request for a Project Review Meeting under false pretenses, the Department denied Trident its due process right to a Public Hearing, and it summarily dismissed Trident's arguments in opposition to the Proposed Project as insufficient to deny the application. See Exhibit A, p. 2.

The Honorable Lisa Lucas Longshore
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claims, "[a]s a result, this project will not result in an increase in diagnostic cardiac catheterization capacity in the service area." *Id.* Roper-Berkeley's CON application cannot be approved because the State Health Plan provides that a new diagnostic service cannot be approved unless "all existing labs in the service area have performed a minimum of 500 diagnostic catheterization procedures per laboratory during the most recent year." State Health Plan, p. VIII-5, ¶ 3 (emphasis added). Bon Secours has not achieved the 500 procedure threshold in the last several years, and in fact, has been averaging less than 10 cath per year for the last four years. According to the State Health Plan, in 2013, the most recent year utilized for State health planning purposes, Bon Secours performed a total of three diagnostic cath in 2013. See State Health Plan, p. XIII-34. In 2015, Bon Secours performed a total of four diagnostic cath. See Exhibit B, p. 6.

Neither the Department nor Roper-Berkeley treat the instant CON application as a transfer of services from Bon Secours, presumably because Roper-Berkeley is aware that it cannot meet the State Health Plan criteria for transferring a health service. See generally State Health Plan, p. II-2. For example, Roper-Berkeley could not demonstrate need for additional capacity based on historical and projected utilization patterns, as required. *Id.* at ¶ 3. Yet, Roper-Berkeley's Proposed Project could not be treated as the establishment of a new service either merely because it proposes that Bon Secours will close its program upon approval of Roper-Berkeley's Proposed Project. The Department's decision to grant Roper-Berkeley's CON application as a "new service" allows Roper-Berkeley to skirt compliance with the State Health Plan by creating its own procedural process, because Roper-Berkeley cannot meet the requirements for either the transfer of a health service or the establishment of a new service. It is fundamentally unjust to create a separate set of standards merely because a provider cannot meet the applicable standards of the State Health Plan. Roper-Berkeley's CON application must be denied because Bon Secours' diagnostic cardiac catheterization program has not met the requisite threshold of 500 annual diagnostic catheterizations procedures to permit approval of a new diagnostic catheterization service provider.³

Setting aside the fact that Roper-Berkeley's CON application cannot be approved because of the low utilization of Bon Secours' program, Roper-Berkeley's CON application fails to meet many of the remaining applicable standards and criteria of the State Health Plan and the project review criteria set forth in the CON Regulations and cannot be approved.

Unrealistic Service Area

The State Health Plan provides that "[t]he service area for a diagnostic catheterization laboratory is defined as all facilities within 45 minutes one way automobile travel time. . . ." *Id.* at p. VIII-4. Roper-Berkeley's service area is much broader than the 45 minute one way automobile travel time standard. Roper-Berkeley's service area is defined to encompass four counties: Berkeley, Dorchester, Charleston, and Colleton. Many portions of Charleston and Colleton Counties lie well outside of the 45 minute drive time service area established in the

³ In fact, Trident learned that DHEC issued an approval letter to East Cooper Regional Medical Center on the same day it approved Roper-Berkeley's diagnostic catheterization lab. For this to occur, Bon Secours hospital had to discontinue its cardiac catheterization program before East Cooper could have been approved because all diagnostic catheterization labs in the service area have to be operating at above 500 diagnostic catheterization procedures per year. However, upon information and belief, DHEC approved Roper-Berkeley's CON application and East Cooper's CON application while Bon Secours' diagnostic catheterization lab was operating with a CON, which is a violation of the State Health Plan standards.

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State Health Plan. More importantly, however, Roper-Berkeley's service area is simply unrealistic.

Roper-Berkeley's sister facility, Roper Hospital, is located in downtown Charleston. Roper Hospital aligned physicians historically refer all patients to the comprehensive cardiac catheterization program at Roper Hospital, not the diagnostic-only catheterization program at Bon Secours. Consequently, as noted above, Bon Secours' diagnostic program is essentially non-existent. Bon Secours performed only four diagnostic catheterizations in 2015. Physicians who believe there is a likelihood that a patient will require percutaneous coronary intervention ("PCI") will naturally refer that patient to a comprehensive cardiac catheterization program where both procedures can be performed during the same visit. It is in the patient's best interest to be referred to a facility that can provide comprehensive services in one setting rather than refer the patient to a diagnostic-only program where the patient may need PCI and require transfer to another facility, or require that the patient be scheduled for a procedure on another day, unnecessarily subjecting the patient to two separate, invasive procedures. Bon Secours' virtually non-existent cardiac catheterization utilization in the past several years reflects that Roper Hospital aligned physicians recognize that referral to a comprehensive cardiac catheterization program is far preferable and in the best interest of the patients. There is simply no reason to believe that the physicians' referral patterns would change upon the opening of a diagnostic-only cardiac catheterization program at a small, 50 bed community hospital, such as Roper-Berkeley.

Furthermore, Roper-Berkeley's service area is unrealistic, because it illogically assumes that patients would travel greater distances past other providers with existing cardiac catheterization programs to have the procedure performed at Roper-Berkeley. It is highly unlikely that any material number of patients who do not reside in close proximity to Roper-Berkeley would bypass other providers, many of which operate comprehensive cardiac catheterization programs, to seek services at Roper-Berkeley.

Roper-Berkeley also asserts that Roper Hospital will transfer some its existing diagnostic caseload to Roper-Berkeley. However, again, there is no evidence that patients or physicians will choose Roper-Berkeley, rather than continue to utilize the comprehensive cardiac catheterization services provided at Roper Hospital, just as they have always done. Roper-Berkeley attempts to bolster its projected utilization under the premise that it will absorb some of the volume from Roper Hospital; however, the fact that the utilization of Bon Secours' diagnostic cardiac catheterization program is virtually non-existent, and has been so for the past several years demonstrates that this premise is meritless and unsupportable.

Roper-Berkeley has abandoned the 45 minute drive time standard for a much broader service area to generate better utilization projections for its Proposed Project, but the facts demonstrate that the service area is unrealistic, and the utilization projections are unsupportable. Roper-Berkeley's CON application fails to meet the service area standard as set forth in the State Health Plan, which means the CON application cannot be approved. See State Health Plan, p. VIII-4, ¶ 2.

Diagnostic Cath Utilization Standards for New Services

Assuming that Roper-Berkeley's Proposed Project can be considered the establishment of a new service, notwithstanding the extremely low utilization of Bon Secours' program, the State Health Plan provides that new diagnostic catheterization services can only be approved "if all existing labs in the service area have performed a minimum of 500 diagnostic catheterization

The Honorable Lisa Lucas Longshore
 August 9, 2016
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procedures per laboratory during the most recent year." *Id.* at p. VIII-5, ¶ 3 (emphasis added). Roper-Berkeley's CON application fails to meet this standard. Roper-Berkeley and the Department apparently misinterpreted this provision of the State Health Plan as requiring existing facilities to have provided 500 diagnostic equivalents per lab in the most recent year; however, the State Health Plan clearly states that the standard is procedures. In its decision letter, the Department states that after excluding Bon Secours, which it should not have done, "the Department concludes that other diagnostic catheterization labs within the service area operate at such an equivalent capacity as to not preclude the addition of the diagnostic catheterization lab contemplated by the Applicant." Exhibit A, p. 2 (emphasis added). Again, pursuant to the clear language of the State Health Plan, diagnostic equivalents are not the standard, diagnostic procedures are. Only one facility, Trident, met the threshold of 500 diagnostic procedures for each of its two catheterization labs. See Exhibit D, p. 6. Roper Hospital, MUSC, and, of course, Bon Secours all fell well below the threshold. Consequently, Roper-Berkeley's CON application fails to meet this criteria and is not in compliance with the State Health Plan as required for CON approval.

Projected Utilization

The State Health Plan states that

An applicant for a fixed diagnostic service must project that the proposed service will perform a minimum of 500 diagnostic equivalent procedures annually within three years of initiation of services, without reducing the utilization of existing diagnostic catheterization services in the service area below 500 diagnostic cardiac catheterization procedures per laboratory.

State Health Plan, p. VIII-5, ¶ 4. Without regard for the fact that Roper-Berkeley's utilization projections are based on an unrealistic, over-sized service area, as addressed above, the utilization projections are unsupportable as a result of several additional, serious flaws. Again, Roper-Berkeley has assumed that it will absorb diagnostic catheterizations from Roper Hospital; however, there is no credible basis to support such an assumption. Why would patients travel, in many cases, greater distances to a smaller hospital that offers a more limited range of services? Why would Roper aligned physicians refer patients to a smaller hospital with a more limited range of services and risk that the patient would require transfer to another hospital if the patient requires PCI, or require the patient to make another appointment for a second, separate, invasive procedure? As noted above, there is no reason to believe that Roper aligned physicians would refer patients to Roper-Berkeley, because they currently do not refer patients to Bon Secours, a larger, more established hospital with a greater range of services. Yet, Roper-Berkeley assumes that eighty (80%) percent of Roper Hospital's Berkeley County cases, sixty-five (65%) percent of its Dorchester County cases, and fifty (50%) percent of its Charleston County cases will be redirected to Roper-Berkeley. Such dramatic shifts in market share between the two facilities is simply not supported by the facts.

The more likely scenario is that Roper will redirect patients currently being served by Trident, because Trident is a major provider of diagnostic and therapeutic catheterization services to residents in Berkeley and Dorchester Counties. It appears that no consideration was given to this likely shift in market share as a result of the Proposed Project. The Department does not address the potential adverse impact on Trident. Instead, the Department states, "[a]s one lab in the service area is being closed as a result of this approval, and as another lab which is to be approved is in the extreme southern portion of the service area relative to this Applicant's proposed location, no unnecessary duplication of services is

The Honorable Lisa Lucas Longshore
August 9, 2016
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expected." See Exhibit A, p. 3. Bon Secours utilization is *de minimis*; at best; therefore, the closure of Bon Secours will have no material impact on utilization at Roper-Berkeley. The absorption of the less than five diagnostic catheterization cases annually performed at Bon Secours will not keep Roper-Berkeley in operation. Roper-Berkeley will have to redirect significant market share from Trident to achieve its volume projections. Nevertheless, both Roper-Berkeley and the Department dismiss this issue despite the fact that Trident is located only seven miles from the Roper-Berkeley campus.

Roper-Berkeley's utilization projections are also based on the assumption that Roper Hospital's historical diagnostic cardiac catheterization volume will grow in conjunction with the projected rate of population growth. However, this assumption is inconsistent with Roper Hospital's recent historical experience, as well as the experience of *all other area service providers*. Every provider in the service area has seen a decline in diagnostic catheterization procedures since 2011, and utilization of diagnostic cardiac catheterization services throughout the service area has declined by twenty (20%) percent between 2011 through 2015. See Exhibit D, p. 8. There is no reason to believe that this trend will not continue.

Essentially all of Roper-Berkeley's patients will likely originate from its primary service area. As such, Roper-Berkeley cannot meet the required 500 diagnostic catheterization equivalents annually, even assuming the redirection of Trident's patients from Roper Hospital. In all likelihood, Roper-Berkeley will operate a low volume program, while redirecting market share from Trident, adversely impacting Trident's utilization. Despite these facts, the Department did not call into question Roper-Berkeley's utilization projections. See Exhibit A, p. 2.

Compliance with the CON Regulations

Community Need

The Department acknowledges that the service area for diagnostic catheterization services is defined by the State Health Plan as an area within a 45 minute one way drive time from the proposed location of the services. See *id.* at p. 2. It further acknowledges that Roper-Berkeley's defined service area is much larger, encompassing four counties. *Id.* However, the Department ignores the fact that Roper-Berkeley's service far exceeds the 45 minute drive time standard because Roper-Berkeley could not project utilization sufficient to meet the State Health Plan requirements without artificially expanding its service area. An applicant should not be allowed to create a fictional service area to bolster its utilization projections and a community need for which there is no basis in fact.

The Department states that all labs within the planning area operate between seventy-nine (79%) percent and nearly ninety-four (94%) percent capacity, and then concludes that the Applicant has sufficiently demonstrated community need. *Id.* The CON project review criteria for community need requires that the Proposed Project:

meet an identified (documented) need of the target population. The assumptions and methods used to determine the level of need should be specified in the application and *based on a reasonable approach* as judged by the review body.

S.C. Code Ann. Regs. 61-15, § 802.2.c. (emphasis added). The project review criteria further provides that "[c]urrent and/or projected utilization should be sufficient to justify the expansion or implementation of a proposed service." *Id.* at § 802.2.e. There is nothing reasonable about

The Honorable Lisa Lucas Longshore
 August 9, 2016
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Roper-Berkeley's assumptions identifying community need or projected utilization. The actual utilization that Roper-Berkeley's Proposed Project will realize is much lower than projected and insufficient to justify the implementation of the Proposed Project.

The service area is already well served by other area providers, including Trident, and other area providers have the capacity to meet the residents' needs, particularly in light of the fact that all area providers have experienced declining utilization of these services over the past several years.

Distribution (Accessibility)

As noted above, the Department concludes that because Roper-Berkeley proposes that Bon Secours will close upon approval of Proposed Project, there is no unnecessary duplication of services. See Exhibit A, p. 3. This conclusion is illogical. Bon Secours' cardiac catheterization program existed essentially only in name. The absorption of less than five diagnostic procedures annually will not support the operation of Roper-Berkeley's Proposed Project. It is unlikely that significant numbers of patients will be redirected from Roper Hospital, and the presumption that utilization volumes will grow with the population contravenes the declining utilization trends in the service area. The likely scenario, based on the facts, is that Roper-Berkeley will rely on the redirection of market share from Trident, adversely impacting Trident's utilization volumes. There is no need for Roper-Berkeley's Proposed Project, and consequently, the Proposed Project is an unnecessary duplication of services. It does nothing to increase accessibility to services, and it does not meet the project review criteria set forth in Section 802.3 of the CON Regulations.

Financial Feasibility

The project review criteria require that the applicant project "both the immediate and long-term financial feasibility of the proposal. Such projection should be reasonable and based upon accepted accounting procedures." S.C. Code Ann. Regs. 61-15, § 802.15. Roper-Berkeley's CON application fails to meet this requirement because the financial projections are based upon unreasonable underlying assumptions that cannot be realized. More reasonable assumptions would have resulted in dramatically lower utilization projections and, therefore, dramatically lower financial projections. The Proposed Project is unlikely to demonstrate an excess of revenues over expenses, and Roper-Berkeley has failed to demonstrate financial feasibility as required for CON approval.

Cost Containment

Contrary to the Department's conclusion, the Proposed Project does not promote cost containment, regardless of any economies of scale realized by the integration of the Proposed Project into Roper-Berkeley's hospital pre-construction phase. See Exhibit A, p. 3. The Proposed Project has a total project cost of almost \$ 2.9 million for a service that is not needed and will likely be underutilized. It will adversely impact Trident and other area providers and will increase health care costs in the service area.

CONCLUSION

Trident respectfully requests that the Board reverse the Department's decision to approve Roper-Berkeley's CON application, because (i) the Proposed Project does not meet the applicable standards and criteria of the State Health Plan; (ii) there is no community need

The Honorable Lisa Lucas Longshore
August 9, 2016
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for the Proposed Project because the area is already well served by other area providers; (iii) the service area is unrealistic and the utilization projections will not be realized; (iv) the Proposed Project will adversely impact Trident and other area providers; (v) the Proposed Project is not financially feasible; and (vi) the Proposed Project will not promote cost containment. "The Department may not issue a Certificate of Need unless an application is in compliance with the South Carolina Health Plan, Project Review Criteria, and other regulations." S.C. Code Ann. §§ 44-7-210(B). Based upon the foregoing, Roper-Berkeley's CON application must be denied.

Trident welcomes the opportunity to present its arguments in support of its position in greater detail and to address any questions or concerns the Board may have at the final review conference held on this matter.

Sincerely,



William R. Thomas

WRT:jbc

Exhibit A

To Request for Final Review



July 25, 2016

VIA CERTIFIED MAIL

Shannon Cantwell
Regulatory Affairs Specialist
Roper St. Francis Healthcare
125 Doughty Street, Suite 760
Charleston, SC 29403

Re: **Decision Granting Application for a Certificate of Need
Roper St. Francis Hospital – Berkeley**
Addition of Cardiac Catheterization services to Roper St. Francis Hospital - Berkeley
at a total project cost of \$2,873,366.
Case No.: 2340
Berkeley County, South Carolina

Dear Ms. Cantwell:

The South Carolina Department of Health and Environmental Control (Department) has reviewed the above-referenced Certificate of Need (CON) Application. After consideration of the entire administrative record in this matter, the Department concludes the Applicant has presented substantial evidence the Project materially complies with the relevant project review criteria and is consistent with the South Carolina Health Plan enacted August 13, 2015 (Plan). Specifically, the Project satisfies the requirements set forth in Section 802 of Regulation 61-15 pertaining to Community Need Documentation, Distribution (Accessibility), Financial Feasibility, and Cost Containment. Accordingly, it is the decision of the Department that a Certificate of Need be granted to Roper St. Francis Hospital – Berkeley.

The Department's decision is based on the following findings:

Compliance with the State Health Plan

In addition to the declarative Certificate of Need Standards #1 and #2 outlined in the Plan for cardiac catheterization services, the following Standards for the Project apply:

3. New diagnostic catheterization services, including mobile services, shall be approved only if all existing labs in the service area have performed a minimum of 500 diagnostic catheterization procedures per laboratory during the most recent year.

A review of relevant Joint Annual Report (JAR) data for all diagnostic catheterization labs within the 45-minute drive time service area showed that all diagnostic catheterization labs met or exceeded the 500 procedure threshold outlined in the Plan with one notable exception. The

SC Department of Health and Environmental Control CON-0237

diagnostic cardiac catheterization lab located at Roper St. Francis Xavier Hospital in West Ashley performed no more than nine (9) procedures per year in any year from 2010 to 2014, according to available JAR data. The Department explained this inconsistency to the Applicant as an agent for both Roper St. Francis Hospital – Berkeley and Bon Secours St. Francis Xavier Hospital. As such an agent, the Applicant agreed to shutter its diagnostic catheterization lab upon approval of the instant application, regardless of the timing of the new lab installation or any potential opposition to the instant application, thus allowing the department to discount the utilization figures of the lab at the Bon Secours St. Francis Xavier location. As such, the Department concludes that other diagnostic catheterization labs within the service area operate at such an equivalent capacity as to not preclude the addition of the diagnostic catheterization lab contemplated by the Applicant.

4. An applicant for a fixed diagnostic service must project that the proposed service will perform a minimum of 500 diagnostic equivalent procedures annually within three years of initiation of services, without reducing the utilization of the existing diagnostic catheterization services in the service area below 500 diagnostic cardiac catheterization procedures per laboratory.

The Applicant projects a minimum of 510 procedures by the close of the third reporting year, and no evidence is provided which shows utilization at other existing diagnostic catheterization labs will drop below the 500 minimum procedure threshold as a result of approving the Project.

Certificate of Need Standards #5 and #6 do not apply to the contemplated Project as it is not an expansion of current cardiac catheterization services and is not a mobile diagnostic catheterization laboratory.

The Department notes that Trident Medical Center has filed as an Affected Person and in opposition to the application. A letter of opposition detailing the opposition's argument was received on July 21, 2016. After consideration of all information presented therein, the Department has determined that Trident's opposition does not present a sufficient reason to deny the Application.

Accordingly, the Department concludes the Applicant has sufficiently complied with the Standards outlined in the Plan, Chapter VIII-4 and Chapter VIII-5.

Community Need Documentation

While the planning area for diagnostic catheterization services is defined as an area within a 45-minute, one-way drive from the Applicant's facility, the Applicant further considers its service area to include Berkeley County as well as parts of Dorchester, Charleston, and Colleton Counties. Within the planning area, there are a total of 11 existing catheterization labs which are open and able to perform the services contemplated by the Applicant's Project. With the notable exception discussed previously, all labs within the planning area operate between 79% and nearly 94% capacity.

Accordingly, the Department concludes Applicant has sufficiently projected Community Need to satisfy the requirements of Section 802.2, Reg. 61-15.

Distribution (Accessibility)

Patients will be admitted regardless of age, race, ethnicity, religion, culture, language, physical or mental disability, socioeconomic status, sex, sexual orientation, or gender identity or expression. Applicant has budgeted an appropriate amount of gross revenue for the treatment of indigent patients. As one lab in the service area is being closed as a result of this approval, and as another lab which is to be approved is in the extreme southern portion of the service area relative to this Applicant's proposed location, no unnecessary duplication of services is expected to occur.

The Department concludes that Applicant has satisfied the requirements of Distribution (Accessibility) pursuant to Section 802.3, Reg. 61-15.

Financial Feasibility

Applicant provided three year budget projections demonstrating financial feasibility. Julie Graudin, CPA for Roper St. Francis Healthcare, attests that the Project will be funded by utilizing existing bond proceeds issued for the development of the larger hospital project.

The Department concludes that Applicant has satisfied the requirements of Financial Feasibility pursuant to Section 802.15, Reg. 61-15.

Cost Containment

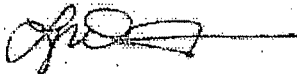
Integrating the contemplated laboratory into the pre-construction phase of the new Roper St. Francis Hospital – Berkeley realizes certain economies of practice which are otherwise lost during later renovation. Quality of cardiac care is increased through the provision of diagnostic services wherein early intervention prevents later invasive treatments at a much higher cost to the patient.

The Department concludes that Applicant has satisfied the requirements of Cost Containment pursuant to Section 802.16, Reg. 61-16.

The Department has determined the findings required by S.C. Code Reg. 61-15 §501 are not applicable to this Project.

The issuance of a Certificate of Need does not constitute approval for any proposed construction, licensing or certification changes. You should contact the following individuals for information concerning these related issues: Bureau of Radiological Health, Mr. Aaron Gantt (803.545.4400); Division of Health Facilities Construction, Mr. William McCallum (803.545.4215); Division of Health Licensing, Ms. Gwendolyn Thompson, (803.545.4370); and Bureau of Certification, Ms. MaryJo Roué (803.545.4293).

Sincerely,



Louis Eubank
Director
Certificate of Need Program

cc: William R. Thomas, Esq. (email/Certified Mail)

Enclosures: Guide to Board Review

CON-0239

South Carolina Board of Health and Environmental Control

Guide to Board Review

Pursuant to S.C. Code Ann. § 44-1-60

The decision of the South Carolina Department of Health and Environmental Control (Department) becomes the final agency decision fifteen (15) calendar days after notice of the decision has been mailed to the applicant, permittee, licensee and affected persons who have requested in writing to be notified, unless a written request for final review accompanied by a filing fee in the amount of \$100 is filed with Department by the applicant, permittee, licensee or affected person.

Applicants, permittees, licensees, and affected parties are encouraged to engage in mediation or settlement discussions during the final review process.

If the Board declines in writing to schedule a final review conference, the Department's decision becomes the final agency decision and an applicant, permittee, licensee, or affected person may request a contested case hearing before the Administrative Law Court within thirty (30) calendar days after notice is mailed that the Board declined to hold a final review conference. In matters pertaining to decisions under the South Carolina Mining Act, appeals should be made to the South Carolina Mining Council.

I. Filing of Request for Final Review

1. A written Request for Final Review (RFR) and the required filing fee of one hundred dollars (\$100) must be received by Clerk of the Board within fifteen (15) calendar days after notice of the staff decision has been mailed to the applicant, permittee, licensee, or affected persons. If the 15th day occurs on a weekend or State holiday, the RFR must be received by the Clerk on the next working day. RFRs will not be accepted after 5:00 p.m.
2. RFRs shall be in writing and should include, at a minimum, the following information:
 - The grounds for amending, modifying, or rescinding the staff decision;
 - a statement of any significant issues or factors the Board should consider in deciding how to handle the matter;
 - the relief requested;
 - a copy of the decision for which review is requested; and
 - mailing address, email address, if applicable, and phone number(s) at which the requestor can be contacted.
3. RFRs should be filed in person or by mail at the following address:

South Carolina Board of Health and Environmental Control
Attention: Clerk of the Board
2600 Bull Street
Columbia, South Carolina 29201

Alternatively, RFR's may be filed with the Clerk by facsimile (803-898-3393) or by electronic mail (boardclerk@dhec.sc.gov).
4. The filing fee may be paid by cash, check or credit card and must be received by the 15th day.
5. If there is any perceived discrepancy in compliance with this RFR filing procedure, the Clerk should consult with the Chairman or, if the Chairman is unavailable, the Vice-Chairman. The Chairman or the Vice-Chairman will determine whether the RFR is timely and properly filed and direct the Clerk to (1) process the RFR for consideration by the Board or (2) return the RFR and filing fee to the requestor with a cover letter explaining why the RFR was not timely or properly filed. Processing an RFR for consideration by the Board shall not be interpreted as a waiver of any claim or defense by the agency in subsequent proceedings concerning the RFR.
6. If the RFR will be processed for Board consideration, the Clerk will send an Acknowledgement of RFR to the Requestor and the applicant, permittee, or licensee, if other than the Requestor. All personal and financial identifying information will be redacted from the RFR and accompanying documentation before the RFR is released to the Board, Department staff or the public.
7. If an RFR pertains to an emergency order, the Clerk will, upon receipt, immediately provide a copy of the RFR to all Board members. The Chairman, or in his or her absence, the Vice-Chairman shall based on the circumstances, decide whether to refer the RFR to the RFR Committee for expedited review or to decline in writing to schedule a Final Review Conference. If the Chairman or Vice-Chairman determines review by the RFR Committee is appropriate, the Clerk will forward a copy of the RFR to Department staff and Office of General Counsel. A Department response and RFR Committee review will be provided on an expedited schedule defined by the Chairman or Vice-Chairman.
8. The Clerk will email the RFR to staff and Office of General Counsel and request a Department Response within eight (8) working days. Upon receipt of the Department Response, the Clerk will forward the RFR and Department Response to all Board members for review, and all Board members will confirm receipt of the RFR to the Clerk by email. If a Board member does not confirm receipt of the RFR within a twenty-four (24) hour period, the Clerk will contact the Board member and confirm receipt. If a Board member believes the RFR should be considered by the RFR Committee, he or she will

respond to the Clerk's email within forty-eight (48) hours and will request further review. If no Board member requests further review of the RFR within the forty-eight (48) hour period, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, stating the Board will not hold a Final Review Conference. Contested case guidance will be included within the letter.

NOTE: If the time periods described above end on a weekend or State holiday, the time is automatically extended to 5:00 p.m. on the next business day.

9. If the RFR is to be considered by the RFR Committee, the Clerk will notify the Presiding Member of the RFR Committee and the Chairman that further review is requested by the Board. RFR Committee meetings are open to the public and will be public noticed at least 24 hours in advance.
10. Following RFR Committee or Board consideration of the RFR, if it is determined no Conference will be held, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, stating the Board will not hold a Conference. Contested case guidance will be included within the letter.

II. Final Review Conference Scheduling

1. If a Conference will be held, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, informing the Requestor of the determination.
2. The Clerk will request Department staff provide the Administrative Record.
3. The Clerk will send Notice of Final Review Conference to the parties at least ten (10) days before the Conference. The Conference will be publically noticed and should:
 - include the place, date and time of the Conference;
 - state the presentation times allowed in the Conference;
 - state evidence may be presented at the Conference;
 - if the conference will be held by committee, include a copy of the Chairman's order appointing the committee; and
 - inform the Requestor of his or her right to request a transcript of the proceedings of the Conference prepared at Requestor's expense.
4. If a party requests a transcript of the proceedings of the Conference and agrees to pay all related costs in writing, including costs for the transcript, the Clerk will schedule a court reporter for the Conference.

III. Final Review Conference and Decision

1. The order of presentation in the Conference will, subject to the presiding officer's discretion, be as follows:
 - Department staff will provide an overview of the staff decision and the applicable law to include [10 minutes]:
 - Type of decision (permit, enforcement, etc.) and description of the program.
 - Parties
 - Description of facility/site
 - Applicable statutes and regulations
 - Decision and materials relied upon in the administrative record to support the staff decision.
 - Requestor(s) will state the reasons for protesting the staff decision and may provide evidence to support amending, modifying, or rescinding the staff decision. [15 minutes] *NOTE: The burden of proof is on the Requestor(s)*
 - Rebuttal by Department staff [15 minutes]
 - Rebuttal by Requestor(s) [10 minutes]

Note: Times noted in brackets are for information only and are superseded by times stated in the Notice of Final Review Conference or by the presiding officer.
2. Parties may present evidence during the conference; however, the rules of evidence do not apply.
3. At any time during the conference, the officers conducting the Conference may request additional information and may question the Requestor, the staff, and anyone else providing information at the Conference.
4. The presiding officer, in his or her sole discretion, may allow additional time for presentations and may impose time limits on the Conference.
5. All Conferences are open to the public.
6. The officers may deliberate in closed session.
7. The officers may announce the decision at the conclusion of the Conference or it may be reserved for consideration.
8. The Clerk will mail the written final agency decision (FAD) to parties within 30 days after the Conference. The written decision must explain the basis for the decision and inform the parties of their right to request a contested case hearing before the Administrative Law Court or in matters pertaining to decisions under the South Carolina Mining Act, to request a hearing before the South Carolina Mining Council. The FAD will be sent by certified mail, return receipt requested.
9. Communications may also be sent by electronic mail, in addition to the forms stated herein, when electronic mail addresses are provided to the Clerk.

The above information is provided as a courtesy; parties are responsible for complying with all applicable legal requirements.

Exhibit B

To Request for Final Review



Catherine E. Heigel, Director

Promoting and protecting the health of the public and the environment

May 26, 2016

VIA CERTIFIED MAIL

Shannon Cantwell
 Regulatory Affairs Specialist
 Roper St. Francis Healthcare
 125 Doughty Street, Suite 760
 Charleston, SC 29403

Article #: 92148969009997901404889441

Re: Roper St. Francis Hospital - Berkeley Inc. d/b/a Roper St. Francis Hospital -
 Berkeley
 Addition of Cardiac Catheterization services to Roper St. Francis Hospital -
 Berkeley at a total project cost of \$2,873,366.
 Matter No.: 2340

Dear Ms. Cantwell:

This is to notify you the South Carolina Department of Health and Environmental Control ("Department") has determined the aforementioned project to be complete for purposes of review by the Certificate of Need Program. Enclosed is an invoice for the required application fee. It may be paid by check made payable to the S.C. Department of Health and Environmental Control or by electronic check through the Department's website (www.scdhec.gov) using the "Pay Invoices" hyperlink at the bottom of each webpage. This is a secure website. If payment is not received within fifteen (15) days of your receipt of this invoice, the pending application will be considered withdrawn and this matter closed. Should this deadline fall on a weekend or State holiday, it will be extended to the next calendar day that is neither weekend nor holiday pursuant to Regulation 61-15, Section 303.

Should the Department receive your application fee within the fifteen (15) day deadline, the Department will render a decision no earlier than thirty (30) days, but no later than one-hundred (120) days from the date notice is provided to affected persons in the State Register, unless a public hearing is held pursuant to Regulation 61-15, Section 305.

The Department has determined the relative importance of the project review criteria, pursuant to Regulation 61-15, Section 304, which will be used to review your application. The specific criteria to be used are set forth below and are ranked according to their relative importance, with the most important being listed first. All other relevant criteria will be given equal importance.

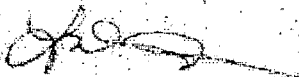
Letter to Shannon Cantwell
May 26, 2016
Page 2

- a. Compliance with the State Health Plan – 1;
- b. Community Need Documentation – 2;
- c. Distribution (Accessibility) – 3;
- d. Financial Feasibility – 15; and
- e. Cost Containment – 16.

The aforementioned criteria are set forth in Regulation 61-15, Section 802. Should you wish to submit any additional information to the Department in support of your application, you have thirty (30) days from the receipt of this correspondence to do so.

If you have any questions, please contact me at 803.545.3652.

Sincerely,



Louis Eubank
Director
Certificate of Need Program

Enclosures: Application Fee Invoice

Exhibit C

To Request for Final Review



Parker Poe

William R. Thomas
 Partner
 Telephone: 803.253.8658
 Direct Fax: 803.255.8017
 willthomas@parkerpoe.com

Atlanta, GA
 Charleston, SC
 Charlotte, NC
 Columbia, SC
 Greenville, SC
 Raleigh, NC
 Spartanburg, SC

June 24, 2016

VIA HAND DELIVERY AND EMAIL

Louis W. Eubank, MSW, MPH
 Director, Certificate of Need Program
 Bureau of Health Facilities and Services Development
 SC Department of Health and Environmental Control
 301 Gervais Street
 Columbia, South Carolina 29201

SCDHEC
 RECEIVED

JUN 24 2016

Certificate of Need Program

Re: Roper St. Francis Hospital – Berkeley Inc. d/b/a Roper St. Francis Hospital – Berkeley
 Certificate of Need Application for the addition of cardiac catheterization services to Roper St. Francis Hospital – Berkeley at a total project cost of \$2,873,366
 DHEC Matter No. 2340

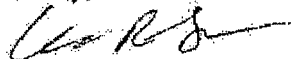
TRIDENT MEDICAL CENTER'S AFFECTED PERSON STATUS AND OPPOSITION

Louis
 Dear Mr. Eubank:

Pursuant to S.C. Code Ann. §§44-7-130(I) and 44-7-210(C) and Regulation 61-15 §§103(1) and 305, I am writing on behalf of Trident Medical Center, LLC, d/b/a Trident Medical Center ("Trident"), an existing provider of similar services located in Charleston, South Carolina, which is in the same health service area and geographic area to be served by the applicant, to notify the Department that Trident is an "affected person" with respect to Roper St. Francis Hospital – Berkeley's CON application referenced above, and that it opposes the approval of Roper St. Francis Hospital – Berkeley's CON application. Trident is also requesting that a project review meeting be held by the Department prior to the Department making a decision on this CON application. More specifically, Trident opposes the above referenced CON application because, among other reasons, the project does not comport with the purposes of the CON Act; the project does not comply with the standards set forth in the 2015 *South Carolina Health Plan*; the project is not needed; the project will have an adverse impact on Trident's cardiac catheterization program and its open heart program; the project does not increase accessibility to catheterization services; and the project will not contain costs.

Please copy Trident on any future correspondence to or from the Department concerning this CON application. Thank you for your consideration of Trident's position, and please let me know if you have any questions or concerns.

Sincerely,



William R. Thomas

WRT/ccq

PPAB 3281931v1

Exhibit D

To Request for Final Review

Sullivan Consulting Group, Inc.

2090 Bethany Way · Alpharetta, Georgia 30004 · (770) 753-4222 · Fax: (770) 753-4223

July 21, 2016

VIA E-MAIL

Louis Eubank, MSW, MPH
Director
Certificate of Need Program
Department of Health and Environmental Control
2600 Bull Street
Columbia, SC 29201

RE: CON Application 2340

Dear Mr. Eubank:

On behalf of Trident Medical Center ("Trident"), I am submitting this letter in opposition to the Certificate of Need ("CON") application filed by Roper St. Francis Hospital-Berkeley ("Roper-Berkeley") to develop a new diagnostic cardiac catheterization program at its approved but not yet constructed hospital to be located in Goose Creek, Berkeley County. The proposed program is scheduled to open in June 2019. The application also proposes to close the existing diagnostic cardiac catheterization program at Bon Secours St. Francis Hospital ("BSSFH"), which is of little consequence given that this program purposefully has only performed only a handful of diagnostic catheterization procedures over the past several years.

I. Summary of Trident's Objections to the Project

- The project does not represent a transfer of an existing diagnostic cardiac catheterization service but instead the initiation of a new service.
- Roper-Berkeley fails to satisfy the criteria in the 2015-2016 South Carolina Health Plan (Criterion 1).
- Roper-Berkeley fails to demonstrate a community need for the project (Criterion 3).
 - In particular, the application fails to define a reasonable service area for its diagnostic cardiac cath program at a new 50-bed hospital.
 - Moreover, the projections of utilization for the project are unreasonable for a number of reasons. Roper-Berkeley failed to consider the declining trend in diagnostic cardiac cath procedures in the service area. Its projections also assume unrealistic market shares from distant areas that would require patients to bypass existing comprehensive cardiac cath providers.

CON.0248

Mr. Louis Eubank

July 21, 2016

Page 2

- o The historical utilization of the BSSFH diagnostic cath program demonstrates that patients and physicians prefer to utilize the comprehensive cardiac cath program at Roper Hospital rather than a diagnostic only program such as the one proposed for Roper-Berkeley.
- The project fails to demonstrate financial feasibility in light of these unrealistic utilization projections (Criterion 15).
- The project will not contribute to cost containment because it is unneeded, will likely be underutilized, and depends on patients traveling long distances to reach a start-up program at a small community hospital (Criterion 16).

The Project is not a Transfer of an Existing Service.

While the BSSFH diagnostic cath program will close upon approval of this CON application, there is no attempt in the Roper-Berkeley application to characterize this project as a "transfer" of the diagnostic cardiac cath service from BSSFH nor would the project, as explained more fully below, qualify as a transfer.

Compliance with the South Carolina Health Plan

Given the Roper-Berkeley application is proposing a new diagnostic cardiac cath service, the relevant standards for review are those for Cardiac Catheterization Services and specifically the criteria relating to Diagnostic Cardiac Catheterization. Roper-Berkeley does not address the Exception to Service Area Standards, which are considered when an applicant seeks to transfer beds or services between two related facilities. Given that these Exceptions are not addressed by the applicant, there is no basis to approve the project under these criteria. In an abundance of caution, however, this letter will address the reasons why the Roper Berkeley project fails to satisfy these Exceptions as well.

Cardiac Catheterization Standards

The Roper-Berkeley application unsuccessfully attempts to demonstrate conformity with the State Health Plan standards for new diagnostic cardiac cath services. Certain of these criteria are discussed below.

Mr. Louis Eubank

July 21, 2016

Page 3

2. *The service area for a diagnostic catheterization laboratory is defined as all facilities within 45 minutes' one way automobile travel time; for comprehensive cardiac catheterization laboratories the service area is all facilities within 60 minutes' one way automobile travel time; a pediatric cardiac program should serve a population encompassing at least 30,000 births per year, or roughly two million people.*

Roper-Berkeley does not utilize a 45-minute one-way automobile travel time to define its service area. Instead, as shown in Exhibit 1, it defines its service area to include a wide ranging region across four counties.

Exhibit 1

Roper St. Francis Hospital-Berkeley Proposed Diagnostic Cardiac Catheterization Service Area

Primary Service Area

Berkeley County - All ZIP Codes

Dorchester County- 29420, 29472, 29483, 29485, 29456

Charleston County - 29406, 29410, 29418, 29420, 29456

Secondary Service Area

Remainder of Charleston County

Remainder of Dorchester County

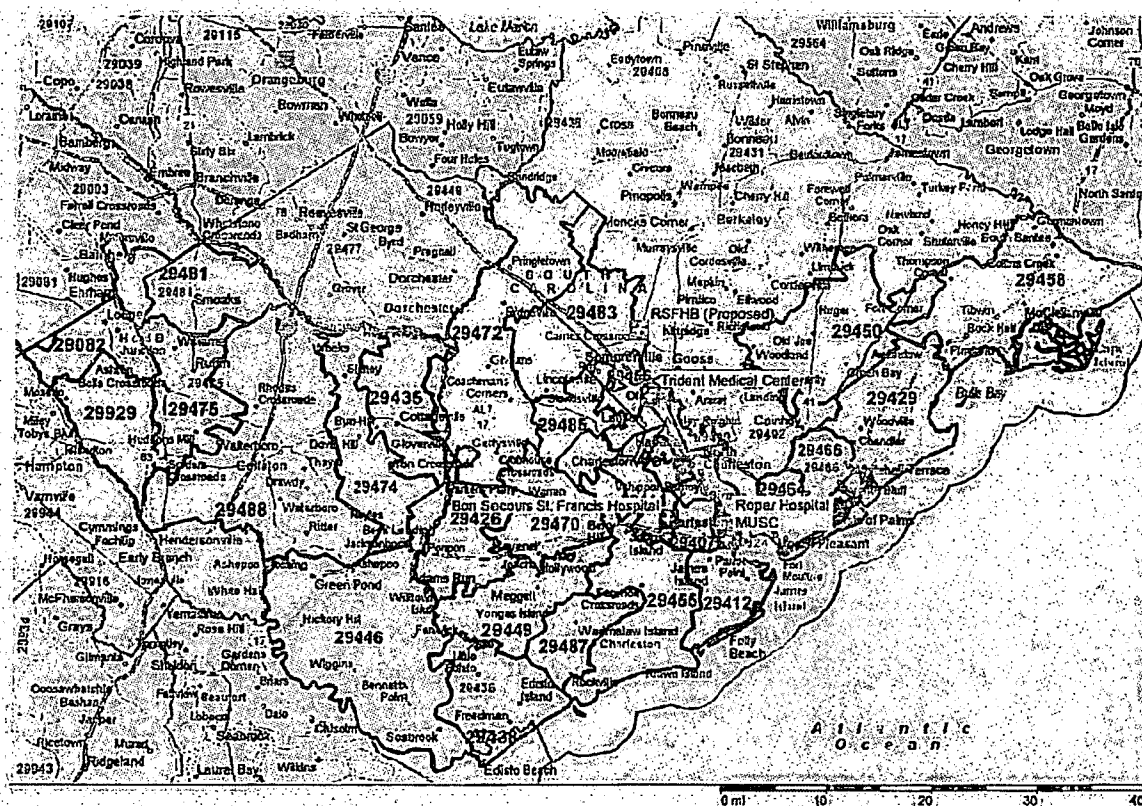
Colleton County

Source: Roper-Berkeley Application, Exhibit 2

A map of this service area is presented in Exhibit 2 and demonstrates the breadth of the service area.

Exhibit 2

Roper St. Francis Hospital-Berkeley Proposed Diagnostic Cardiac Cath Service Area



Many portions of Charleston and Colleton Counties are outside of a 45-minute one-way automobile travel time from the Roper-Berkeley site. More importantly, it is unlikely that a start-up diagnostic cardiac cath program at a 50-bed hospital would attract patients from such a large area for a number of reasons. The most important reason is that historically referring physicians in the Roper St. Francis system area have referred virtually all of their patients to the comprehensive cardiac cath program at Roper Hospital rather than the diagnostic-only program at BSSFH. In 2015 BSSFH performed only 2 diagnostic caths, which is consistent with its experience over the past several years.

BSSFH, with 204 inpatient beds, is a substantially larger and more established hospital than Roper-Berkeley, and there is no reason to expect that physicians affiliated with Roper St. Francis will change these historical referral patterns to utilize a 50-bed hospital with substantially fewer resources than BSSFH. There are valid clinical reasons for choosing a comprehensive cardiac cath program over a diagnostic-only program. Patients who are high risk are more appropriately served in a program with open heart surgery back-up. If a physician believes that there is a strong likelihood that a patient will require percutaneous coronary intervention ("PCI"), it is

Mr. Louis Eubank

July 21, 2016

Page 5

more appropriate to refer the patient to a comprehensive center where both the diagnostic cath and the PCI could be performed in a single cath lab session.

Another factor undermining the credibility of the Roper-Berkeley service area definition is the fact that many patients would have to drive past one or more existing cardiac cath programs to reach Roper-Berkeley. For example, Trident is located only 7 miles from Roper-Berkeley and is more proximate to areas south and west of Roper-Berkeley. These existing providers, with the exception of BSSFH, offer comprehensive ranges of cardiac interventions, which makes it highly unlikely that any material number of patients not residing in close proximity to Roper-Berkeley will seek cardiac cath services at the 50-bed facility.

An additional argument presented in the application is that Roper Hospital is well utilized and it could "off-load" some of its existing diagnostic cath volume to Roper-Berkeley to reduce current utilization levels. There is simply no evidence that patients and physicians will choose to go to Roper-Berkeley rather than utilize the comprehensive services at Roper Hospital, particularly if the patients do not live in areas near Roper-Berkeley. In fact, if this were the case, BSSFH would be a thriving program; however, it appears to be the most underutilized program in state.

The expansive Roper-Berkeley service area appears to have been cobbled together in an effort to bolster the utilization projections for the proposed program, as discussed in more detail below. The service area is not reasonable, and the projections that result from the use of this service area are unreliable.

Diagnostic and Mobile Catheterization Services

3. *New diagnostic catheterization services, including mobile services, shall be approved only if all existing labs in the service area have performed a minimum of 500 diagnostic catheterization procedures per laboratory during the most recent year;*

All existing labs in the service area have not performed a minimum of 500 diagnostic catheterization procedures per laboratory in 2015. Roper-Berkeley misinterpreted this criterion in its application response by addressing the number of diagnostic cardiac catheterization equivalents per laboratory, which is inconsistent with the plain language of this criterion. Exhibit 3 displays 2015 cardiac cath utilization data for all providers in the service area. Only one provider, Trident, exceeded the standard of 500 diagnostic catheterizations per laboratory. Roper hospital averaged only 398 diagnostic catheterizations per laboratory.

Mr. Louis Eubank

July 21, 2016

Page 6

Exhibit 3
Roper St. Francis Hospital-Berkeley Service Area
2015 Diagnostic Catheterizations per Laboratory

Facility	Cath Labs	Diagnostic Caths	Diagnostic Caths Per Lab
MUSC*	6	1,804	301
Roper Hospital	3	1,193	398
Bon Secours St. Francis	1	4	4
Trident Medical Center	2	1,081	541
Total	12	4,082	340

*Includes adult and pediatric procedures

Source: Joint Annual Reports of Hospitals

Based on the most recent utilization data, the Roper-Berkeley project fails to satisfy this criterion.

4. *An applicant for a fixed diagnostic service must project that the proposed service will perform a minimum of 500 diagnostic equivalent procedures annually within three years of initiation of services, without reducing the utilization of the existing diagnostic catheterization services in the service area below 500 diagnostic cardiac catheterization procedures per laboratory.*

Exhibit 4 on the following page recreates the utilization projections presented in the application. The problems with Roper-Berkeley's utilization projections begin with the unreasonable service area discussed above. Even putting aside the reasonableness of the service area, there are several other serious flaws with the projections presented.

The first assumption is that Roper-Berkeley will only serve patients who otherwise would have utilized diagnostic cath services at Roper Hospital. There is no basis to support this assumption. There is no reason to expect that patients would in many cases travel farther to receive a diagnostic cath at a small hospital with a limited range of services. Given the proximity of Roper-Berkeley to Trident and the fact that Trident is a major provider of diagnostic and therapeutic cath services to residents of Roper-Berkeley's primary service area, the more likely scenario is that Roper will redirect patients within its primary service area from Trident. No consideration was given by Roper-Berkeley to the shift in market shares that is probable when developing a program in a new location.

Exhibit 4

Roper St. Francis Hospital-Berkeley Projected Diagnostic Cardiac Cath Utilization

	2015 Diagnostic Caths at RSF Labs	CAGR for Population	Diagnostic Caths			% Shifted to Roper Berkeley			for Roper Berkeley		
			2019	2020	2021	2019	2020	2021	2019	2020	2021
Primary Service Area											
Berkeley County - All ZIPs	292	1.30%	307	311	316	45%	60%	80%	138	187	252
Dorchester County											
29420	27	1.83%	29	30	30	45%	55%	65%	13	16	20
29472	5	5.50%	6	7	7	45%	55%	65%	3	4	4
29483	62	1.81%	67	68	69	45%	55%	65%	30	37	45
29485	42	1.60%	45	45	46	45%	55%	65%	20	25	30
29456*	-	2.00%	-	-	-	45%	55%	65%	-	-	-
Charleston County											
29406	46	1.67%	49	50	51	30%	40%	50%	15	20	25
29410	-	1.11%	-	-	-	30%	40%	50%	-	-	-
29418	60	1.74%	64	65	67	30%	40%	50%	19	26	33
29420	-	1.83%	-	-	-	30%	40%	50%	-	-	-
29456*	-	2.00%	-	-	-	30%	40%	50%	-	-	-
Total PSA	534		568	576	585				238	315	410
Secondary Service Area											
Remainder of Charleston County	782	0.56%	800	804	809	2.5%	5.0%	7.5%	20	40	61
Remainder of Dorchester County	13	1.95%	14	14	15	5.0%	8.0%	10.0%	1	1	1
Colleton County	118	0.10%	118	119	119	5.0%	8.0%	10.0%	6	9	12
Total Secondary Service Area	913		932	937	942				27	51	74
In-Migration	121	7.89%				6.0%	6.0%	6.0%	17	23	31
Total Cath Patients	1,568		1,500	1,513	1,527				282	389	515
Actual In-migration											
		7.72%									

Source: Roper-Berkeley Application, Exhibit 13

J01-254

CON 0254

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Another fundamental assumption in the projections is that Roper Hospital's historical diagnostic cardiac catheterization volume will grow in the future at the rate of population growth. That assumption is inconsistent with Roper Hospital's recent historical experience as well as the experience of all service area providers. Exhibit 5 presents the trend in diagnostic cardiac cath volume at all service area providers.

- Roper Hospital has seen its diagnostic cath procedures decline from 1,776 in 2011 to 1,193 in 2015¹, a drop of 32.8 percent despite population growth in the Charleston area.
- The total diagnostic cath procedures performed by service area providers decreased from 5,103 in 2011 to 4,082 in 2015, a 20.0 percent reduction.

There is no reason to expect that there will be any growth in diagnostic caths over the next five years as Roper-Berkeley has projected. If Roper Hospital's 2015 diagnostic cath volumes were held constant, the projected utilization for Roper-Berkeley would have been 475 diagnostic caths in 2021, although this even figure is significantly overstated as discussed below.

Exhibit 5
Roper St. Francis Hospital-Berkeley Service Area
Trend in Diagnostic Catheterizations: 2011 to 2015

	2011	2012	2013	2014	2015	% Change 2011-15
Roper Hospital	1,776	1,785	1,651	1,578	1,193	-32.8%
Bon Secours St. Francis	7	9	3	4	4	-42.9%
MUSC*	1,994	1,996	1,954	1,982	1,804	-9.5%
Trident Medical Center	1,326	1,332	995	1,007	1,081	-18.5%
Total	5,103	5,122	4,603	4,571	4,082	-20.0%

*Includes adult and pediatric patients.

Source: Joint Annual Reports of Hospitals

¹ In the Roper-Berkeley application reports 1,568 diagnostic catheterizations performed by Roper Hospital, which is significantly higher than 1,193 reported on its 2015 JAR.

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The percentage of Roper Hospital's patients to be shifted to Roper-Berkeley is similarly unreasonable. As shown in Exhibit 4, 80 percent of Berkeley County cases, 65 percent of Dorchester County primary service area patients, and 50 percent of Charleston County primary service area patients are expected to be redirected from Roper Hospital to Roper-Berkeley. Such dramatic shifts in volume from a comprehensive program to a diagnostic-only program are not reasonable, particularly in light of Roper's experience of operating a diagnostic-only program at BSSFH. In the secondary service area, it is unlikely that there will be any material redirection of diagnostic caths from Roper Hospital to Roper-Berkeley given the distances these patients would have to travel and the more limited nature of the Roper-Berkeley services.

Given that virtually all of the patients will be drawn from Roper-Berkeley primary service area, Roper-Berkeley will not reach 500 diagnostic cath procedures annually, as its own projections indicate. Even with the unrealistically high assumed redirection of patients from Roper hospital to Roper-Berkeley, the primary service area is expected to provide only 405 diagnostic cath procedures in 2021. Under more realistic assumptions, the projected utilization would be far less. The likelihood is that Roper-Berkeley will operate a low volume diagnostic cath program, just as BSSFH has done for many years.

Exceptions to Service Area Standards

As discussed previously, Roper-Berkeley did not address the Exceptions to Service Area Standards, apparently recognizing that the closure of a program at BSSFH that has been effectively unutilized for many years and opening a new program nearly three years later in a new hospital did not constitute a transfer of the program. Even if the project were reviewed under these Exceptions, the project fails to satisfy the requirements for a transfer of a service.

1. *A transfer or exchange of service may be approved only if there is no overall increase in the number or amount of such services.*

Roper-Berkeley does not satisfy this criterion because there is an overall increase in the number of diagnostic cath services in the service area. There currently is no legitimate cath lab program at BSSFH, nor has there been since 2007, when Roper St. Francis made the decision to discontinue services at the lab. See Exhibit 6.

Exhibit 6 Bon Secours St. Francis Hospital Trend in Diagnostic Catheterizations

Year	2007	2008	2009	2010	2011	2012	2013	2014	2015	Total	Ave/Yr
Diagnostic Caths	0	0	0	2	7	9	3	4	2	27	3

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As the chart details, BSSFH has average only 3 diagnostic caths a year since 2007, and zero caths each year from 2007 to 2009. Roper-Berkeley is applying to open a new diagnostic cath service at its Goose Creek campus three years from now, while Roper St. Francis is maintaining a fictional program at BSSFH to foreclose any new applicants for diagnostic catheterization services in the tri-county region. New applicants cannot apply unless "all existing labs in the service area have performed a minimum of 500 diagnostic catheterization procedures per laboratory during the most recent year." 2015 State Health Plan, p. VIII-5. The Department should not recognize BSSFH's diagnostic catheterization program as an existing service merely because only (3) three diagnostic caths are performed on average each year, which is not indicative of an actual program.

3. *The facility receiving the service must demonstrate the need for the additional capacity based on both historical and projected utilization patterns.*

Roper-Berkeley fails to satisfy this criterion. There is simply no need for additional capacity in either the Roper St. Francis system or in the service area generally. As discussed above, the BSSFH diagnostic cath program has performed a *de minimus* number of procedures each year. If Roper needed additional capacity, it could have redirected patients to BSSFH. Given that Roper's diagnostic cardiac cath volume has declined by nearly 33 percent and the service area by 20 percent, there is no basis to conclude that a new cardiac cath laboratory is needed based on historical utilization patterns. A reasonable projection of future utilization would indicate that service area diagnostic cath procedures will not increase materially.

4. *The applicants must explain the impact of transferring the technology on the health care delivery system of the county and/or service area from which it is to be taken; any negative impact must be detailed, along with the perceived benefits of the proposal.*

Roper-Berkeley never addressed the impact of its proposed opening of a new diagnostic cath program in Berkeley County other to make the unreasonable and undocumented assumption that all of the patients served by Roper-Berkeley would otherwise have gone to Roper Hospital. As discussed above, the more likely scenario is that Roper-Berkeley would seek to capture the patients Trident is currently serving given Roper-Berkeley's proximity to Trident and its position in the middle of Trident's primary service area. This adverse impact on Trident should not be permitted for a project that is unneeded and will likely be underutilized.

For all of the foregoing reasons, the Roper-Berkeley project is not consistent with the either Cardiac Catheterization Standards or the Exceptions to Service Area Standards in the State Health Plan.

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Community Need

The Roper-Berkeley proposal to develop a diagnostic cath program meets no community need. As discussed in the preceding section, Roper St. Francis has available cardiac cath lab capacity within its own system given the miniscule volumes served by BSSFH in recent years. In addition, Roper Hospital's volumes have been declining as have the volumes of other providers in the Roper-Berkeley service area.

There is no demonstration that patients in Berkeley County or any other portion of Roper-Berkeley's service area require enhanced access to diagnostic cardiac cath services. Roper-Berkeley is located only 7 miles from Trident, which offers comprehensive cardiac care. Trident has and will continue to serve patients in need of diagnostic cath services in the Roper-Berkeley primary service area.

Roper-Berkeley has not defined a reasonable service area for its project. If patients were to indeed travel from distant parts of Charleston and Colleton Counties to Roper-Berkeley, they would have to pass by other providers who offer more comprehensive care. A more reasonably defined service area would not support the approval of another diagnostic cath provider.

The proposed closure of BSSFH's existing diagnostic-only program, contingent on the approval of the Roper-Berkeley proposal, has no relevance from a health planning standpoint. The BSSFH program has been serving so few patients that Roper St. Francis should have closed it many years ago. BSSFH's inability to attract diagnostic cath patients from the comprehensive program at Roper Hospital is also a strong indicator that the Roper-Berkeley program will similarly experience poor utilization.

Financial Feasibility

The financial projections for the project are presented in Attachment 6 of the application. These projections are based on the projected volumes, which as discussed above, are wholly unreasonable. More reasonable projections would result in dramatically lower volumes for the Roper-Berkeley program, and it is unlikely to generate an excess of revenues over expenses. Financial feasibility is not demonstrated.

Cost Containment

This project will not promote cost containment. It requires a capital expenditure of \$2,873,366 for a program that is not needed and will be underutilized. To achieve its projected utilization, patients will be required to travel long distances to reach a start-up program in a small community hospital.

Mr. Louis Eubank

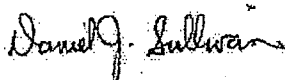
July 21, 2016
Page 12

Moreover, the proposed program will increase costs and time for the patients who otherwise would have received diagnostic cath services at Roper Hospital but will be redirected to Roper-Berkeley. Currently, when a patient presents to Roper Hospital for a diagnostic cath and it is determined that PCI is required, the PCI can be performed during the same cath lab session. Patients seen at Roper-Berkeley who are determined to need PCI will have to travel to Roper Hospital by ambulance or a present to Roper Hospital at a later scheduled appointment. A second cath procedure must be performed and a second catheter inserted into the patient, which increases the cost as well as the physical discomfort to the patient.

The diagnostic cath program at Roper-Berkeley will unnecessarily duplicate existing services. Trident is located squarely within Roper-Berkeley's primary service area, offers a more comprehensive range of cardiac services, and has ample available capacity to serve additional cardiac cath patients in the future.

We appreciate the opportunity to submit this comments and will be happy to provide any additional information you require.

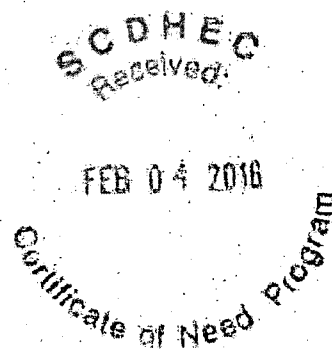
Sincerely,



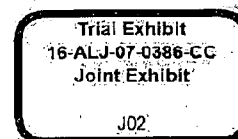
Daniel J. Sullivan



**Certificate of Need Application for
Diagnostic Catheterization Services**



February 2016



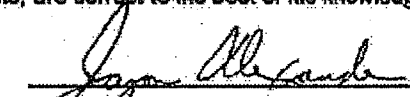
East Cooper CON 0001

APPLICATION FOR CERTIFICATION OF NEED
FOR A HEALTH FACILITY OR SERVICE

Proposal Prepared By:

Name: Jason Alexander
Title: Chief Executive Officer
Organization: East Cooper Medical Center
Address: 2000 Hospital Drive
City: Mount Pleasant State: SC
Zip Code: 29484 Telephone Number: (843) 418-6212

The Applicant hereby certifies that the information contained in this Application, including all assurances and attachments, are correct to the best of his knowledge and belief.

Signature: Date: January 29, 2016

Please copy all correspondence related to this application to:

David S. Levitt
Levitt Healthcare Affiliates
9 River Place
Beaufort, SC 29908
843-379-9372

Forward to:
Bureau of Health Facilities and Services Development
S.C. Department of Health and Environmental Control
2600 Bull Street, Columbia, SC 29201

Certificate of Need Application

East Cooper Medical Center
Diagnostic Catheterization Services

East Cooper CON 0002

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- A. Published Notification of Project
- B. Letter Regarding Equipment Capabilities
Equipment Quotes
Facility Site Plan and First Floor
- C. Board of Trustees
Organizational Charts
Articles of Incorporation
Bylaws
- D. Cardiac Patient Transfer Agreement
- E. Charity Care Policies
Patient Rights and Responsibilities
Tenet Compact with Uninsured Patients
- F. Letters of Support
- G. Population and Patient Data
- H. *Heart Disease and Stroke Statistics – 2015 Update* (American Heart Association)
The Burden of Heart Disease and Stroke in South Carolina, 2010 Edition (South Carolina DHEC)
Coordinated Chronic Disease Fact Sheet for Charleston County (South Carolina DHEC)
- I. MUSC Collaborating Cardiologists
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APPLICATION FOR CERTIFICATION OF NEED FOR A HEALTH FACILITY OR SERVICE

NOTE: A "complete" application shall include a written narrative report by the applicant (Regulation 61-15, Section 202).

PART A - QUESTIONNAIRE (Page 1)	
1. Name of Facility: East Cooper Community Hospital, Inc. d/b/a East Cooper Medical Center	
2. Address, City, County, State, ZIP Code: 2000 Hospital Drive Mount Pleasant, South Carolina Charleston County 29464	
3. Type of Facility (Circle) ☒ A. Hospital B. Nursing Home C. Psychiatric Facility D. Rehabilitation Facility E. Substance Abuse Facility F. Ambulatory Surgery Center G. Other (Specify):	
4. Purpose of Review (Circle) A. New Facility B. Change of Licensure C. Addition to Existing Facility D. Renovation of Existing Facility ☒ E. Change of Services Addition of Diagnostic Catheterization Services F. Other	
5. Management A. Name of Administrator: Jason Alexander B. Address, City, State, ZIP Code: 2000 Hospital Drive Mount Pleasant, South Carolina 29464 C. Telephone: (843) 416-6210 D. Name of Licensee: East Cooper Community Hospital, Inc. d/b/a East Cooper Medical Center	
6. Ownership or control of the facility (attach a list of names and address of the owners of the facility, indicating percent of ownership of each owner, the person responsible for the proposal and the attorney(s) representing the proposal). Circle the appropriate information regarding ownership. A. Individual B. Partnership ☒ C. Corporation* ☒ D. Proprietary* E. Non-Profit F. Government - State G. Other (Specify)	
*The 100 percent owner of the East Cooper Regional Medical Center facility is East Cooper Community Hospital, Inc., a South Carolina corporation. The address is 2000 Hospital Drive, Mt. Pleasant, South Carolina 29464. Refer to question B.8 herein for additional information.	

PART A - QUESTIONNAIRE (Page 2)

7. Is the Proposed Site of the Property?

A. Owned B. Leased C. Length of Site Lease

D. Option E. Length of Option

F. Name and Address of Owner(s) of Real Property:

East Cooper Medical Center
 2000 Hospital Drive
 Mount Pleasant, South Carolina 29464

Total Bed Capacity for Which Application is Made: **Not applicable. The proposed project does not involve a change in bed capacity.**

Type of Beds	New Facility Only	Existing Facilities		
		Existing Beds	# Gained or Lost	Bed Total
A. Medical/Surgical				
B. Obstetrics				
C. NICU Bassinets				
D. Substance Abuse				
E. Psychiatric				
F. Rehabilitation				
G. Nursing Care				
H. RTC's				
I. ICU/CCU				
J. Observation				
K. Total				

Part A - Questionnaire (Page 3)	
9. Construction and Site:	
A. Type of Construction: N/A	B. Number of Buildings: One
	C. Number of Stories: One
D. Size of the Site in Acres: Hospital campus is approximately 55 acres	E. Square Footage of Facility: Diagnostic Catheterization Laboratory - 560 square feet
F. Anticipated Date of Beginning Construction: N/A	G. Anticipated Date of Licensing or Project Completion: Implemented as soon as possible after Certificate of Need approval (anticipated August 2016)
10. Zoning of Construction Site: Not applicable.	
11. Costs (Provide Estimated Cost Statement from Either the Architect or Engineer)	
A. Land Value: Not applicable	B. Construction Cost: N/A
C. Professional Fees: \$40,000	D. Equipment Costs Equipment \$ 313,309 Taxes and Freight \$ 26,631 Subtotal, Equipment \$ 339,940
E. Financing Cost During Construction: Not applicable	
F. Other Costs: Contingency \$62,672	G. Total Project Cost: \$442,612
H. Construction and Equipment Cost 1) Per Square Foot: Construction & Equipment: \$607; Construction Only: N/A 2) Per Bed: N/A	

PART B: ADDITIONAL INFORMATION

- (1) Document that the applicant has published notification of this project in a local newspaper as required by Section 201 of these Regulations.

Response: The published notification of the intent to file this CON is provided as **Attachment A**.

- (2) Describe the project setting forth the proposed change in services or facilities in as much detail as possible. State whether the project will change the existing licensed or survey bed capacity, will encompass the development of a new service, or result in the discontinuance of an existing service. If a new facility is proposed, list all services to be provided.

Response:

Introduction

East Cooper Medical Center ("ECMC") is one of South Carolina's leading hospitals. ECMC, part of Tenet Healthcare, aims to put the patient first, and everything is designed to provide the patient with more successful procedures, faster recovery times and a better quality of life. The hospital combines expertise with compassionate and detail-oriented care; ECMC has found the perfect blend so that patients leave the hospital in better health and with smiles on their faces.

In 1985, several physicians practicing east of the Cooper River recognized the difficulty their patients and neighbors experienced accessing hospital care. The bridges were unstable and the travel time to reach a hospital was greater than an hour. Foreseeing major population growth in the area, these doctors proposed the idea to build a full-service medical facility with the primary mission to care for those residents who could not make it into downtown Charleston. The idea was shared with Mayor Johnnie Dodds II, and in January 1986 the first hospital east of the Cooper River opened. The original ECMC was a 100-bed hospital with 4 operating rooms and an Emergency Department. Since then, ECMC has expanded to 130 acute care beds, and in 2010 moved into a new and larger facility to meet the needs of the growing community.

The South Carolina floods were a poignant reminder of the need to have advanced community-based services deployed into population centers. ECMC was originally established for situations such as this. The leadership of ECMC is committed to expanding its service offering to ensure that residents east of the Cooper River have access to the necessary medical services, regardless of the situation. Establishing an expanded network of community based resources will enhance the state's readiness and mitigate the risk of natural disasters for the residents of South Carolina.

Although ECMC was originally established for the residents East of the Cooper, the hospital's expanded scope of services, commitment to quality and safety, and outstanding team of caregivers has attracted patients from throughout the Lowcountry and beyond. Care is provided in a new, state-of-the-art facility that is rich in technology, 24-hour emergency care, women's services, diagnostic imaging and interventional services, orthopedics, sports medicine, adult and pediatric rehabilitation services, wound care and surgical care, including nationally recognized spine surgery and breast reconstruction surgery are all offered. Services include but are not limited to:

Comprehensive Orthopedic Services

- Comprehensive Joint Program
- Total & Partial Knee & Hip Surgery
- MAKOplasty Partial Joint Surgery
- Sports Medicine Specialists
- Treatment of Shoulder & Elbow Injuries
- Minimally Invasive Spine Surgery

Emergency Care

- 24-hour Full-service Care
- Advanced Primary Stroke Center
- Level III Trauma Center
- Board-certified Emergency Physicians
- Helicopter Landing Pad
- Online check-in: "ER Express"

Maternity Care

- Level II Neonatal Nursery
- Childbirth Classes
- Breastfeeding Support Groups
- Certified Lactation Specialists

Women's Services

- Comprehensive Breast Care
- Gynecological Services
- Fertility Specialists

Rehabilitation Services

- Inpatient Services
- Adult & Pediatric Outpatient Centers
- Physical Therapy
- Occupational Therapy
- Speech Therapy

Surgical Care

- Breast Reconstructive Surgery
- Minimally Invasive Colorectal Surgery
- 10 Operating Rooms
- Live Data System

Specialty Services

- Advanced Diabetes Care and Education
- Comprehensive Wound Care Center
- Sleep Disorder Center
- Laboratory/Pathology Services
- Charleston Breast Center
- Charleston Imaging Center

East Cooper Medical Center strives for excellence and is committed to delivering high-quality care. The facility has received numerous awards and accolades over the years recognizing the state of the art care provided to the community. Most notably, ECMC was awarded nine Gold Seals of Approval from one of the nation's most respected health care organizations, the Joint Commission. This is more Gold Seals than any other South Carolina hospital, and is an example of the hospital's unwavering commitment to quality. These awards include disease-specific care for:

Laminectomy

Heart Failure

Pneumonia

Advanced Primary Stroke Center

Advanced Inpatient Diabetes

Minimally-Invasive Colorectal

Joint Replacement-Hip

Joint Replacement-Knee

Perinatal Care

Other awards and distinctions include:

- American Heart Association's "Get with the Guidelines Stroke Gold Plus Achievement Award"
- American Heart Association's "Get with the Guidelines Heart Failure Gold Plus Achievement Award"
- Five-Star Patient Satisfaction for 10 consecutive years
- Tenet Healthcare's Circle of Excellence Award

Project Overview

As mentioned, the South Carolina floods were a poignant reminder of the need to have advanced community-based services deployed into population centers. ECMC was originally established for situations such as this. The leadership of ECMC is committed to expanding its service offering to ensure that residents east of the Cooper River have access to the necessary medical services, regardless of the situation. Establishing an expanded network of community based resources will enhance the state's readiness and mitigate the risk of natural disasters for the residents of South Carolina.

With this in mind and in order to better serve its patients, ECMC proposes the addition of diagnostic cardiac catheterization services. Mount Pleasant is the fourth largest municipality in South Carolina, but does not have any cardiac catheterization laboratories. By providing diagnostic cardiac catheterization services at ECMC, the hospital will be able to provide state-of-the-art cardiology resources closer to its service area patients. Patients and their families will benefit from the increased convenience of seeking care at a location closer to home. Through the project, patients will be able to receive treatment at a more convenient location while staying at a hospital they have come to know and trust. Additionally, ECMC is developing the proposed project with support from the Medical University of South Carolina ("MUSC")

Division of Cardiology, and patients will benefit from the experience of an academic medical center known for its comprehensive cardiology services.

ECMC strives to keep pace with evolving medicine and the needs of its service area residents. It is ECMC's intention to increase access to diagnostic cardiac catheterization services to the service area and with the proposed project, ECMC will be able to successfully achieve this goal.

- (3) Provide the total cost of the project, indicating design fees, land cost, interest cost, construction cost, equipment cost, and any other cost involved in the project. Provide an estimate of the construction cost from a licensed architect or engineer; in the case of equipment, an estimate from a vendor is acceptable.

Response: The total project cost of \$442,612 is composed of the following elements:

**Figure 1
East Cooper Medical Center
Project Costs**

Equipment	
Equipment	\$ 313,309
Taxes and Freight	\$ 26,631
<u>Subtotal, Equipment</u>	<u>\$ 339,940</u>
Professional Fees	\$ 40,000
Contingency	\$ 62,672
<u>Total</u>	<u>\$ 442,612</u>

No construction or renovation is required for the proposed project. Equipment quotes related to the project are included in **Attachment B**.

- (4) State the specific location of the facility or service and/or equipment, including, where applicable, specific areas of an existing facility to be affected by the project. Provide room numbers of all patient rooms affected. Sufficient detail should be provided to allow the Department to visually inspect the site. The number of private and semi-private patient rooms shall be identified.

Response: East Cooper Medical Center is located at 2000 Hospital Drive in Mount Pleasant, South Carolina. The existing interventional radiology laboratory, which is 560 square feet, will be used for the proposed project, serving as both a diagnostic catheterization and interventional radiology laboratory. After some minor equipment related modifications, the existing interventional radiology equipment will have capabilities related to both diagnostic catheterization and interventional radiology (**Attachment B**).

No beds or patient rooms will be affected as a result of the proposed project. The site plan and schematic documents are included in **Attachment B**.

- (5) Provide details regarding any proposed construction and/or renovations. Discuss alternatives to new construction and why these alternatives were rejected. For a multi-floor project, construction and/or renovation must be described, by floor, to include any additions and/or deletions made to each floor. Provide evidence that the applicant has adequately planned for any temporary move or relocation of any department, facility, or services, which may be necessary during the construction period. Document that plans exist to assure adequate protection (from fire, noise, dust, etc.) and continuation of all services during the proposed construction period.

Response: The existing interventional radiology laboratory, which is 560 square feet, will be used for the proposed project, serving as both a diagnostic catheterization and interventional radiology laboratory. As such, no construction or renovations are necessary for the proposed project. After some minor equipment related modifications, the existing interventional radiology equipment will have capabilities related to both diagnostic catheterization and interventional radiology (**Attachment B**). All services, including interventional radiology services, will continue during the implementation of the proposed project.

No beds or patient rooms will be affected as a result of the proposed project. The site plan and schematic documents are included in **Attachment B**.

- (6) If a replacement facility or ancillary service is being constructed, describe plans for disposition of the existing facility or ancillary service area upon completion of the project.

Response: The proposed project does not involve replacement of any existing facility or service.

- (7) Provide a timetable for development and completion of the project to include, at a minimum, the date of site acquisition, date of architectural contract, architectural design schedule, date of closing for financing, date of valid construction contract, date that all necessary permits (grading, building, sewer, etc.) will be obtained, and date of start of construction. The timetable shall be presented in one-month increments commencing with the month following receipt of the Certificate of Need and ending with the execution of a contract or purchase order for equipment only projects.

Response: The proposed project will be will be implemented as soon as possible after approval of this Certificate of Need application (anticipated August 2016).

(8) Provide the following ownership information:**(a) Proposed name of facility**

Response: East Cooper Community Hospital, Inc. d/b/a East Cooper Medical Center

(b) Name and address of licensee or prospective licensee. (Note: The licensee is defined as the legal entity who, or whose governing body, has the ultimate responsibility and authority for the conduct of the facility or service; the owner of the business. The licensee must be the entity to whom the Certificate of Need is issued.)

Response: East Cooper Medical Center
2000 Hospital Drive
Mount Pleasant, South Carolina 29464

(c) Complete title of the licensee's governing body.

Response: Board of Directors

(d) Name, title and mailing address of presiding officer of the governing body.

Response: The presiding officer of the governing body is Mr. Danny Mullis. His address is:

2000 Hospital Drive
Mount Pleasant, South Carolina 29464

Please refer to **Attachment C** for the full membership list of the governing body.

(e) Name and mailing address of all persons and/or legal entities having any ownership interest or owner's equity of the licensee to include a schedule of percent and type ownership claim of each.

Response: East Cooper Medical Center is 100 percent owned by Tenet Health. The mailing address for Tenet Health is: P.O. Box 809088, Dallas, Texas 75380.

(f) Name and mailing address of all persons and/or legal entities claiming an ownership interest of the licensee or of the facility or service for which this Certificate of Need is requested to include a schedule of percent and type of claim of each.

Response: See response to (e) above.

(g) Provide a listing which identifies all officers of the licensee.

Response: Please refer to **Attachment C** for the full membership list of the governing body.

(h) Is the land and/or building on/in which the proposed facility or service is to be conducted owned by the applicant. ☒ YES ☐ NO If no, provide information on the land and building similar to that required in (b) through (g) above.**(i) Has the licensee engaged an entity other than an employee of the licensee to manage or operate the facility or service? ☐ YES ☒ NO If yes, provide information similar to that required in (b) through (g) above.**

- (j) Is there any agreement, contract, option, understanding, intent or other arrangement that will effect a change in any of the information requested and/or provided in (b) through (g) above. ☐ YES ☒ NO If yes, provide information similar to that required in (b) through (g) above.
- (k) Provide a complete listing of all existing licensed health care facilities and/or services and Certificates of Need in which the proposed licensee currently has an ownership interest, to include names and addresses of each facility or service. In the cases of Certificates of Need for undeveloped facilities and services, provide the name, address, and telephone number of a contact person representing the authority which issued the Certificate of Need.

Response: East Cooper Community Hospital, Inc. d/b/a East Cooper Regional Medical Center has a license to operate 130 acute care beds and is located at 2000 Hospital Drive, Mount Pleasant, South Carolina 29464. This is the only facility or service in which the licensee has an interest.

There are no Certificates of Need for undeveloped facilities and services.

- (i) Should the licensee be a subsidiary corporation, provide a diagram of the licensee's relationship to the parent corporation and list the name and address of the parent corporation as well as the corporation which has ultimate control. In addition, please provide the name and mailing address of all persons and/or legal entities having ownership interest of 5 percent or more or any person with any agreement, contract, option, arrangement, or intent to acquire ownership interest of 5 percent or more, of all corporations in the corporate organizational structure which have ultimate control of the licensee.

Response: East Cooper Community Hospital, Inc. d/b/a East Cooper Medical Center is a South Carolina corporation. East Cooper Community Hospital, Inc. is a wholly owned subsidiary of Tenet Health System Medical, Inc. Tenet Health System Medical, Inc. is a wholly-owned subsidiary of Tenet Health System Holdings, Inc. Tenet Health System Holdings, Inc. is a wholly owned subsidiary of Tenet Healthcare Corporation. Tenet Healthcare Corporation is a publicly traded corporation.

Tenet Health System Medical, Inc.
1445 Ross Avenue
Dallas, TX 75202

Tenet Health System Holdings, Inc.
1445 Ross Avenue
Dallas, TX 75202

Tenet Healthcare Corporation
1445 Ross Avenue
Dallas, TX 75202

Please see **Attachment C** for East Cooper Medical Center's organizational chart. Also included in **Attachment C** are East Cooper Medical Center's Articles of Incorporation and By-laws.

- (9) Provide documentation that the applicant has sought cooperative agreements such as transfer agreements with other facilities, as applicable.

Response: East Cooper Medical Center currently holds transfer agreements with numerous facilities in the region. The proposed project does not affect any of the transfer agreements already in place. Through the proposed project, East Cooper Medical Center has a transfer agreement specific to cardiac catheterization with the Medical University of South Carolina; please refer to **Attachment D** for a signed letter regarding the transfer of cardiac catheterization patients.

- (10) Indicate the means by which a person will have access to the facility's services (i.e. physician referral, self admission, etc.) Identify the specific facilities or agencies the applicant expects to receive referrals from (i.e. hospitals, home health agencies, etc.) Describe any limitations placed on admissions.

Response: Persons have access to ECMC's facilities through the following means:

- Medical referrals by physicians;
- Self-referrals/admissions;
- Other acute care hospitals; and
- Other health care providers (for example, health departments, skilled nursing facilities, home health agencies, and rehabilitation facilities).

As is currently the practice, there will be no limitations placed on patients in need of services. All potential patients for the proposed service to be offered as part of this project will be treated without regard to age, race, religion, national origin, sex, handicap, or ability to pay. Please see **Attachment E** for ECMC's provision of patient care, patients rights and responsibilities and charity care policies as well as Tenet's compact with uninsured patients.

- (11) Demonstrate that the proposed project is needed or projected as necessary to meet an identified need of the public. This shall address at a minimum: identification of the target population; the degree of unmet need; projected utilization of the proposed facility or service; utilization of existing facilities and services; past utilization of existing similar services within the facility; and justification that the proposed project will not unnecessarily duplicate existing entities. The applicant must show all assumptions, data sources, and methodologies used. The applicant must use population statistics consistent with those generated by the State Demographer, State Budget and Control Board.

Response:

Introduction

East Cooper Medical Center ("ECMC") is one of South Carolina's leading hospitals. ECMC, part of Tenet Healthcare, aims to put the patient first, and everything is designed to provide the patient with more successful procedures, faster recovery times and a better quality of life. The hospital combines expertise with compassionate and detail-oriented care; ECMC has found the perfect blend so that patients leave the hospital in better health and with a smile on their faces.

In 1985, several physicians practicing east of the Cooper River recognized the difficulty their patients and neighbors experienced accessing hospital care. The bridges were unstable and the travel time to reach a hospital was greater than an hour. Foreseeing major population growth in the area, these doctors proposed the idea to build a full-service medical facility with the primary mission to care for those residents who could not make it into downtown Charleston. The idea was shared with Mayor Johnnie Dodds II, and in January 1986 the first hospital east of the Cooper River opened. The original ECMC was a 100-bed hospital with 4 operating rooms and an Emergency Department. Since then, ECMC expanded to 130 acute care beds, and in 2010 moved into a new and larger facility to meet the needs of the growing community.

The South Carolina floods were a poignant reminder of the need to have advanced community-based services deployed into population centers. ECMC was originally established for situations such as this. The leadership of ECMC is committed to expanding its service offering to ensure that residents east of the Cooper River have access to the necessary medical services, regardless of the situation. Establishing an expanded network of community based resources will enhance the state's readiness and mitigate the risk of natural disasters for the residents of South Carolina.

Although ECMC was originally established for the residents East of the Cooper, the hospital's expanded scope of services, commitment to quality and safety, and outstanding team of caregivers has attracted patients from throughout the Lowcountry and beyond. Care is provided in a new, state-of-the-art facility that is rich in technology. 24-hour emergency care, women's services, diagnostic imaging and interventional services, orthopedics, sports medicine, adult and pediatric rehabilitation services, wound care and surgical care, including nationally recognized spine surgery and breast reconstruction surgery are all offered. Services include but are not limited to:

Comprehensive Orthopedic Services

- Comprehensive Joint Program
- Total & Partial Knee & Hip Surgery
- MAKOplasty Partial Joint Surgery
- Sports Medicine Specialists
- Treatment of Shoulder & Elbow Injuries
- Minimally Invasive Spine Surgery

Emergency Care

- 24-hour Full-service Care
- Advanced Primary Stroke Center
- Level III Trauma Center
- Board-certified Emergency
- Physicians
- Helicopter Landing Pad
- Online check-in: "ER Express"

Maternity Care

- Level II Neonatal Nursery
- Childbirth Classes
- Breastfeeding Support Groups
- Certified Lactation Specialists

Women's Services

- Comprehensive Breast Care
- Gynecological Services
- Fertility Specialists

Rehabilitation Services

- Inpatient Services
- Adult & Pediatric Outpatient Centers
- Physical Therapy
- Occupational Therapy
- Speech Therapy

Surgical Care

- Breast Reconstructive Surgery
- Minimally Invasive Colorectal Surgery
- 10 Operating Rooms
- Live Data System

Specialty Services

- Advanced Diabetes Care and Education
- Comprehensive Wound Care Center
- Sleep Disorder Center
- Laboratory/Pathology Services
- Charleston Breast Center
- Charleston Imaging Center

East Cooper Medical Center strives for excellence and is committed to delivering high-quality care. The facility has received numerous awards and accolades over the years recognizing the state of the art care provided to the community. Most notably, ECMC was awarded nine Gold Seals of Approval from one of the nation's most respected health care organizations, the Joint Commission. This is more Gold Seals than any other South Carolina hospital, and is an example of the hospital's unwavering commitment to quality. These awards include disease-specific care for

Laminectomy

Heart Failure

Pneumonia

Advanced Primary Stroke Center

Advanced Inpatient Diabetes

Minimally-Invasive Colorectal

Joint Replacement-Hip

Joint Replacement-Knee

Perinatal Care

Other awards and distinctions include:

- American Heart Association's "Get with the Guidelines Stroke Gold Plus Achievement Award"
- American Heart Association's "Get with the Guidelines Heart Failure Gold Plus Achievement Award"
- Five-Star Patient Satisfaction for 10 consecutive years
- Tenet Healthcare's Circle of Excellence Award

Project Overview

As mentioned, the South Carolina floods were a poignant reminder of the need to have advanced community-based services deployed into population centers. ECMC was originally established for situations such as this. The leadership of ECMC is committed to expanding its service offering to ensure that residents east of the Cooper River have access to the necessary medical services, regardless of the situation. Establishing an expanded network of community based resources will enhance the state's readiness and mitigate the risk of natural disasters for the residents of South Carolina.

With this in mind and in order to better serve its patients, ECMC proposes the addition of diagnostic cardiac catheterization services. Mount Pleasant is the fourth largest municipality in South Carolina, but does not have any cardiac catheterization laboratories. By providing diagnostic cardiac catheterization services at ECMC, the hospital will be able to provide state-of-the-art cardiology resources closer to its service area patients. Patients and their families will benefit from the increased convenience of seeking care at a location closer to home. Through the project, patients will be able to receive treatment at a more convenient location while staying at a hospital they have come to know and trust. Additionally, ECMC is developing the proposed project with support from the MUSC Division of Cardiology, and patients will benefit from the experience of an academic medical center known for its comprehensive cardiology services. Please refer to **Attachment F** for the numerous letters of support from MUSC.

The existing interventional radiology laboratory will be used for the proposed project, serving as both a diagnostic catheterization and interventional radiology laboratory. As such, no construction or renovations are necessary for the proposed project. After some minor equipment related modifications, the existing interventional radiology equipment will have capabilities related to both diagnostic catheterization and interventional radiology (**Attachment B**). Please refer to **Attachment B** for a letter from Eric R. Powers, M.D., Director of the Acute Coronary Syndrome Center and Director of the Heart and Vascular Service Line at MUSC, regarding the equipment. The proposed project is a cost effective way to increase access to diagnostic cardiac catheterization services for area residents.

ECMC strives to keep pace with evolving medicine and the needs of its service area residents. It is ECMC's intention to increase access to diagnostic cardiac catheterization services to the service area and with the proposed project, ECMC will be able to successfully achieve this goal.

Service Area

Based on ECMC's historical patient origin trends for inpatients, the primary service area is comprised of Charleston and Berkeley Counties. As shown in Figure 2, approximately 66 percent of ECMC's inpatient volume originated from the primary service area in 2014. The secondary service area, which is comprised of Dorchester, Horry and Georgetown Counties, makes up approximately 16 percent of ECMC's inpatient volume. This data, obtained from the South Carolina Revenue and Fiscal Affairs Office, Health and Demographics, is included in **Attachment G**.

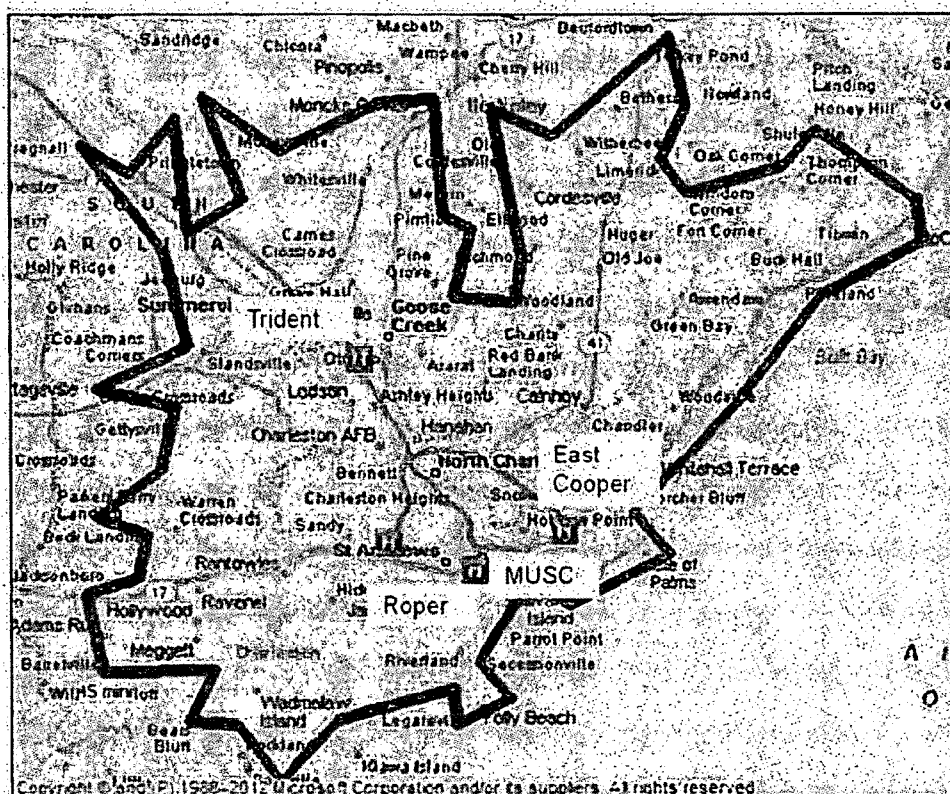
Figure 2
East Cooper Medical Center
Patient Origin for Inpatients, CY2014

County	Discharges	Percent of Total
Primary Service Area		
Charleston	2,672	54.5%
Berkeley	576	11.7%
Subtotal, PSA	3,248	66.2%
Secondary Service Area		
Dorchester	287	5.9%
Horry	267	5.4%
Georgetown	225	4.6%
Subtotal, SSA	779	15.9%
Total, PSA and SSA	4,027	82.1%
Other	878	17.9%
Total	4,905	

Source: SC Budget and Control Board, Office of Research and Statistics.

Per the *Health Plan*, the service area for a diagnostic catheterization laboratory is defined as all facilities within 45 minutes' one-way automobile travel time. Facilities offering catheterization services within this service area include MUSC, Roper St. Francis, and Trident Medical Center. The following figure shows a map of the service area with the blue line representing 45 minutes' one-way automobile travel time from ECMC.

Figure 3
East Cooper Medical Center
Diagnostic Cardiac Catheterization
Service Area



It's important to note that although Bon Secours St. Francis Hospital was approved for one catheterization laboratory in 1988 to provide diagnostic catheterization services, no volume was reported for 2007-2009 and very minimal volumes in recent years. The following figure provides Bon Secours St. Francis Hospital's diagnostic cardiac catheterization experience:

Figure 4
Bon Secours St. Francis Hospital
Diagnostic Cardiac Catheterization
Historical Utilization, 2007-2014

2007	2008	2009	2010	2011	2012	2013	2014
-	-	-	2	7	9	3	4

Source: Joint Annual Reports.

Per Regulation No. 61-15 Certification of Need for Health Facilities and Services, Section 102 Applicability 1(e):

1. A person or health care facility as defined in this Regulation is required to obtain a Certificate of Need from the Department of Health and Environmental Control before undertaking any of the following:

...the offering of any health service by or on behalf of a health care facility which has not been offered by the facility in the preceding twelve months and for which specific standards or criteria are prescribed in the South Carolina Health Plan...

With this in mind, Bon Secours St. Francis Hospital's catheterization laboratory is considered non-operational and requires a CON application if it is to be included in the inventory for catheterization laboratories. As such, it is excluded from the service area analysis.

Demographics

Based on population projections, the primary service area of Charleston and Berkeley Counties had approximately 589,000 residents in 2015 (Figure 5). It is estimated that the population of the primary service area will increase by approximately 9 percent between 2015 and 2020 to approximately 643,000 residents. The secondary service area, comprised of Dorchester, Horry and Georgetown Counties, had approximately 514,000 residents in 2015 and is projected to grow approximately 9 percent by 2020. The total service area is also projected to grow approximately 9 percent between 2015 and 2020. The projected growth of the service area is higher than the projected growth for the state of South Carolina for the same time period (approximately 5 percent). Population growth for the service area has been consistently strong, and growth is expected to continue in the future. This data, obtained from the South Carolina Revenue and Fiscal Affairs Office, Health and Demographics, is included in Attachment G.

Figure 5
East Cooper Medical Center
Service Area Population Projections
All Ages

County	2015	2020	2015-2020
	Projection	Projection	Percent Change
Primary Service Area			
Charleston	385,080	415,240	7.8%
Berkeley	203,590	228,040	12.0%
Subtotal, PSA	588,670	643,280	9.3%
Secondary Service Area			
Dorchester	151,510	167,290	10.4%
Horry	301,920	333,120	10.3%
Georgetown	60,240	59,550	-1.1%
Subtotal, SSA	513,670	559,960	9.0%
Total, PSA and SSA	1,102,340	1,203,240	9.2%
South Carolina	4,873,470	5,116,870	5.0%

Source: SC Budget and Control Board, Office of Research and Statistics.

Persons age 65 and older represent a notable portion of cardiology patients in any given area. For this age cohort, the primary and secondary service areas are expected to increase by approximately 27 percent and 26 percent, respectively, between 2015 and 2020. Over this same time period, the total service area is projected to grow approximately 26 percent. The 65-plus growth rate in the service area is expected to be greater than that of the entire state of South Carolina (approximately 20 percent). There will be approximately 47,000 additional 65-plus residents by 2020 in the service area. This growing elderly population will require increasing access to healthcare services in the future, including diagnostic cardiac catheterization services. Figures 5 and 6 detail the projected growth for all ages as well as the 65-plus population in the service area.

Figure 6
East Cooper Medical Center
Service Area Population Projections
Age 65 and Over

County	2015 Projection	2020 Projection	2015-2020 Percent Change
Primary Service Area			
Charleston	57,800	71,620	23.9%
Berkeley	25,910	34,290	32.3%
Subtotal, PSA	83,710	105,910	26.5%
Secondary Service Area			
Dorchester	17,850	22,370	25.3%
Horry	63,740	82,090	28.8%
Georgetown	15,090	17,470	15.8%
Subtotal, SSA	96,680	121,930	26.1%
Total, PSA and SSA	180,390	227,840	26.3%
South Carolina	789,130	945,640	19.8%

Source: SC Budget and Control Board, Office of Research and Statistics.

It's also helpful to look at the primary service area, which includes Charleston and Berkeley Counties, by ZIP Code for all ages as well as the 65-and-over age cohort (Figure 7). All ZIP Codes within both counties are experiencing growth for all ages, with notable growth in 29492-Charleston (almost 16 percent), 29466-Mount Pleasant (almost 14 percent) and 29455-Johns Island (approximately 12 percent). There's significant growth for ZIP Codes in the 65-and-over age cohort as well, particularly 29492-Charleston (approximately 41 percent) and 29466-Mount Pleasant (37 percent). It's important to note that both high growth ZIP Codes (29492-Charleston and 29466-Mount Pleasant) are located in the East Cooper area.

Figure 7
East Cooper Medical Center
Service Area Population Projections
Primary Service Area Counties by ZIP Code
All Ages and Age 65 and Over

County	ZIP Code	Geo Name	All Ages		Age 65-Plus		Percent Change	
			2015	2020	2015	2020	All Ages	Age 65-Plus
			Projection	Projection	Projection	Projection		
Charleston County			375,423	405,163	55,901	69,425	7.9%	24.2%
	29401	Charleston	10,352	10,766	1,846	2,141	4.0%	16.0%
	29403	Charleston	24,480	25,663	2,746	3,236	4.8%	17.8%
	29404	Charleston AFB	2,033	2,137	45	43	5.1%	-4.4%
	29405	North Charleston	27,493	28,645	3,626	4,336	4.2%	19.6%
	29406	Charleston	32,628	35,447	2,932	3,600	8.6%	22.8%
	29407	Charleston	36,700	38,719	6,395	7,408	5.5%	15.8%
	29412	Charleston	41,199	44,202	7,002	8,406	7.3%	20.1%
	29414	Charleston	37,374	41,028	5,024	6,518	9.8%	29.7%
	29418	North Charleston	25,933	28,266	2,684	3,615	9.0%	34.7%
	29424	Charleston	525	546	60	58	4.0%	-3.3%
	29425	Charleston	6	6	-	-	0.0%	0.0%
	29426	Adams Run	1,861	1,920	293	346	3.2%	18.1%
	29429	Awendaw	2,873	3,006	536	676	4.6%	26.1%
	29438	Edisto Island	2,533	2,693	706	828	6.3%	17.3%
	29449	Hollywood	7,897	8,240	1,551	1,918	4.3%	23.7%
	29451	Isle of Palms	4,349	4,541	1,118	1,342	4.4%	20.0%
	29455	Johns Island	22,726	25,509	4,843	6,253	12.2%	29.1%
	29458	Mc Clellanville	2,763	2,867	562	669	3.8%	19.0%
	29464	Mount Pleasant	47,491	51,269	7,915	9,959	8.0%	25.8%
	29466	Mount Pleasant	34,777	39,594	4,261	5,836	13.9%	37.0%
	29470	Ravenel	4,679	5,084	745	973	8.7%	30.6%
	29482	Sullivan's Island	1,848	1,920	345	440	3.9%	27.5%
	29487	Wadmalaw Island	2,903	3,095	666	824	6.6%	23.7%
Berkeley County			155,459	170,047	19,955	25,468	9.4%	27.6%
	29410	Hanahan	18,926	20,003	2,472	2,963	5.7%	19.9%
	29431	Bonneau	6,681	7,139	1,183	1,450	6.9%	22.6%
	29434	Cordesville	789	843	126	154	6.8%	22.2%
	29436	Cross	4,748	4,966	915	1,072	4.6%	17.2%
	29445	Goose Creek	61,565	67,662	6,102	8,101	9.9%	32.8%
	29450	Huger	3,229	3,434	464	601	6.3%	29.5%
	29453	Jamestown	1,294	1,352	213	265	4.5%	24.4%
	29461	Möncks Comer	34,106	37,648	5,011	6,416	10.4%	28.0%
	29468	Pineville	2,087	2,175	456	534	4.2%	17.1%
	29469	Pinopolis	803	852	157	190	6.1%	21.0%
	29479	Saint Stephen	7,798	8,412	1,397	1,660	7.9%	18.8%
	29492	Charleston	13,433	15,561	1,459	2,060	15.8%	41.2%
Total, PSA			530,882	575,210	75,856	94,891	8.3%	25.1%

Source: Claritas, 2015/2020 (Accessed October 2014).

As mentioned, ECMC is developing the proposed project with support from the MUSC Division of Cardiology. During the development of the proposed project, MUSC's service area definition was analyzed. MUSC splits the market into eight tri-county sub areas, one of which is the East Cooper area which includes selected ZIP Codes in Charleston and Berkeley Counties (Figure 8). All ZIP Codes within the East Cooper area are experiencing growth for all ages (approximately 10 percent between 2015 and 2020). There's significant growth for this area in the 65 and over age cohort as well, with a projected

growth of approximately 30 percent for this same time period. As previously mentioned, ZIP Codes 29492-Charleston and 29466-Mount Pleasant are both in the East Cooper area and have the highest projected percentage growth for all of Charleston and Berkeley Counties.

Figure 8
East Cooper Medical Center
Service Area Population Projections
East Cooper Area by ZIP Code
All Ages and Age 65 and Over

County		All Ages		Age 65-Plus		Percent Change	
		2015	2020	2015	2020	All Ages	Age 65-Plus
ZIP Code	Geo Name	Projection	Projection	Projection	Projection		
Charleston County							
29429	Awendaw	2,873	3,006	536	676	4.6%	26.1%
29451	Isle of Palms	4,349	4,541	1,118	1,342	4.4%	20.0%
29458	Mc Clellanville	2,763	2,867	562	669	3.8%	19.0%
29464	Mount Pleasant	47,491	51,269	7,915	9,959	8.0%	25.8%
29466	Mount Pleasant	34,777	39,594	4,261	5,836	13.9%	37.0%
29482	Sullivan's Island	1,848	1,920	345	440	3.9%	27.5%
Berkeley County							
29450	Huger	3,229	3,434	464	601	6.3%	29.5%
29453	Jamestown	1,294	1,352	213	265	4.5%	24.4%
29492	Charleston	13,433	15,561	1,459	2,060	15.8%	41.2%
Total, East Cooper Area		112,057	123,544	16,873	21,848	10.3%	29.5%

Source: Claritas, 2015/2020 (Accessed October, 2014).

The demographic analysis reveals a service area with a strong population base and a growing 65-plus population, and ECMC must be prepared to provide diagnostic cardiac catheterization services to its ever growing patient population.

Utilization

Historically, cardiac catheterization services in the 45-minute drive time service area have been well utilized. Figure 9 details historical cardiac catheterization volume and equivalents for 2012-2014.

Figure 9
East Cooper Medical Center
Diagnostic Cardiac Catheterization Service Area
Historical Catheterization Volume and Equivalents, 2012-2014

Facilities	Cath Labs	2012						2013						2014					
		Adult			Peds			Adult			Peds			Adult			Peds		
		Dx	Ther	Dx	Ther	Other		Dx	Ther	Dx	Ther	Other		Dx	Ther	Dx	Ther	Other	
MUSC	6	1,747	1,363	249	239	99		1,692	1,326	262	260	86		1,697	1,156	285	284	112	
Roper Hospital	3	1,785	904	-	-	-		1,651	908	-	-	-		1,575	896	-	-	-	
Trident Medical Center	2	1,332	390	-	-	-		995	479	-	-	-		1,007	445	-	-	-	
Total	11	4,864	2,657	249	239	99		4,338	2,713	262	260	86		4,282	2,497	285	284	112	

Equivalents

Facilities	Cath Labs	2012						2013						2014					
		Adult			Peds			Adult			Peds			Adult			Peds		
		Dx	Ther	Dx	Ther	Other		Dx	Ther	Dx	Ther	Other		Dx	Ther	Dx	Ther	Other	
MUSC	6	1,747	2,726	498	717	181		1,692	2,652	524	780	202		1,697	2,312	570	852	196	
Roper Hospital	3	1,785	1,608	-	-	-		1,651	1,816	-	-	-		1,575	1,782	-	-	-	
Trident Medical Center	2	1,332	780	-	-	-		995	958	-	-	-		1,007	890	-	-	-	
Total	11	4,864	5,314	498	717	181		4,338	5,426	524	780	202		4,282	4,994	570	852	196	

Source: State Health Plan; Joint Annual Reports.

Figure 10 details historical cardiac catheterization equivalents and capacity for 2012-2014. The service area remains above 80 percent of capacity.

Figure 10
East Cooper Medical Center
Diagnostic Cardiac Catheterization Service Area
Historical Catheterization Equivalents and Capacity, 2012-2014

Facilities	Cath Labs	2012				2013				2014			
		Equivalents		Capacity		Equivalents		Capacity		Equivalents		Capacity	
		Total	Per Lab	Total	Percent	Total	Per Lab	Total	Percent	Total	Per Lab	Total	Percent
MUSC	6	5,869	978	7,200	81.5%	5,850	975	7,200	81.3%	5,827	938	7,200	78.2%
Roper Hospital	3	3,593	1,198	3,600	99.8%	3,487	1,156	3,600	96.3%	3,370	1,123	3,600	93.6%
Trident Medical Center	2	2,112	1,056	2,400	88.0%	1,953	977	2,400	81.4%	1,897	949	2,400	79.0%
Total	11	11,574	1,052	13,200	87.7%	11,270	1,025	13,200	85.4%	10,894	890	13,200	82.5%

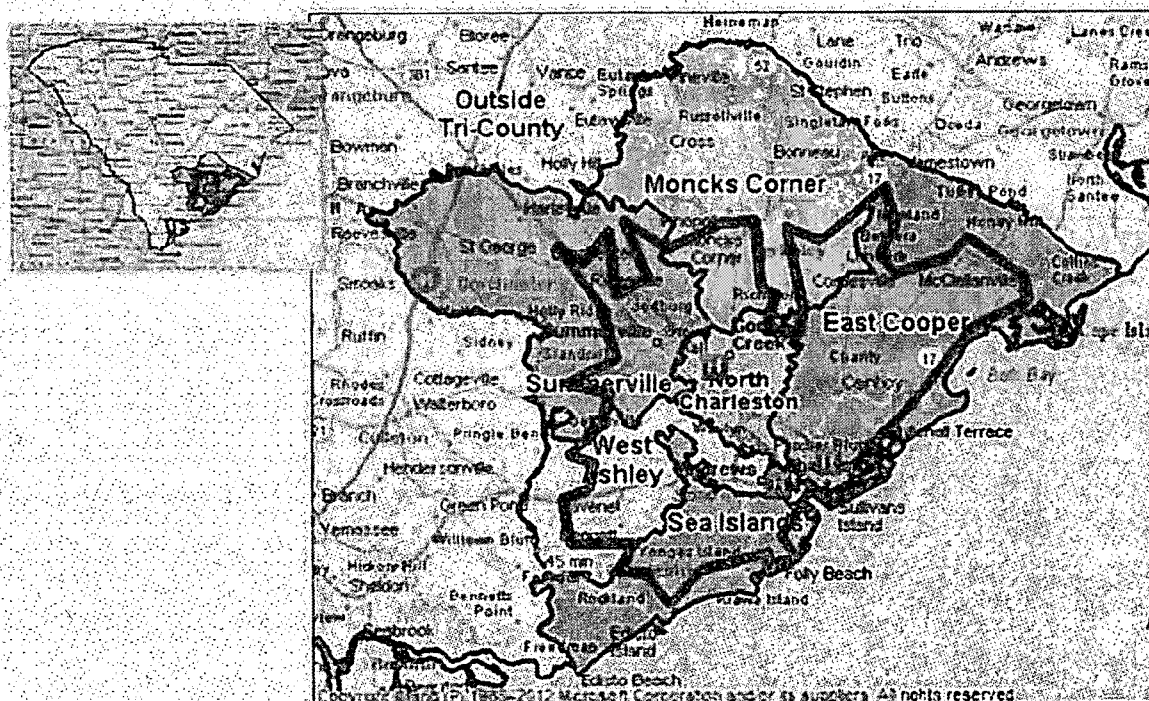
Source: State Health Plan; Joint Annual Reports.

As mentioned, ECMC is developing the proposed project with support from the MUSC Division of Cardiology (please refer to Attachment F for the numerous letters of support from MUSC). It's expected that a portion of the diagnostic catheterization patients at MUSC will shift to ECMC for services. In order to determine projected volume, MUSC's service area definition was analyzed. MUSC splits the market into eight tri-county sub areas:

East Cooper	Peninsula Charleston
Moncks Corner	Sea Islands
North Charleston	Summerville
Outside Tri-County	West Ashley

These areas are depicted in the following map, as well as the existing market providers within the 45-minute drive time zone (shown as a blue line).

Figure 11
MUSC Defined Service Area



The following figure shows historical utilization for MUSC's diagnostic cardiac catheterization service by the eight tri-county sub areas:

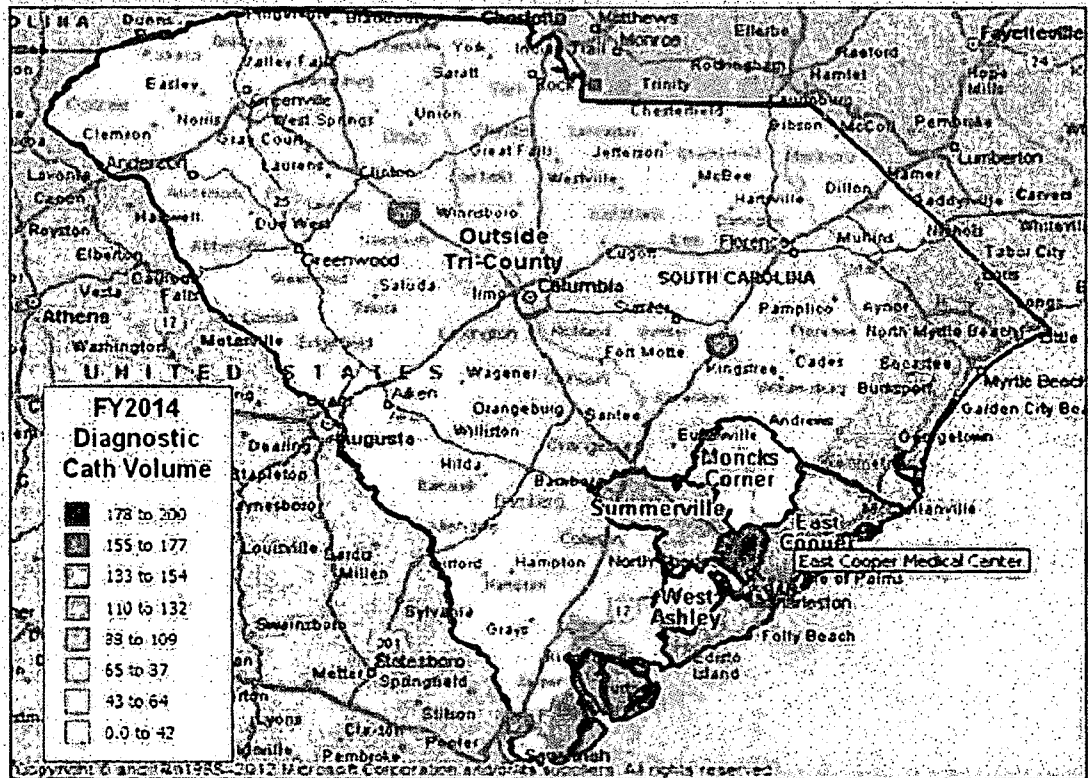
Figure 12
MUSC Defined Service Area
Diagnostic Cardiac Catheterization, 2012-2014

Market Area	2012	2013	2014	Change, 2012-2014	
				Percent	Number
East Cooper	112	123	128	14.3%	16
Moncks Corner	35	34	33	-5.7%	(2)
North Charleston	170	171	196	15.3%	26
Outside Tri-County	1,041	987	991	-4.8%	(50)
Peninsula Charleston	41	41	41	0.0%	-
Sea Islands	95	92	74	-22.1%	(21)
Summerville	92	95	89	-3.3%	(3)
West Ashley	87	76	88	1.1%	1
Other	74	73	57	-23.0%	(17)
Total	1,747	1,692	1,697	-2.9%	(50)

Source: Internal Data from MUSC.

MUSC's diagnostic catheterization volume was 1,697 patients in 2014. This volume is also depicted in the following map.

Figure 13
MUSC Defined Service Area
Diagnostic Cardiac Catheterization, 2014



It's assumed that various 2014 volume percentages from each market area will shift from MUSC to ECMC for adult diagnostic catheterization and volumes will remain flat. However, since MUSC is an academic medical center providing tertiary and quaternary care, it's assumed that only certain adult diagnostic catheterization inpatient cases will shift to ECMC, specifically MS-DRGs 286 Circulatory Disorders Except AMI, with Cardiac Cath w MC and 287 Circulatory Disorders Except AMI, with Cardiac Cath w/o. Based on MUSC's diagnostic catheterization volume for 2014, these assumptions result in a shift of 514 procedures, as shown in the following figure. Refer to **Attachment G** for more detail.

Figure 14
East Cooper Medical Center
Projected Diagnostic Cardiac
Catheterization Shift from MUSC, 2014

Tri Cty Sub Area	FY2014 Procedures				To East Cooper			
	Inpatient*	Outpatient	Total	% Total	Percent	Inpatient*	Outpatient	Total
East Cooper	23	75	98	7.6%	90%	21	68	89
Moncks Corner	7	16	23	1.8%	90%	6	14	20
North Charleston	45	95	140	10.8%	90%	41	86	127
Outside Tri-County	144	645	789	60.9%	Varied	34	168	202
Peninsula Charleston	10	17	27	2.1%	0%	-	-	-
Sea Islands	13	36	49	3.8%	45%	6	16	22
Summerville	14	50	64	4.9%	50%	7	25	32
West Ashley	17	47	64	4.9%	35%	6	16	22
Other	11	31	42	3.2%	0%	-	-	-
Total	284	1,012	1,296			121	393	514

Source: Internal data from MUSC.

*Note-Inpatient includes only MSDRGs 286 and 287.

Assuming a gradual volume shift from MUSC to ECMC (50 percent, 75 percent and 100 percent in Project Years One-Three, respectively) results in the following projected volumes for ECMC (Figure 15). Again, ECMC assumes that volumes will remain flat for these projections to be extremely conservative.

Figure 15
East Cooper Medical Center
Projected Diagnostic Cardiac Catheterization
Project Years One-Three

	Project Year		
	One	Two	Three
Inpatient	61	91	121
Outpatient	197	295	393
Total	258	386	514

A projected volume of 514 procedures for Project Year Three leaves 1,183 adult diagnostic catheterization procedures at MUSC and does not impact any other providers in the service area. Additionally, ECMC exceeds the required minimum of 500 diagnostic cardiac catheterization procedures by Project Year Three.

Impact on Existing Facilities

As previously discussed, the South Carolina floods were a poignant reminder of the need to have advanced community-based services deployed into population centers. ECMC was originally established for situations such as this. The leadership of ECMC is committed to expanding its service offering to ensure that residents east of the Cooper River have access to the necessary medical services, regardless of the situation. With this in mind and in order to better serve its patients, ECMC proposes the addition of diagnostic cardiac catheterization services with support from the MUSC Division of Cardiology. It's expected that a portion of the diagnostic catheterization patients at MUSC will shift to ECMC for services. The existing patient population at MUSC can fully support the proposed project with no impact on other providers in the service area.

**Cardiac Catheterization Standards
2015-2016 South Carolina State Health Plan**

1. The capacity of a fixed cardiac catheterization laboratory shall be 1,200 diagnostic equivalents per year. Adult diagnostic catheterizations shall be weighted as 1.0 equivalents, while therapeutic catheterizations shall be weighted as 2.0 equivalents. For pediatric and adult congenital catheterization labs, diagnostic catheterizations shall be weighted as 2.0 equivalents, therapeutic catheterizations shall be weighted as 3.0 equivalents, electrophysiology (EP) studies shall be weighted as 2.0 equivalents, and biopsies performed after heart transplants shall be weighted as 1.0 equivalents. The capacity of mobile cardiac catheterization labs will be calculated based on the number of days of operation per week.

Response: Applying these capacity thresholds to the proposed cardiac catheterization lab at ECOMC results in the following projected utilization levels for the lab in the first three years of operation.

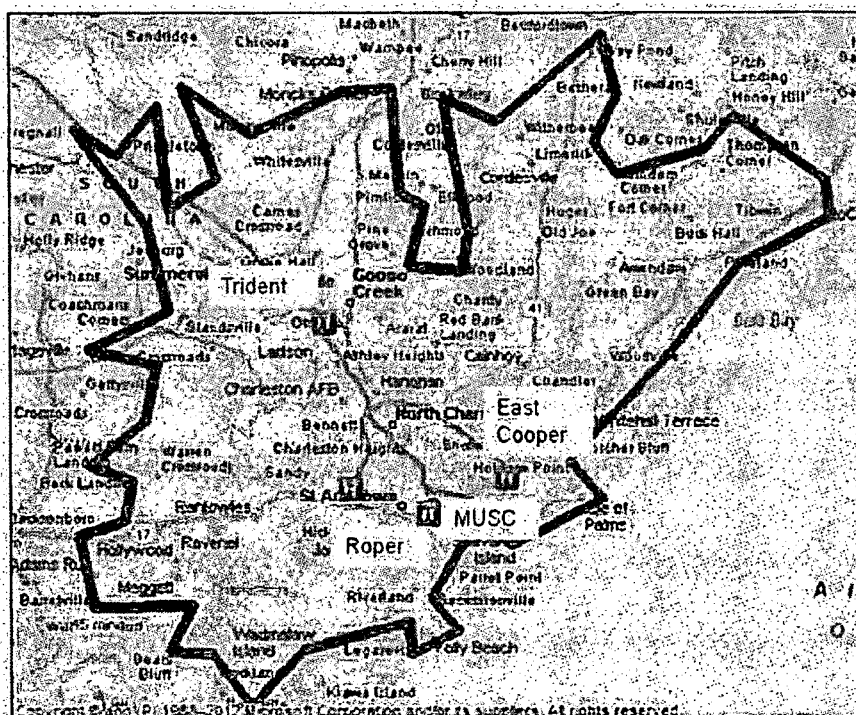
**Figure 16
East Cooper Medical Center
Projected Diagnostic Cardiac Catheterization
Project Years One-Three**

	Project Year		
	One	Two	Three
Diagnostic Caths	258	386	514
Therapeutic Caths	-	-	-
Total	258	386	514
Equivalents	258	386	514
Labs	1	1	1
Per Lab	258	386	514
Capacity	1,200	1,200	1,200
Occupancy	21.5%	32.2%	42.8%

2. The service area for a diagnostic catheterization laboratory is defined as all facilities within 45 minutes' one way automobile travel time; for comprehensive cardiac catheterization laboratories the service area is all facilities within 60 minutes' one way automobile travel time; a pediatric cardiac program should serve a population encompassing at least 30,000 births per year, or roughly two million people.

Response: Facilities offering catheterization services within this service area for the proposed diagnostic catheterization laboratory includes MUSC, Roper St. Francis and Trident Medical Center. The following figure shows a map of the service area with the blue line representing 45 minutes' one way automobile travel time from ECOMC.

Figure 17
East Cooper Medical Center
Diagnostic Cardiac Catheterization
Service Area



It's important to note that although Bon Secours St. Francis Hospital was approved for one catheterization laboratory in 1988 to provide diagnostic catheterization services, no volume was reported for 2007-2009 and very minimal volumes in recent years. The following figure provides Bon Secours St. Francis Hospital's diagnostic cardiac catheterization experience.

Figure 18
Bon Secours St. Francis Hospital
Diagnostic Cardiac Catheterization
Historical Utilization, 2007-2014

2007	2008	2009	2010	2011	2012	2013	2014
-	-	-	2	7	9	3	4

Source: Joint Annual Reports.

Per Regulation No. 61-15 Certification of Need for Health Facilities and Services, Section 102, Applicability 1(e).

1. A person or health care facility as defined in this Regulation is required to obtain a Certificate of Need from the Department of Health and Environmental Control before undertaking any of the following:

...the offering of any health service by or on behalf of a health care facility which has not been offered by the facility in the preceding twelve months and for which specific standards or criteria are prescribed in the South Carolina Health Plan...

With this in mind, Bon Secours St. Francis Hospital's catheterization laboratory is considered non-operational and requires a CON application if it is to be included in the inventory for catheterization laboratories. As such, it is excluded from the service area analysis.

Diagnostic and Mobile Catheterization Services

3. New diagnostic catheterization services, including mobile services, shall be approved only if all existing labs in the service area have performed a minimum of 500 diagnostic catheterization procedures per laboratory during the most recent year;

Response: Historically, cardiac catheterization services in the 45-minute drive time service area have been well utilized; all exceeded 500 diagnostic catheterization procedures in the most recent year. The providers in the service area are not dedicated diagnostic only providers and do not have dedicated diagnostic-only laboratories. Figure 5 details historical cardiac catheterization volume for the service area for 2012-2014.

Figure 19
East Cooper Medical Center
Diagnostic Cardiac Catheterization Service Area
Historical Catheterization Volume and Equivalents, 2012-2014

Facilities	Cath Labs	2012					2013					2014				
		Adult		Peds		Other	Adult		Peds		Other	Adult		Peds		Other
		Dx	Ther	Dx	Ther		Dx	Ther	Dx	Ther		Dx	Ther	Dx	Ther	
MUSC	6	1,747	1,363	249	239	99	1,692	1,326	262	260	86	1,697	1,156	285	284	112
Roper Hospital	3	1,785	904	-	-	-	1,651	908	-	-	-	1,578	896	-	-	-
Trident Medical Center	2	1,332	390	-	-	-	995	479	-	-	-	1,007	445	-	-	-
Total	11	4,864	2,657	249	239	99	4,338	2,713	262	260	86	4,282	2,497	285	284	112

Equivalents

Facilities	Cath Labs	2012					2013					2014				
		Adult		Peds		Other	Adult		Peds		Other	Adult		Peds		Other
		Dx	Ther	Dx	Ther		Dx	Ther	Dx	Ther		Dx	Ther	Dx	Ther	
MUSC	6	1,747	2,726	498	717	181	1,692	2,652	524	780	202	1,697	2,312	570	852	196
Roper Hospital	3	1,785	1,908	-	-	-	1,651	1,816	-	-	-	1,578	1,792	-	-	-
Trident Medical Center	2	1,332	780	-	-	-	995	958	-	-	-	1,007	880	-	-	-
Total	11	4,864	5,314	498	717	181	4,338	5,426	524	780	202	4,282	4,994	570	852	196

Source: State Health Plan; Joint Annual Reports.

4. An applicant for a fixed diagnostic service must project that the proposed service will perform a minimum of 500 diagnostic equivalent procedures annually within three years of initiation of services, without reducing the utilization of the existing diagnostic catheterization services in the service area below 500 diagnostic cardiac catheterization procedures per laboratory.

Response: It's assumed that various 2014 volume percentages from each market area will shift from MUSC to ECMC for adult diagnostic catheterization and volumes will remain flat. However, since MUSC is an academic medical center providing tertiary and quaternary care, it's assumed that only certain adult diagnostic catheterization inpatient cases will shift to ECMC, specifically MS-DRGs 286 Circulatory Disorders Except AMI, with Cardiac Cath w MC, and 287 Circulatory Disorders Except AMI, with Cardiac Cath w/o. Based on MUSC's diagnostic catheterization volume for 2014, these assumptions result in a shift of 514 procedures, as shown in the following figure. Refer to Attachment G for more detail.

Figure 20
East Cooper Medical Center
Projected Diagnostic Cardiac
Catheterization Shift from MUSC, 2014

Tri Cty Sub Area	FY2014 Procedures				Percent	To East Cooper		
	Inpatient*	Outpatient	Total	% Total		Inpatient*	Outpatient	Total
East Cooper	23	75	98	7.6%	90%	21	68	89
Moncks Comer	7	16	23	1.8%	90%	6	14	20
North Charleston	45	95	140	10.8%	90%	41	86	127
Outside Tri-County	144	645	789	60.9%	Varied	34	168	202
Peninsula Charleston	10	17	27	2.1%	0%	-	-	-
Sea Islands	13	36	49	3.8%	45%	6	16	22
Summerville	14	50	64	4.9%	50%	7	25	32
West Ashley	17	47	64	4.9%	35%	6	16	22
Other	11	31	42	3.2%	0%	-	-	-
Total	284	1,012	1,296			121	393	514

Source: Internal Data from MUSC.

*Note-Inpatient includes only MSDRGs 286 and 287.

Assuming a gradual volume shift from MUSC to ECMC (50 percent, 75 percent and 100 percent in Project Years One-Three, respectively) results in the following projected volumes for ECMC (Figure 21). Again, ECMC assumes that volumes will remain flat for these projections to be extremely conservative.

Figure 21
East Cooper Medical Center
Projected Diagnostic Cardiac Catheterization
Project Years One-Three

	Project Year		
	One	Two	Three
Inpatient	61	91	121
Outpatient	197	295	393
Total	258	386	514

A projected volume of 514 procedures for Project Year Three leaves 1,183 adult diagnostic catheterization procedures at MUSC and does not impact any other providers in the service area. Additionally, ECMC exceeds the required minimum of 500 diagnostic cardiac catheterization procedures by Project Year Three.

5. Expansion of an existing diagnostic catheterization service shall only be approved if the service has operated at a minimum use rate of 80% of capacity (i.e., 960 equivalents per laboratory) for each of the past two years and can project a minimum of 500 procedures per year on the additional equipment within three years of its implementation.

Response: Not applicable. The proposed project is for a new diagnostic cardiac catheterization service.

6. An applicant for a mobile diagnostic catheterization laboratory must be able to project a minimum of 100 diagnostic equivalents annually for each day of the week that the mobile lab is located at the applicant's facility by the end of the third year following initiation of the service, without reducing the utilization of the existing diagnostic catheterization services in the service area below 500 diagnostic catheterization procedures per laboratory (i.e., an applicant wishing to have a mobile catheterization lab 2 days per week must project a minimum of 200 equivalents at the applicant's facility by the end of the third year of operation). In addition:

- a. The applicant must document that the specific mobile unit utilized by the vendor will perform a combined minimum of 500 diagnostic equivalents per year;
- b. The applicant must include vendor documentation of the complication rate of the mobile units operated by the vendor; and
- c. If an application for a mobile lab is approved and the applicant subsequently desires to change vendors, the Department must approve such change in order to insure that appropriate minimum utilization can be documented.

Response: Not applicable. The proposed project is for a new diagnostic cardiac catheterization service.

Emergent and Elective PCI without On-Site Cardiac Backup

7. In 2005, the ACCF/AHA/SCAI Writing Committee determined that Emergency PCI (Primary PCI) is reasonable in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished. Hospitals with diagnostic laboratories may be approved to perform emergency PCI without an on-site open heart surgery program only if all of the following criteria based on the 2005 ACC/AHA Guideline Update for PCI are met:

- a. Therapeutic catheterizations must be limited to Percutaneous Coronary Interventions (PCIs) performed only in emergent circumstances (Primary PCIs). Elective PCI may not be performed at institutions that do not provide on-site cardiac surgery except as provided for in Standard 8 below.

- b. The applicant has performed a minimum of 250 diagnostic catheterization procedures in the most recent year and can reasonably demonstrate that it will perform a minimum of 500 diagnostic catheterizations annually within three years of the initiation of services.

- c. The hospital must acquire an intra-aortic balloon pump (IABP) dedicated solely to this purpose.

- d. The chief executive officer of the hospital must sign an affidavit assuring that the criteria listed below are and will continue to be met at all times.

- e. An application shall be approved only if it is consistent with the criteria from Smith et al., ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACCF/AHA/SCAI Writing Committee to Update the 2001 Guidelines for Percutaneous Coronary Intervention) and the 2007 Focused Update of the guidelines. A complete copy of the guidelines can be found at: www.acc.org/clinical/guidelines/percutaneous/update/index.pdf.

1) Criteria for the Performance of Emergency (Primary) PCI:

- a) The physicians must be experienced interventionalists who regularly perform elective intervention at a surgical center (75 cases/year). The institution must perform a minimum of 35 primary PCI procedures per year.

- b) The nursing and technical catheterization laboratory staff must be experienced in handling acutely ill patients and comfortable with interventional equipment. They must have acquired experience in dedicated interventional laboratories at a surgical center. They participate in a 24-hour, 365-day call schedule.
- c) The catheterization laboratory itself must be well-equipped, with optimal imaging systems, resuscitative equipment, intra-aortic balloon pump (IABP) support, and must be well-stocked with a broad array of interventional equipment.
- d) The cardiac care unit nurses must be adept in hemodynamic monitoring and IABP management.
- e) The hospital administration must fully support the program and enable the fulfillment of the above institutional requirements.
- f) There must be formalized written protocols in place for immediate (within one hour) and efficient transfer of patients to the nearest cardiac surgical facility that are reviewed/tested on a regular (quarterly) basis.
- g) Primary (emergency) intervention must be performed routinely as the treatment of choice around the clock for a large proportion of patients with acute myocardial infarction (AMI) to ensure streamlined care paths and increased case volumes.
- h) Case selection for the performance of primary (emergency) angioplasty must be rigorous. Criteria for the types of lesions appropriate for primary (emergency) angioplasty and for the selection for transfer for emergent aortocoronary bypass surgery are shown in Section E.2.
- i) There must be an ongoing program of outcomes analysis and formalized periodic case review. Institutions should participate in a three-to-six month period of implementation during which time development of a formalized primary PCI program is instituted that includes establishing standards, training staff, detailed logistic development, and creation of a quality assessment and error management system.

2) Patient Selection Guidelines

- a) Avoid intervention in hemodynamically stable patients with:
 - (1) Significant (60%) stenosis of an unprotected left main (LM) coronary artery upstream from an acute occlusion in the left coronary system that might be disrupted by the angioplasty catheter.
 - (2) Extremely long or angulated infarct-related lesions with TIMI grade 3 flow.
 - (3) Infarct-related lesions with TIMI grade 3 flow in stable patients with 3-vessel disease.
 - (4) Infarct-related lesions of small or secondary vessels.
 - (5) Lesions in other than the infarct artery.
- b) Transfer emergent aortocoronary bypass surgery patients after PCI of occluded vessels if high-grade residual left main or multi-vessel coronary disease and clinical or hemodynamic instability are present, preferably with intra-aortic balloon pump support.

Response: Not applicable. The proposed project is for a new diagnostic cardiac catheterization service.

8. In 2011, the ACCF/AHA/SCAI Writing Committee determined that elective PCI might be considered in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection. Hospitals with diagnostic laboratories that have been approved to perform primary PCI without on-site open heart surgical backup under the 2005 ACC/AHA Guideline Update for PCI must obtain a *Certificate of Need* in order to upgrade to designation as providing elective PCI without on-site cardiac surgery backup. The following standards must be met:

a. The applicant has performed a minimum of 250 diagnostic catheterization procedures in the most recent year and can reasonably demonstrate that it will perform a minimum of 500 diagnostic catheterizations annually within three years of the initiation of services.

b. All existing comprehensive cardiac catheterization facilities in the service area performed a minimum of 300 therapeutic catheterizations in the most recent year.

c. An applicant must project that the proposed service will perform a minimum of 300 therapeutic catheterization procedures annually within three years of initiation of services, without reducing the cardiac catheterizations performed at existing comprehensive catheterization programs in the service area below the minimum thresholds of 300 therapeutic procedures and 500 diagnostic procedures at each facility.

d. The physicians must be experienced interventionalists who perform a minimum of 75 elective PCI cases per year and preferably at least 11 PCI procedures for STEMI each year. Ideally, operators with an annual procedure volume of fewer than 75 procedures per year should only work at institutions with an activity level of more than 600 procedures per year. Operators who perform fewer than 75 procedures per year should develop a defined mentoring relationship with a highly experienced operator who has an annual procedural volume of at least 150 procedures.

e. For catheterization labs in facilities without on-site surgical backup, there must be formalized written protocols in place for immediate (within one hour by appropriate transportation) and efficient transfer of patients to the nearest cardiac surgical facility that are reviewed and tested on a regular basis. Applicants must provide documentation of an agreement with an ambulance or transport service capable of advanced life support and intra aortic balloon pump and that guarantees a thirty (30) minute or less response time from contact.

f. The catheterization laboratory must be well-equipped, with optimal imaging systems, resuscitative equipment, intra-aortic balloon pump (IABP) support, and must be well-stocked with a broad array of interventional equipment.

g. The nursing and technical catheterization laboratory staff must be experienced in handling acutely ill patients and comfortable with interventional equipment. They must have acquired experience in dedicated interventional laboratories at a surgical center. They participate in a 24-hour, 365-day call schedule.

h. The cardiac care unit nurses must be adept in hemodynamic monitoring and IABP management.

i. Applicants must offer primary percutaneous coronary intervention (PCI) services and procedures twenty-four (24) hours a day, seven (7) days a week, three hundred and sixty five (365) days a year.

j. Applicants must provide documentation to show that guidelines for determining patients appropriate for PCI procedures in a setting without on-site open heart backup

consistent with standards of the American College of Cardiology have been developed and will be maintained.

k. Applicants must agree to participate in the South Carolina STEMI Mission Lifeline Program.

l. Every therapeutic catheterization program should operate a quality-improvement program that routinely:

- 1) reviews quality and outcomes of the entire program;
- 2) reviews results of individual operators;
- 3) includes risk adjustment;
- 4) provides peer review of difficult or complicated cases; and
- 5) performs random case reviews.

m. Every PCI program should participate in a regional or national PCI registry for the purpose of benchmarking its outcomes against current national norms.

n. An applicant for provision of elective PCI without on-site surgical backup agrees, as a condition for issuance of its Certificate of Need for such service, to discontinue therapeutic catheterization services and surrender the Certificate of Need for that service if they have failed to achieve 200 therapeutic catheterizations per year by the expiration of the first three years of operation of such services.

Response: Not applicable. The proposed project is for a new diagnostic cardiac catheterization service.

Comprehensive Catheterization Services

9. Comprehensive catheterization laboratories, which perform diagnostic catheterizations, PCI and other therapeutic procedures, shall only be located in hospitals that provide open heart surgery. New comprehensive cardiac catheterization services shall be approved only if the following conditions are met:

- a. All existing comprehensive cardiac catheterization facilities in the service area performed a minimum of 300 therapeutic catheterizations in the most recent year; and
- b. An applicant must project that the proposed service will perform a minimum of 300 therapeutic catheterization procedures annually within three years of initiation of services, without reducing the therapeutic catheterizations performed at existing comprehensive catheterization programs in the service area below 300 procedures at each facility.

Response: Not applicable. The proposed project is for a new diagnostic cardiac catheterization service.

10. To prevent the unnecessary duplication of comprehensive cardiac catheterization services, expansion of an existing comprehensive cardiac catheterization service shall be approved only if the service has operated at a minimum use rate of 80% of capacity (960 equivalents per lab) for each of the past two years and can project a minimum of 600 equivalents per year on the additional equipment within three years of its implementation. The 600 equivalents may consist of a combination of diagnostic and therapeutic procedures.

Response: Not applicable. The proposed project is for a new diagnostic cardiac catheterization service.

Pediatric Catheterization Services

11. New pediatric cardiac catheterization services shall be approved only if the following conditions are met:

- a. All existing facilities have performed at a combined use rate of 80% of capacity for the most recent year; and
- b. An applicant must project that the proposed service will perform a minimum of 500 diagnostic equivalent procedures annually within three years of initiation of services.

Response: Not applicable. The proposed project is for a new diagnostic cardiac catheterization service.

12. Expansion of an existing pediatric cardiac catheterization service shall only be approved if the service has operated at a minimum use rate of 80% of capacity (960 equivalents) for each of the past two years and can project a minimum of 500 equivalents per year on the additional equipment within three years of its implementation.

Response: Not applicable. The proposed project is for a new diagnostic cardiac catheterization service.

13. Documentation of need for the proposed service:

- a. The applicant shall provide epidemiologic evidence of the incidence and prevalence of conditions for which diagnostic, comprehensive or pediatric catheterization is appropriate within the proposed service area, to include the number of potential candidates for these procedures;

Response: According to the American Heart Association's *Heart Disease and Stroke Statistics – 2015 Update (Attachment H)*, South Carolina's cardiovascular disease (CVD) death rate ranks 39th highest in the nation (the rate is 253.8 in South Carolina, compared to 234.5 for the United States). According to the South Carolina DHEC's *The Burden of Heart Disease and Stroke in South Carolina, 2010 Edition*, a total of 12,223 people in South Carolina died of CVD in 2008 (*Attachment H*). CVD causes over 30 percent of all deaths in South Carolina, making it the leading cause of death. African-Americans are particularly hard-hit by CVD and carry a disproportionate burden of CVD deaths, hospitalizations and risk factors. In the most recent year, more than half of ECMC's inpatient discharges originated from Charleston County, which has a minority population (29.5 percent) slightly higher than the State (28.5 percent) according to South Carolina DHEC's 2013 edition of the *Coordinated Chronic Disease Fact Sheet for Charleston County (Attachment H)*. The increased minority population in Charleston County indicates a need for additional cardiac services for the service population. It's also important to note that the prevalence of heart disease in Charleston County (4.7 percent) is comparable to the state of South Carolina (4.9 percent). The addition of diagnostic catheterization services at ECMC will help to address the high mortality rate from heart disease in the area and increase access.

As mentioned, ECMC is developing the proposed project with support from the MUSC Division of Cardiology (please refer to *Attachment F* for the numerous letters of support from MUSC). It's expected that a portion of the diagnostic catheterization patients at MUSC will shift to ECMC for services. The following figure shows historical utilization for MUSC's diagnostic cardiac catheterization service by the eight tri-county sub areas as defined by MUSC.

Figure 22
MUSC Defined Service Area
Diagnostic Cardiac Catheterization, 2012-2014

Market Area	2012	2013	2014	Change, 2012-2014	
				Percent	Number
East Cooper	112	123	128	14.3%	16
Moncks Corner	35	34	33	-5.7%	(2)
North Charleston	170	171	196	15.3%	26
Outside Tri-County	1,041	987	991	-4.8%	(50)
Peninsula Charleston	41	41	41	0.0%	-
Sea Islands	95	92	74	-22.1%	(21)
Summerville	92	95	89	-3.3%	(3)
West Ashley	87	76	88	1.1%	1
Other	74	73	57	-23.0%	(17)
Total	1,747	1,692	1,697	-2.9%	(50)

Source: Internal data from MUSC.

b. The applicant shall project the utilization of the service and the effect of its projected utilization on other cardiac catheterization services within its service area, to include:

- 1) The number of patients of the applicant hospital who were referred to other cardiac catheterization services in the preceding three years and the number of those patients who could have been served by the proposed service;

Response: Since ECMC does not currently offer advanced cardiac services, including diagnostic cardiac catheterization, patients and transport services typically bypass the hospital for this type of service. Despite this, there is a notable number of patients who could have potentially benefitted from increased access to services at ECMC, in closer proximity to their homes. In 2013-2015, there were 103, 90 and 88 patients, respectively, who were discharged from ECMC and transferred to another facility for cardiovascular services.

As mentioned, ECMC is developing the proposed project with support from the MUSC Division of Cardiology (please refer to **Attachment F** for the numerous letters of support from MUSC). It's expected that a portion of the diagnostic catheterization patients at MUSC will shift to ECMC for services. The following figure shows historical utilization for MUSC's diagnostic cardiac catheterization service by the eight tri-county sub areas as defined by MUSC.

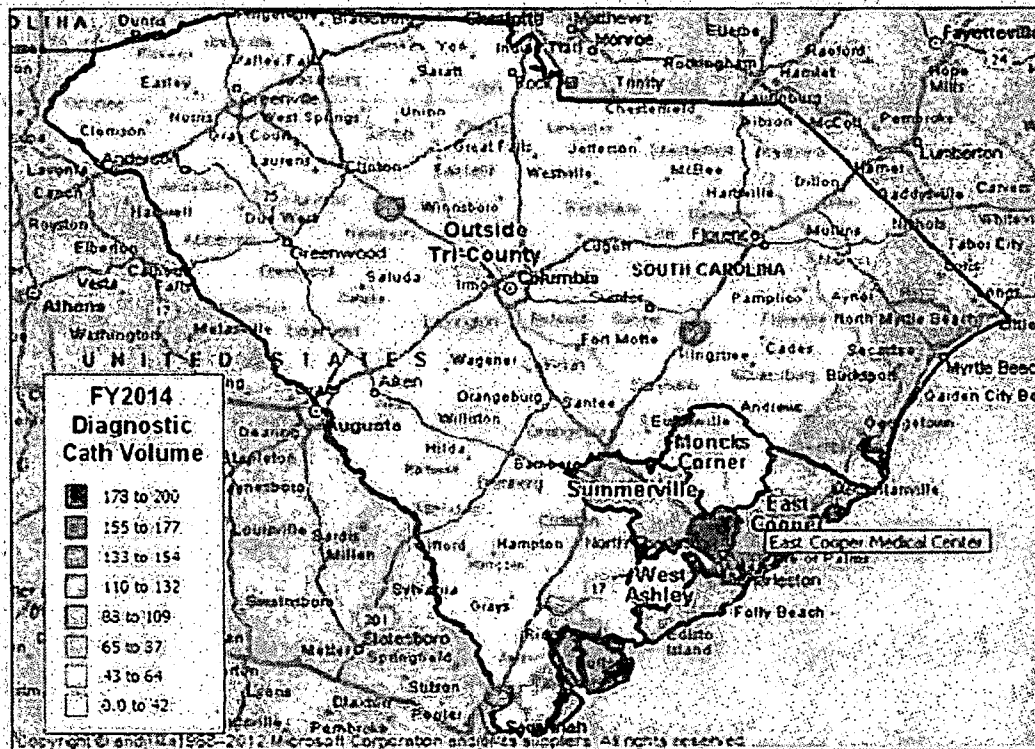
Figure 23
MUSC Defined Service Area
Diagnostic Cardiac Catheterization, 2012-2014

Market Area	2012	2013	2014	Change, 2012-2014	
				Percent	Number
East Cooper	112	123	128	14.3%	16
Moncks Corner	35	34	33	-5.7%	(2)
North Charleston	170	171	196	15.3%	26
Outside Tri-County	1,041	987	991	-4.8%	(50)
Peninsula Charleston	41	41	41	0.0%	-
Sea Islands	95	92	74	-22.1%	(21)
Summerville	92	95	89	-3.3%	(3)
West Ashley	87	76	88	1.1%	1
Other	74	73	57	-23.0%	(17)
Total	1,747	1,692	1,697	-2.9%	(50)

Source: Internal data from MUSC.

MUSC's diagnostic catheterization volume was 1,697 patients in 2014. This volume is also depicted in the following map.

Figure 24
MUSC Defined Service Area
Diagnostic Cardiac Catheterization, 2014



It's assumed that various 2014 volume percentages from each market area will shift from MUSC to ECMC for adult diagnostic catheterization and volumes will remain flat. However, since MUSC is an academic medical center providing tertiary and quaternary care, it's assumed that only certain adult diagnostic catheterization inpatient cases will shift to ECMC, specifically MS-DRGs 286 Circulatory Disorders Except AMI, with Cardiac Cath w MC, and 287 Circulatory Disorders Except AMI, with Cardiac Cath w/o. Based on MUSC's diagnostic catheterization volume for 2014, these assumptions result in a shift of 514 procedures, as shown in the following figure. Refer to **Attachment G** for more detail.

Figure 25
East Cooper Medical Center
Projected Diagnostic Cardiac
Catheterization Shift from MUSC, 2014

Tri Cty Sub Area	FY2014 Procedures				Percent	To East Cooper		
	Inpatient*	Outpatient	Total	% Total		Inpatient*	Outpatient	Total
East Cooper	23	75	98	7.6%	90%	21	68	89
Moncks Corner	7	16	23	1.8%	90%	6	14	20
North Charleston	45	95	140	10.8%	90%	41	86	127
Outside Tri-County	144	645	789	60.9%	Varied	34	168	202
Peninsula Charleston	10	17	27	2.1%	0%	-	-	-
Sea Islands	13	36	49	3.8%	45%	6	16	22
Summerville	14	50	64	4.9%	50%	7	25	32
West Ashley	17	47	64	4.9%	35%	6	16	22
Other	11	31	42	3.2%	0%	-	-	-
Total	284	1,012	1,296			121	393	514

Source: Internal Data from MUSC.

*Note-Inpatient includes only MSORs 286 and 287.

If ECMC is granted diagnostic catheterization capabilities, these patients would be treated at ECMC close to home rather than having to be transferred elsewhere.

- 2) The number of additional patients, if any, who will be generated through changes in referral patterns, recruitment of specific physicians, or other changes in circumstances. The applicant shall document the services, if any, from which these patients will be drawn; and

Response: As previously discussed, the South Carolina floods were a poignant reminder of the need to have advanced community-based services deployed into population centers. ECMC was originally established for situations such as this. The leadership of ECMC is committed to expanding its service offering to ensure that residents east of the Cooper River have access to the necessary medical services, regardless of the situation. With this in mind and in order to better serve its patients, ECMC proposes the addition of diagnostic cardiac catheterization services with support from the MUSC Division of Cardiology. It's expected that a portion of the diagnostic catheterization patients at MUSC will shift to ECMC for services. The existing patient population at MUSC can fully support the proposed project with no impact on other providers in the service area.

- 3) Existing and projected patient origin information and referral patterns for each cardiac catheterization service serving patients from the area proposed to be served shall be provided.

Response: As stated above, the referral patterns for cardiovascular services in the service area are not expected to change as a result of the proposed project, as the patients redirected from MUSC. The projected shift in cases from MUSC will be more than adequate to support the proposed program at ECMC without adversely affecting other providers. The following figure shows historical utilization for MUSC's diagnostic cardiac catheterization service by the eight tri-county sub areas as defined by MUSC.

Figure 26
MUSC Defined Service Area
Diagnostic Cardiac Catheterization, 2012-2014

Market Area	2012	2013	2014	Change, 2012-2014	
				Percent	Number
East Cooper	112	123	128	14.3%	16
Moncks Corner	35	34	33	-5.7%	(2)
North Charleston	170	171	196	15.3%	26
Outside Tri-County	1,041	987	991	-4.8%	(50)
Peninsula Charleston	41	41	41	0.0%	-
Sea Islands	95	92	74	-22.1%	(21)
Summerville	92	95	89	-3.3%	(3)
West Ashley	87	76	88	1.1%	1
Other	74	73	57	-23.0%	(17)
Total	1,747	1,692	1,697	-2.9%	(50)

Source: Internal data from MUSC.

It's assumed that various 2014 volume percentages from each market area will shift from MUSC to ECMC for adult diagnostic catheterization and volumes will remain flat. However, since MUSC is an academic medical center providing tertiary and quaternary care, it's assumed that only certain adult diagnostic catheterization inpatient cases will shift to ECMC, specifically MS-DRGs 286 Circulatory Disorders Except AMI, with Cardiac Cath w MC and 287 Circulatory Disorders Except AMI, with Cardiac Cath w/o. Based on MUSC's diagnostic catheterization volume for 2014, these assumptions result in a shift of 514 procedures, as shown in the following figure. Refer to **Attachment G** for more detail.

Figure 27
East Cooper Medical Center
Projected Diagnostic Cardiac
Catheterization Shift from MUSC, 2014

Tri-City Sub Area	FY2014 Procedures				Percent	To East Cooper		
	Inpatient*	Outpatient	Total	% Total		Inpatient*	Outpatient	Total
East Cooper	23	75	98	7.6%	90%	21	68	89
Moncks Corner	7	16	23	1.8%	90%	6	14	20
North Charleston	45	95	140	10.8%	90%	41	86	127
Outside Tri-County	144	645	789	60.9%	Varied	34	168	202
Peninsula Charleston	10	17	27	2.1%	0%	-	-	-
Sea Islands	13	38	49	3.8%	45%	6	16	22
Summerville	14	50	64	4.9%	50%	7	25	32
West Ashley	17	47	64	4.9%	35%	6	16	22
Other	11	31	42	3.2%	0%	-	-	-
Total	284	1,012	1,296			121	393	514

Source: Internal Data from MUSC.

*Note: Inpatient includes only MS-DRGs 286 and 287.

14. Both fixed and mobile diagnostic cardiac catheterization laboratories must provide a written agreement with at least one hospital providing open heart surgery, which states specified arrangements for referral and transfer of patients, to include:

- a. Criteria for referral of patients on both a routine and an emergency back-up basis;**
- b. Regular communications between cardiologists performing catheterizations and surgeons to whom patients are referred;**
- c. Acceptability of diagnostic results from the cardiac catheterization service to the receiving surgical service to the greatest extent possible to prevent duplication of services; and**
- d. Development of linkages with the receiving institution's peer review mechanism.**

Response: Through the proposed project, East Cooper Medical Center has a transfer agreement specific to cardiac catheterization with the Medical University of South Carolina; please refer to **Attachment D** for a signed letter regarding the transfer of cardiac catheterization patients.

15. The application shall include standards adopted or to be adopted by the service, consistent with current medical practice as published by clinical professional organizations, such as the American College of Cardiology or the American Heart Association, defining high-risk procedures and patients who, because of their conditions, are at high risk. For diagnostic catheterization laboratories, this description of patient selection criteria shall include referral arrangements for high-risk patients. For comprehensive laboratories, these high-risk procedures should only be performed with open heart surgery back-up. The cardiac team must be promptly available and capable of successfully operating on unstable acute ischemic patients in an emergency setting.

Response: The proposed cardiac catheterization lab at ECMC will adopt standards, similar to those already adopted by MUSC, that are consistent with current medical practice as published by clinical professional organizations, such as the American College of Cardiology or the American Heart Association, and will ensure that the description of the patient selection criteria includes referral arrangements for high-risk patients.

16. Cardiac catheterization services should be staffed by a minimum of two physicians licensed by the State of South Carolina who possess the qualifications specified by the governing body of the facility. Protocols should be established that govern initial and continuing granting of clinical staff privileges to physicians to perform diagnostic, therapeutic and/or pediatric catheterizations. Applicants must provide documentation that one (1) or more interventional cardiologist(s) will be required to respond to a call in a timely manner consistent with the hospital Medical Staff bylaws and clinical indications. In addition, standards should be established to assure that each physician using the service would be involved in adequate numbers of applicable types of cardiac catheterization procedures to maintain proficiency.

Response: The proposed cardiac catheterization lab at ECMC will be staffed with at least two physicians licensed by South Carolina who possess the qualifications specified by the governing body of the facility. ECMC will be collaborating with MUSC for the proposed project, and the required protocols and standards for the proposed lab will be consistent with those currently in place at MUSC. Eric R. Powers, M.D., Daniel H. Steinberg, M.D., Thomas M. Todoran, and Valerian L. Fernandes, M.D., are four MUSC cardiologists who will staff the proposed diagnostic catheterization laboratory, and all are Board certified cardiologists with extensive experience. Please refer to **Attachment I** for their resumes.

17. Applicants must agree to report annually the data on number of PCI procedures, type, and outcomes to the National Cardiovascular Data Registry Cat/PCI registry.

a. Applicants must agree to provide accurate and timely data, including outcomes analysis and formal periodic external and internal case review by appropriate entities.

b. The Department encourages all applicants and providers to share their outcomes data with appropriate registries and research studies designed to improve the quality of cardiac care.

Response: ECMC agrees to comply with this standard.

Summary

The proposed project will increase access for patients in need of diagnostic cardiac catheterization services in a cost effective manner. Through the project, ECMC will be able to more effectively serve its service area residents and patients and their families will benefit from the increased convenience of seeking care at a location closer to home. Patients will be able to receive treatment at a more convenient location while staying at a hospital they have come to know and trust, and patients will benefit from the experience of MUSC, which is known for its comprehensive cardiology services.

- (12) Discuss alternative facilities and/or services considered including the advantages and disadvantages of each alternative. Include a statement as to why this project alternative was adopted.

Response: The project presented in this application is the most appropriate solution to address the need for diagnostic cardiac catheterization services at East Cooper Medical Center. The alternatives considered by ECMC are discussed below.

1. Maintain the Status Quo—Under the status quo, ECMC won't be able to increase access for patients in need of diagnostic cardiac catheterization services. Patients and their families will have to seek care further from home to receive treatment and access would not be enhanced.

2. Offer Diagnostic Cardiac Catheterization at ECMC—The proposed project will increase access for patients in need of diagnostic cardiac catheterization services in a cost effective manner. Through the project, ECMC will be able to more effectively serve its service area residents and patients and their families will benefit from the increased convenience of seeking care at a location closer to home. Residents east of the Cooper River will have enhanced access to diagnostic cardiac catheterization services. Patients will be able to receive treatment at a more convenient location while staying at a hospital they have come to know and trust, and patients will benefit from the experience of MUSC, which is known for its comprehensive cardiology services.

- (13) Discuss any serious problems, such as costs, availability, or accessibility in obtaining care of the type proposed, experienced by patients in the absence of this project.

Response: The South Carolina floods were a poignant reminder of the need to have advanced community-based services deployed into population centers. ECMC was originally established for situations such as this. The leadership of ECMC is committed to expanding its service offering to ensure that residents east of the Cooper River have access to the necessary medical services, regardless of the situation. Establishing an expanded network of community based resources such as diagnostic catheterization services will enhance the state's readiness and mitigate the risk of natural disasters for the residents of South Carolina.

The proposed project will allow ECMC to enhance access for diagnostic catheterization services for service area residents. The delivery of care will be enhanced by making this service available in a convenient, accessible location. Additionally, patients will benefit from the expertise and knowledge of physicians at MUSC, which will have a positive impact on the quality of services offered to service area residents.

- (14) Where a project affects an increase or decrease in bed capacity, provide annual occupancy rates for the facility based on licensed beds, for the past three years by category (i.e. general acute, psychiatric, obstetric, nursing home, etc.)

Response: The proposed project does not affect bed capacity.

- (15) Identify the method of financing the cost of the project, including the start-up costs. Provide documentation that the applicant can obtain such financing. Alternative sources and/or methods of financing should be identified and the method chosen demonstrated to be the most feasible option.

Response: The proposed project will be funded with existing case reserves by Tenet Healthcare, the parent company of East Cooper Medical Center. A letter from Wes James, Chief Financial Officer, Southern Region at Tenet Healthcare, confirming the availability of funds, is provided as Attachment J.

- (16) For an addition to an existing facility or service, provide a current annual budget and at least a three fiscal year projected budget for both the overall facility and the proposed project on forms provided by the department. The projections must be developed by an accountant. For a new facility or service, provide a projected annual budget for not less than three fiscal years following the completion of the proposed project on forms provided by the department. The projections must be developed by an accountant. These budgets must at a minimum include how proposed charges, proposed cost of service, utilization, depreciation, reimbursement rates and contractual adjustments were calculated. All assumptions used must be shown.

Response: The budget and projections for the first three years of operation after the proposed project is implemented at East Cooper Medical Center are provided as **Attachment K**. The assumptions to the financial projections include proposed charges, proposed cost of service, utilization, depreciation, and other key variables. Additionally, a letter from Brandon Williams, Chief Financial Officer at East Cooper Medical Center, attesting to the accuracy of the assumptions and calculations used in these projections is provided as part of **Attachment K**.

- (17) Provide a list of proposed charges for the project. The charges provided may be used for comparison with the average charges in the final completion report as required in Section 607.3.b

Response: The projected charges associated with the proposed project will be based on ECMC's historical experience as well as MUSC's historical experience, and will be comparable to those of other facilities in the area. The average charge per procedure is projected to be \$45,550 and \$24,163 for inpatients and outpatients, respectively, for Year One.

- (18) Document that the proposed project is economically feasible, both immediately and long-term. In the case of existing facilities, what impact will the proposed project have on patient charges and cost per unit of service?

Response: As presented in the financial projections for the first three years of operation of the proposed project, this project is financially feasible. ECMC will continue to operate in an efficient manner, and the proposed project is a cost effective option.

- (19) State how the project will foster cost containment and improve quality of care through the promotion of such services as ambulatory and home health care, preventive health care, promotion of shared services, economies of scale, and design and construction economies.

Response: The South Carolina floods were a poignant reminder of the need to have advanced community-based services deployed into population centers. ECMC was originally established for situations such as this. The leadership of ECMC is committed to expanding its service offering to ensure that residents east of the Cooper River have access to the necessary medical services, regardless of the situation. Establishing an expanded network of community based resources, including diagnostic catheterization services, will enhance the state's readiness and mitigate the risk of natural disasters for the residents of South Carolina.

The proposed project will also have a positive impact on quality of care by improving access to service area residents. By providing diagnostic cardiac catheterization services at ECMC, the hospital will be able to provide state-of-the-art cardiology resources closer to its service area patients. Patients and their families will benefit from the increased convenience of seeking care at a location closer to home. Through the project, patients will be able to receive treatment at a more convenient location while staying at a hospital they have come to know and trust. ECMC strives to provide state-of-the-art care with advanced treatment options in a patient-friendly environment.

Additionally, ECMC is developing the proposed project with support from the MUSC Division of Cardiology, and patients will benefit from the experience of an academic medical center known for its comprehensive cardiology services. Please refer to **Attachment F** for the numerous letters of support from MUSC. Patients will benefit from the expertise and knowledge of physicians at MUSC, which will have a positive impact on the quality of services offered to service area residents.

The existing interventional radiology laboratory will be used for the proposed project, serving as both a diagnostic catheterization and interventional radiology laboratory. As such, no construction or renovations are necessary for the proposed project. After some minor equipment related modifications, the existing interventional radiology equipment will have capabilities related to both diagnostic catheterization and interventional radiology (**Attachment B**). Please refer to **Attachment B** for a letter from Eric R. Powers, M.D., Director of the Acute Coronary Syndrome Center and Director of the Heart and Vascular Service Line at MUSC, regarding the equipment. The proposed project fosters cost containment by using existing equipment and space at ECMC rather than incur the high costs of construction, renovation or equipment for a separate, new laboratory and equipment. The proposed project is a cost effective way to increase access to diagnostic cardiac catheterization services for area residents, and economies of scale will be achieved.

- (20) In the case of projects involving additional long-term care beds, discuss how the plans of other agencies, organizations, or programs responsible for providing and financing long-term care have been considered.

Response: The proposed project does not involve long-term beds.

- (21) Provide a three-year projected manpower budget in full-time equivalents (FTE's) detailing the existing and proposed nursing, other professional, and non-professional personnel required for the staffing of the new project. Include the name of the Nurse Supervisor or Director, if available.

Response: The manpower budget is included in Attachment K. ECMC will be collaborating with MUSC for the proposed project. Eric R. Powers, M.D., Daniel H. Steinberg, M.D., Thomas M. Todoran, and Valerian L. Fernandes, M.D., are four MUSC cardiologists who will staff the proposed diagnostic catheterization laboratory, and all are Board-certified cardiologists with extensive experience. Please refer to Attachment I for their resumes.

- (22) Provide the number of existing and proposed medical staff by specialty, to include physicians and dentists employed by, or with admission privileges to, the facility. Include the name of the Chief of the Medical Staff, if available.

Response: See Attachment 1 for a roster of the East Cooper Medical Center Medical Staff. The Chief of Medical Staff is Matthew Davis, MD.

- (23) Indicate those physicians who have expressed a willingness to utilize the proposed services or to refer patients to the facility for the provision of services.

Response: Letters of support for the project from the community and physicians are included in Attachment F. Additional letters have been mailed to DHEC under separate cover.

- (24) Discuss the availability of health manpower resources for the provision of the proposed services, including the contemplated program and plan for recruiting and training personnel.

Response: ECMC will be collaborating with MUSC for the proposed project. Eric R. Powers, M.D., Daniel H. Steinberg, M.D., Thomas M. Todoran, and Valerian L. Fernandes, M.D., are four MUSC cardiologists who will staff the proposed diagnostic catheterization laboratory, and all are Board-certified cardiologists with extensive experience. Please refer to **Attachment I** for their resumes. ECMC does not anticipate any difficulty in recruiting the other personnel required to staff the proposed project. ECMC will utilize recruitment tools such as newspaper advertisements and attendance at job fairs.

- (25) Describe the previous experience of the applicant in the proposed health care field. If the applicant has no prior experience, specify the anticipated sources of technical assistance, either from specific individuals or organizations.

Response: ECMC, part of Tenet Healthcare, aims to put the patient first, and everything is designed to provide the patient with more successful procedures, faster recovery times and a better quality of life. The hospital combines expertise with compassionate and detail-oriented care; ECMC has found the perfect blend so that patients leave the hospital in better health and with smiles on their faces.

In 1985, several physicians practicing east of the Cooper River recognized the difficulty their patients and neighbors experienced accessing hospital care. The bridges were unstable and the travel time to reach a hospital was greater than an hour. Foreseeing major population growth in the area, these doctors proposed the idea to build a full-service medical facility with the primary mission to care for those residents who could not make it into downtown Charleston. The idea was shared with Mayor Johnnie Dodds II, and in January 1986 the first hospital east of the Cooper River opened. The original ECMC was a 100-bed hospital with 4 operating rooms and an Emergency Department. Since then, ECMC expanded to 130 acute care beds, and in 2010 moved into a new and larger facility to meet the needs of the growing community.

The South Carolina floods were a poignant reminder of the need to have advanced community-based services deployed into population centers. ECMC was originally established for situations such as this. The leadership of ECMC is committed to expanding its service offering to ensure that residents east of the Cooper River have access to the necessary medical services, regardless of the situation. Establishing an expanded network of community based resources will enhance the state's readiness and mitigate the risk of natural disasters for the residents of South Carolina.

Although ECMC was originally established for the residents east of the Cooper, the hospital's expanded scope of services, commitment to quality and safety, and outstanding team of caregivers has attracted patients from throughout the Lowcountry and beyond. Care is provided in a new, state-of-the-art facility that is rich in technology. 24-hour emergency care, women's services, diagnostic imaging and interventional services, orthopedics, sports medicine, adult and pediatric rehabilitation services, wound care and surgical care, including nationally recognized spine surgery and breast reconstruction surgery are all offered.

East Cooper Medical Center strives for excellence and is committed to delivering high-quality care. The facility has received numerous awards and accolades over the years recognizing the state-of-the-art care provided to the community. Most notably, ECMC was awarded nine Gold Seals of Approval from one of the nation's most respected health care organizations, the Joint Commission. This is more Gold Seals than any other South Carolina hospital, and is an example of the hospital's unwavering commitment to quality.

- (26) Discuss the impact of the project on the clinical training programs of health professional schools, particularly the extent to which these schools will have access to the services for training.

Response: Please refer to **Attachment L** for a list of institutions ECMC has affiliated agreements with to provide student rotations and internship programs for undergraduate and graduate students. ECMC provides clinical rotations for the students of these institutions to participate in hands on patient care and in many cases provides participating graduates with opportunities for employment at ECMC. These institutions will have access to cardiac catheterization services for training, if appropriate.

- (27) Provide documentation of policies and procedures to assure the quality of healthcare services by addressing patient safety and quality indicators, as applicable. Documents may include, but are not limited to, measures of patient care, patient safety, healthcare-acquired infections and the following of best practices established by recognized organizations. Applicable quality standards in the South Carolina Health Plan must be addressed.

Response: The following details ECMC's quality related standards. Please see **Attachment M** for ECMC's Quality and Safety Policies.

a. Accuracy of patient identification.

ECMC utilizes a patient safety policy which requires the use of ID bracelets that presents accurate patient identification. No care is administered if a patient does not have an ID bracelet.

b. Effectiveness of communication among caregivers.

Consistency of care will be guaranteed with effective verbal and written policies. Documented clinical indications and protocols will be verbally communicated between the clinical staff to ensure accuracy of tests and quality patient care.

c. Safety of using medications.

Safes or locked areas will be provided for all high alert medications and access will be limited to Physicians, RNs, RTs and other appropriate and fully trained clinical staff. Clinical manuals will be provided listing all drugs in stock. The manual will list all drug side effects, contraindications, dosing, and reversal protocols. Daily logs will be documented for all drugs administered to include patient name, dosage and any clinically observed reactions.

d. Reduce risk of health-care associated infections.

Universal Precautions will be used by all staff for delivery of care. Training and monitoring of all staff will be conducted.

e. Accurately and completely reconcile medications across continuum of care.

Medication administration will be documented and monitored appropriately. Patients' charts will accurately reflect their medications to include date, medication prescribed, dosage, and the amount provided. All of this information is reviewed prior to administering medications.

f. Reduce the risk of patient harm resulting from falls.

All installed alarm systems will be tested for effectiveness and operational accuracy at least once a month by the monitoring company. An intercom system is available to alert designated on-site staff of the appropriate emergency code if needed. Staff will be trained in emergency protocols.

g. Reduce the risk of influenza and pneumococcal disease in institutionalized older adults.

All staff are encouraged to receive annual flu and pneumonia vaccines.

h. Reduce the risk of surgical fires.

The proposed project involves diagnostic cardiac catheterization. This standard is not applicable.

i. Implementation of applicable National Patient Safety Goals and associated requirements by components and practitioner sites.

ECMC implements applicable National Patient Safety Goals and associated requirements as applicable.

j. Encourage patients' active involvement in their own care as a patient safety strategy.

All patients are encouraged to actively participate in their care.

k. Prevent health care-associated pressure ulcers (decubitus ulcers).

ECMC implements appropriate protocols to prevent health care-associated pressure ulcers.

I. The organization identifies safety risks inherent in its patient population.

Please see **Attachment M** for a copy of the patient safety policies and procedures that are followed by ECMC. These policies and procedures confirm ECMC's commitment to safety and quality of care issues. These same policies will apply to the proposed project. Also included in **Attachment M** are policies currently followed by MUSC related to cardiac catheterization services, and will be implemented by ECMC for the proposed project.

A discussion of deficiencies related to any of the foregoing, including complaints, cited by the SCDHEC Bureau of Health Facilities Regulation and/or Bureau of Certification within the past year. The applicant may provide additional information and discuss additional time spans if desired.

ECMC has no known citations by the SCDHEC Bureau of Health Facilities or the Bureau of Certification within the past year.

PART C: PROGRAMMATIC DOCUMENTS

Provide adequate programmatic documents in support of the various elements of the proposed project. These documents will include as appropriate:

(1) An Indigent Care Plan as required by the Board of Health and Environmental Control. It shall address at a minimum, the following:

- a. The existing and proposed admission and treatment policies of the facility or agency with regard to race, sex, creed, national origin, and ability to pay.**

Response: ECMC admits and provides treatment to all patients regardless of race, sex, creed, national origin, or ability to pay. Additionally, Tenet has developed a compact with uninsured patients, in which ECMC participates, that states the following:

- Patients without insurance will be treated fairly and with respect during and after their treatment, and regardless of their ability to pay for the services they receive.
- Tenet, including ECMC, will provide financial counseling to uninsured patients and offer them discounted pricing for services provided at rates equivalent to the hospital's current managed care rates, which are substantially discounted from retail or "gross" charges.
- All patients without insurance will be offered reasonable payments and payment schedules and will be billed at discounted local market rates.
- Tenet hospitals will not pursue legal action for non-payment of bills against any patient who is unemployed or without other significant income.

ECMC also provides emergency care without consideration of a person's ability to pay. ECMC, as the first provider of acute hospital care in Mount Pleasant, always has and will continue to provide uncompensated and indigent care to the citizens of Mount Pleasant and Charleston County, as well as the surrounding counties. These policies will remain unchanged as a result of the approval of this project. Please see **Attachment E** for ECMC's provision of patient care, patients rights and responsibilities and charity care policies as well as Tenet's compact with uninsured patients.

- b. The proposed admission and treatment policies of the facility or agency with respect to admission and care of indigent patients including those patients unable to pay at the time of admission and those whose benefits expire while in the care of the facility or agency.**

Response: Tenet has developed a compact with uninsured patients, in which ECMC participates, that states the following:

- Patients without insurance will be treated fairly and with respect during and after their treatment, and regardless of their ability to pay for the services they receive.
- Tenet, including ECMC, will provide financial counseling to uninsured patients and offer them discounted pricing for services provided at rates equivalent to the hospital's current managed care rates, which are substantially discounted from retail or "gross" charges.
- All patients without insurance will be offered reasonable payments and payment schedules and will be billed at discounted local market rates.
- Tenet hospitals will not pursue legal action for non-payment of bills against any patient who is unemployed or without other significant income.

ECMC also provides emergency care without consideration of a person's ability to pay. ECMC, as the first provider of acute hospital care in Mount Pleasant, always has and will continue to provide uncompensated and indigent care to the citizens of Mount Pleasant and Charleston County, as well as the surrounding counties. These policies will remain unchanged as a result of the approval of this project. Please see **Attachment E** for ECMC's provision of patient care, patients rights and responsibilities and charity care policies as well as Tenet's compact with uninsured patients.

- c. In existing facilities or agencies, provide the amount, in dollars and percent of gross revenues, that the facility or agency provided in indigent care during the past three fiscal years. NOTE: Indigent care does not include bad debt; contractual adjustments; or care which is reimbursed by a governmental program (Medicare, Medicaid, county indigent program), church, or philanthropic organization.

Response: ECMC is committed to providing needed health care to all patients regardless of ability to pay. In order to demonstrate the organization's commitment to providing indigent and charity care, the indigent care expenditures from 2013-2015 are shown in Figure 28.

Figure 28
2013-2015 Indigent Care

	2013	2014	2015
Indigent Care	\$3,372,946	\$3,690,664	\$2,414,496
Percent of Gross Revenue	0.76%	0.74%	0.48%

Source: Internal data.

- d. Provide the proposed amount of indigent care the facility or agency projects to provide during the existing fiscal year and next fiscal year. This projection should be expressed in both dollars and a percent of gross revenues.

Response: The amount of indigent care ECMC projects to provide during the existing and next fiscal year is as follows:

Figure 29
2016-2017 Projected Indigent Care

	2016	2017
Indigent Care	\$2,610,070	\$2,621,486
Percent of Gross Revenue	0.43%	0.39%

Source: Internal data.

- e. A discussion of why the above figures are adequate or inadequate for the needs of the community; the need of indigent care within the proposed service area; and any solutions, remedial plans or proposals by the facility or agency to better address the indigent care problem in the service area. Include any initiatives or undertakings the facility or agency has begun to address the indigent care problem in the proposed service area.

Response: ECMC has historically provided indigent care. As the first provider of acute care services in Mt. Pleasant, ECMC has consistently met the patient care needs of the population regardless of the patient's ability to pay. As previously discussed, Tenet has also developed a Compact with the Uninsured which ECMC also offers, that states all patients without insurance will be treated fairly and with respect during and after their treatment, and regardless of their ability to pay for the services they receive. This has been a commitment of the ECMC's management and Board of Directors and will remain as such with the proposed project. ECMC provides medical care and access to its facility without regard to race, sex, creed, national origin or the ability to pay.

- f. Describe any Board or Advisory Board established to implement or control the indigent problem at the facility or agency. Include the Board's functions, responsibilities, and limitations.

Response: Any changes to the policy must be approved by ECMC's Board of Directors.

- (2) A map of sufficiently large scale to be meaningful, indicating the location of the project site and its geographical area.

Response: A map indicating ECMC's location within Charleston County is provided as Attachment N.

- (3) A plot plan of the project site showing existing buildings, roads, parking areas, walks, service and entrance courts, existing utilities (electricity, telephone, water, railroads, sewer, gas, etc.) and other natural land features necessary for adequate analysis of site conditions.

Response: A site plan for ECMC, including the location of the proposed project, is provided as part of Attachment B.

- (4) A legal description of the project site indicating its physical characteristics and existing easements.

Response: The proposed project will take place on ECMC's existing site.

- (5) A square foot program of space and/or equipment elements, and scale drawings describing the existing space and proposed alterations and additions.

Response: Please see Attachment B for the project schematics.

- (6) Evidence that the site will be properly zoned for the proposed project.

Response: Not applicable. The proposed project is located within ECMC's existing hospital which is located on a site that is properly zoned.

- (7) Documentation from appropriate sources that utilities supplied to the site are adequate for the project to include electricity, gas, water, and sewerage.

Response: All of the required utilities currently provided to the site are sufficient to support the existing hospital services and the proposed project.

- (8) Endorsement from the community that the project is desirable. This may include but is not limited to members of the medical community, citizen's groups, and other health and social service disciplines in the community.

Response: Community support for the proposed project is evidenced by the letters of support provided in Attachment F. Additional letters have been mailed to DHEC under separate cover.

- (9) Documentation that the proposed project has been approved by the health facility's planning committee and governing body.

Response: Please see Attachment D for documentation that the proposed project has been approved by the ECMC Board of Directors.

- (10) For the facilities or services not licensed by the Department of Health and Environmental Control, provide documentation of coordination and support from the appropriate licensing agency.

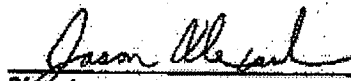
Response: Not applicable to this project.

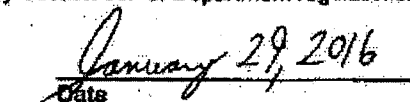
PART D: ASSURANCES

The applicant must furnish written assurance of each of the following where applicable:

The applicant assures to the following:

- (1) The applicant has a fee simple title to the proposed site which includes all necessary easements and rights of way sufficient to assure use and possession for the purpose of construction operation of the facility.
- (2) Final drawings and specifications for the project will be prepared by an architect/and or engineer who is legally regulated and licensed under laws of the state of South Carolina and approval of the same will be obtained from the Department.
- (3) The applicant will submit to the Department for prior approval, changes that substantially alter the scope of work, function, utilities, major items of equipment, safety or cost of the facility during the construction period.
- (4) The applicant will ensure that the project will be completed in accordance with all the Certificate of Need application regulations and guidelines.
- (5) The applicant will ensure that the project will be completed in accordance with approved plans and specifications by maintaining competent and adequate architectural and engineering services throughout the construction administration phase of the project. At the completion of the project, the architect of record will be required to issue a statement that to the best of his knowledge and belief, based upon available records, supplemental documents, and periodic observation of the work, the project was constructed according to those documents approved by the Department.
- (6) The facility will be operated and maintained in accordance with the standards prescribed by law and regulations for the maintenance and operation of such facilities.
- (7) The applicant understands the Certificate of Need shall become void at the end of the specified time period from the date of issuance unless otherwise extended under Chapter 6 of Department regulations.
- (8) The Department of Health and Environmental Control or its authorized representatives may at any time during the course of construction and upon completion of the project make an on-site inspection to check for compliance of the construction in accordance with the application for which the Certificate of Need was issued.
- (9) The controlling interest as specified shall not be sold or leased or otherwise disposed of without a Certificate of Need or exemption by the Department being received by the appropriate individual.
- (10) The applicant will provide the Department with a certified letter stating that the contractual agreement has been completed.
- (11) The applicant will provide the Department with written notice of the date that a new or expanded service has been implemented, completed or terminated.
- (12) The applicant will provide the Department with monthly progress reports and a final completion report as indicated which contain information required by Section 607 of Department regulations.


Signature


Date

Certificate of Need Application

East Cooper Medical Center
Diagnostic Catheterization Services

East Cooper CON 0067

AP & Opposition

NEXSEN|PRUET

Ralph W. Barbier
Member
Admitted in SC

April 20, 2016

VIA EMAIL & HAND DELIVERY

LEUBANKLW@dhec.sc.gov

Louis Eubank
Director, Certificate of Need (C.O.N.) Program
South Carolina Department of Health & Environmental Control
301 Gervais Street
Columbia, SC 29201

SCDHEC
Received
APR 20 2016
Certificate of Need Program

Re: East Cooper Medical Center
Certificate of Need Application for Diagnostic Catheterization Services
February 2016
S442.612

Charleston

Charlotte

Columbia

Greensboro

Greenville

Hilton Head

Myrtle Beach

Raleigh

Dear Mr. Eubank:

On behalf of our clients CareAlliance Health Services d/b/a Roper St. Francis Healthcare, Bon Secours St. Francis Hospital, and Roper St. Francis Berkeley Hospital (collectively from time to time "Roper St. Francis"), we respectfully request that Roper St. Francis be considered and notified as an "affected person" on the above referenced Certificate of Need application ("East Cooper Application"). This request is made pursuant to S.C. Code Ann. § 44-7-200 and § 44-7-210, and S.C. Code Regs. 61-15, Section 103(1). We further request that all notices be sent to me at the address provided and to Roper St. Francis, c/o Shannon Cantwell, 125 Doughty Street Suite 600, Charleston, SC 29403. This request includes, but is not limited to, notice of all DHEC staff decisions regarding the above referenced CON application.

Further, Roper St. Francis noted that on pages 20-21 of the East Cooper Application, East Cooper asserts that the Bon Secours St. Francis Hospital cath lab "is considered non-operational and requires a CON application if it is to be included in the inventory for catheterization laboratories. As such, it is excluded from the service area analysis." *East Cooper Application page 20-21.*

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E RBarbier@nexsenpruet.com
Nexsen Pruet, LLC
Attorneys and Counselors at Law

East Cooper CON 0354

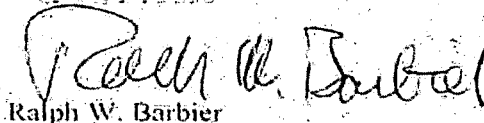
J02-069

Louis Eubank, Esq.
April 20, 2016
Page 2

East Cooper's position regarding the St. Francis cath lab is inconsistent with the applicable CON laws and the South Carolina Health Plan. In fact, East Cooper took this same position in 2010, which was rejected by the DHEC Staff. Please see documents attached as Exhibit 1. However, as we discussed on March 10 and again on April 19, 2016, Roper St. Francis has made the decision to open a new diagnostic catheterization laboratory at its hospital that is currently under development in Berkeley County. Roper St. Francis is preparing a CON application that will be filed with DHEC in the near future requesting approval for this cath lab at Roper St. Francis Berkeley Hospital. If Roper St. Francis' application is approved, Roper St. Francis intends to close its cath lab at Bon Secours St. Francis Hospital. This should allow DHEC to also approve the East Cooper Application consistent with the South Carolina Health Plan and the applicable CON laws. Until Roper St. Francis' CON application is approved, Roper St. Francis intends to continue to operate the cath lab at Bon Secours St. Francis Hospital.

Roper St. Francis does not intend to impede East Cooper's development of a cardiac cath lab at East Cooper Medical Center. Roper St. Francis believes that it will be in the best interest of the Lowcountry medical community for Roper St. Francis to open a cath lab at Roper St. Francis Berkeley Hospital in Berkeley County where a large portion of Roper St. Francis' patient population currently resides while also allowing East Cooper to open a cath lab that may serve its patient population. Accordingly, Roper St. Francis requests that DHEC consider both the Roper St. Francis CON Application and the East Cooper Application in the same review cycle so that both can be approved consistent with the South Carolina Health Plan and the CON laws.

Very truly yours,



Ralph W. Barbier

cc: Shannon Cantwell (via email)

EXHIBIT 1

85/26/2010 14:16

803-545-4579

DHEC

PAGE 01/09



C. Earl Murray, Commissioner

Promoting and protecting the health of the public and the environment

Fax Message

Date: 5-26-10Number of pages including cover sheet: 9*Please deliver this fax message***To:**Name: Ralph Barbina

Organization/Department: _____

Fax: _____

Phone: _____

From:Name: Beverly Brandt

Region/Bureau/Division/Section: _____

Health Facilities & Services Dev. (CON)Fax: 803-545-4579Phone: 803-545-4200**Subject/Comments:**

Confidentiality Notice

This transmission is intended only for the use of the individual or entity to which it is addressed and may contain information which is privileged and confidential. If the reader of this message is not the intended recipient, you are hereby notified that any disclosure, distribution, or copying of this information is strictly prohibited. If you received this transmission in error, please notify the sender immediately by calling the above telephone number.

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

DHEC 0504 (04/2008)

www.scdhec.gov

East Cooper CON 0357

J02-072

05/26/2010 14:16 803-545-4579

DHEC

PAGE 02/09

1005208

NEXSEN|PRUET

Ralph W. Barbier
Member
Admitted in SC

May 14, 2010

VIA EMAIL to Beverly Brandt

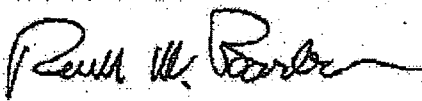
Mr. Jody M. Hamm
FOI Coordinator
SC Department of Health and Environmental Control
Freedom of Information Department
2600 Bull Street
Columbia, SC 29201

Re: East Cooper Regional Medical Center

Dear Mr. Hamm:

Pursuant to the Freedom of Information Act SC Code Ann. § 30-4-10 et seq., I hereby request copies of all documents in the Department's possession, including correspondence, regarding the addition of cardiac catheterization services by East Cooper Regional Medical Center. Please call me when available, and we will send a courier. If you have any questions, please contact me. Thank you for your attention to this matter.

Very truly yours,


Ralph W. Barbier

Charleston
Charleston
Columbia
Greenville
Greenville
Hilton Head
Myrtle Beach

1441 Main Street
Suite 1500 (21201)
PO Drawer 2402
Columbia, SC 29202
www.nexsenpruet.com

T 803.540.2004
F 803.263.8277
E RBarbier@nexsenpruet.com
Nathan Paul Adams (Kemper, LLC)
Attorneys and Counselors at Law

NPCOL1:1006853.1-17 (RWB), 020520-00120

East Cooper CON 0358

J02-073

05/26/2010 14:16

803-545-4579

DHEC

PAGE 03/09

(5/18/2010) Les Shelton - RE: JAR Question

Page 1

From: "Ray, Evan" <Evan.Ray@tenethealth.com>
 To: "Les Shelton" <SHELTOLW@dhec.sc.gov>
 CC: "Beverly Brandt" <BRANDTBA@dhec.sc.gov>, "Misty Hallman" <HALLMAMD@dhec...
 Date: 5/8/2010 3:18 PM
 Subject: RE: JAR Question

Thanks Les, I look forward to hearing your feedback.

Thanks again for your help.

Evan Ray, FACHE
 Chief Operating Officer

East Cooper Medical Center
 2000 Hospital Drive
 Mount Pleasant, SC 29464
 843-418-8212 office
 843-418-6886 fax
 843-469-9448 mobile
 evan.ray@tenethealth.com

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-----Original Message-----

From: Les Shelton [mailto:SHELTOLW@dhec.sc.gov]
 Sent: Thursday, May 06, 2010 2:59 PM
 To: Ray, Evan
 Cc: Beverly Brandt; Misty Hallman; Sallie Harrell; Lisa Sanders; Christopher Ward; Fatimah Wilson
 Subject: RE: JAR Question

Mr. Ray:

St. Francis last reported utilization of 21 cases in 2006; presumably it was shuttered mid-year. The 2006 utilization of 98 cases and 2004 utilization of 111 cases indicate that it was significantly below capacity long before 2006 (the highest utilization this century was 304 cases back in 2000). I inquired last year and they indicated an intent to bring the cath lab back on-line, although they weren't firm on a date. I just called and left a message seeking an update on the status.

We do not have the ability to "close" the lab and remove it from the inventory. However, given that it has been out of operation for more than 3 years, it is certainly a fair question to ask whether it should be considered in the need calculations. We don't want to create a scenario where stockpiling an unused service unduly impacts the service area.

This is a question we are going to have to discuss internally, so I will have to get back to you with a response. If you have any questions, please contact me or Misty at (803) 545-4200.

Les Shelton
 Division of Planning & CON
 SC DHEC

East Cooper CON 0359

J02-074

05/26/2010 14:16

803-545-4579

DHEC

PAGE 04/05

(5/18/2010) Les Shelton - RE: JAR Question

Page 2

>>> "Ray, Evan" <Evan.Ray@tenethealth.com> 5/8/2010 12:17 PM >>>

Les, on the attached analysis, the St. Francis cath lab is part of the equation to arrive at the equivalent procedures per lab.

If this lab is removed and the denominator moves to 10, the 80% or 860 equivalent benchmark would be achieved.

Since the St. Francis lab is not operational from 2007-2009 and potentially before that date, would the requirements be met to move forward with a cath lab CON application?

Thanks for your guidance.

Evan Ray, FACHE
Chief Operating Officer
East Cooper Medical Center

-----Original Message-----

From: Les Shelton [mailto:SHELTOLW@dhec.sc.gov]
Sent: Tuesday, May 04, 2010 10:02 AM
To: Misty Hallman; Ray, Evan
Subject: Fwd: RE: JAR Question

Mr. Ray:

Misty asked me to look at your calculations. I have attached an Excel spreadsheet that shows the calculations both including and excluding Georgetown's cath lab. MUSC has 5 cath labs for adults and a dedicated pediatric cath lab, so the calculations are only based on the adult labs and utilization. The "Other" procedures on the JAR are not included in the adult utilization calculations. If you have any questions, please contact me or Misty at (803) 545-4200.

Les Shelton
Division of Planning & CON
SC DHEC

>>> Misty Hallman 5/3/2010 2:13 PM >>>

I thought you may have a better perspective on this particular situation. Please copy me on the response so that I can have the answer for future reference.

Misty Hallman

>>> "Ray, Evan" <Evan.Ray@tenethealth.com> 5/3/2010 2:02 PM >>>

Misty,
In looking at the numbers, I have calculated the following:

Average per lab (including Georgetown)
2007 = 982 cath lab equivalents per lab for the 12 cath labs
2008 = 943 cath lab equivalents per lab for the 12 cath labs
2009 = 940 cath lab equivalents per lab for the 12 cath labs

Average per lab (excluding Georgetown)
2007 = 874 cath lab equivalents per lab for the 11 cath labs

05/25/2010 14:16 803-545-4579

DHEC

PAGE 05/09

(5/18/2010) Les Shelton - RE: JAR Question

Page 3

2008 = 940 cath lab equivalents per lab for the 11 cath labs
2009 = 959 cath lab equivalents per lab for the 11 cath labs

In order to achieve the 80% or 960 equivalent procedures, per year, per lab; how are the "other" procedures weighted under the cardiac cath section of the JAR reports? Do they play a factor in the equivalent calculation?

Thanks for your help, please let me know if you need clarification surrounding my question.

Evan Ray, FACHE
Chief Operating Officer

East Cooper Medical Center
2000 Hospital Drive
Mount Pleasant, SC 29464
843-416-6212 office
843-416-6886 fax
843-489-9446 mobile
evan.ray@lenethhealth.com

CARDIAC CATH EQUIVALENTS

WITH GEORGETOWN

	# CATH LABS	2007 DIAG	2007 THERP	2008 DIAG	2008 THERP	2009 DIAG	2009 THERP
GEORGETOWN MEMORIAL HOSPITAL	1	951	58	951	58	611	63
BON SECOURS ST. FRANCIS XAVIER	1	0	0	0	0	0	0
MUSC MEDICAL CENTER	5	1,617	1,334	1,435	1,038	1,517	1,184
ROPER HOSPITAL	3	1,898	942	1,979	992	1,943	910
TRIDENT MEDICAL CENTER	2	1,456	372	1,417	392	1,429	370
TOTAL	12	5,922	2,706	5,782	2,480	5,500	2,527
			<u>x 2</u>		<u>x 2</u>		<u>x 2</u>
			5,412		4,960		5,054
			5,922		5,782		5,500
			<u>+ 5,412</u>		<u>+ 4,960</u>		<u>+ 5,054</u>
			11,334		10,742		10,554
			/ 12		/ 12		/ 12
DIAGNOSTIC EQUIVALENTS/CATH LAB			944.5		895.2		879.5

J02-077

CARDIAC CATH EQUIVALENTS**WITHOUT GEORGETOWN**

	# CATH LABS	2007 DIAG	2007 THERP	2008 DIAG	2008 THERP	2009 DIAG	2009 THERP
BON SECOURS ST. FRANCIS XAVIER	1	0	0	0	0	0	0
MUSC MEDICAL CENTER	5	1,617	1,334	1,435	1,038	1,517	1,184
ROPER HOSPITAL	3	1,898	942	1,979	992	1,943	910
TRIDENT MEDICAL CENTER	2	1,456	372	1,417	392	1,429	370
TOTAL	11	4,971	2,648	4,831	2,422	4,889	2,464
			<u>x 2</u>		<u>x 2</u>		<u>x 2</u>
			5,296		4,844		4,928
			4,971		4,831		4,889
			<u>+ 5,296</u>		<u>+ 4,844</u>		<u>+ 4,928</u>
			10,267		9,675		9,817
			/ 11		/ 11		/ 11
DIAGNOSTIC EQUIVALENTS/CATH LAB			933.4		879.5		892.5

J02-078

05/26/2010 14:15

883-645-4579

DHEC

PAGE 08/09



Embracing your health. Embracing you - life.

May 12, 2010

Beverly A. Brandt, MPH
Chief
Bureau of Health Facilities & Services Development
Department of Health and Environmental Control
2600 Bull Street
Columbia, South Carolina 29201

Dear Beverly,

Thank you for assembling your team and taking time to discuss the South Carolina State Health Plan and Certificate of Need process on April 27, 2010. As a follow-up to our discussion, I have worked with Les Shelton and Misty Hallman from your organization to outline the cardiac catheterization equivalent procedures that are performed in the 11 area catheterization laboratories.

Included in the attached document is the complete analysis of the 11 area catheterization laboratories from the annual JAR reports. In summary, the following diagnostic equivalent procedures were performed in the previous 3 years:

2007 - 933 equivalent procedures
2008 - 880 equivalent procedures
2009 - 893 equivalent procedures

Based on the benchmark of 960 equivalent procedures per lab, per year, these numbers do not support an additional laboratory in the service area. However, during this time period, the Bon Secours St. Francis Hospital catheterization laboratory performed 0 diagnostic equivalent procedures and was not operational as a catheterization laboratory.

I am requesting a determination of this catheterization laboratory to identify if it should be included in the equivalent calculation. By removing this laboratory from the equivalent calculation, the procedural volume in the 10 service area operational laboratories will be as follows:

2007 - 1,027 equivalent procedures
2008 - 968 equivalent procedures
2009 - 982 equivalent procedures

These volume levels would certainly support an additional catheterization laboratory in the market and I believe that East Cooper Medical Center has the ability to provide this service. With the addition of our new hospital, we have the technology in place to provide this service and the clinicians and physicians available to take care of these patients.

If you have any questions about the analysis or about our operation, please do not hesitate to contact me via email; evan.ray@ehealthsc.com or telephone; (843) 416-6212.

Sincerely,

Evan Ray, FACHE
Chief Operating Officer
East Cooper Medical Center

cc: Janie Simacore-Jaberg, CEO, East Cooper Medical Center
cc: Les Shelton, Division of Planning & CON, SC DHEC

2000 HOSPITAL DRIVE • MOUNT PLEASANT, SOUTH CAROLINA 29464 • (843) 88-0100 • WWW.EASTCOOPERMEDICAL.COM

East Cooper CON 0364

J02-079

CARDIAC CATH EQUIVALENTS

WITHOUT GEORGETOWN

	# CATH LABS	2007 DIAG	2007 THERP	2008 DIAG	2008 THERP	2009 DIAG	2009 THERP
BON SECOURS ST. FRANCIS XAVIER	1	0	0	0	0	0	0
MUSC MEDICAL CENTER	5	1,617	1,334	1,435	1,038	1,517	1,184
ROPER HOSPITAL	3	1,898	942	1,979	982	1,943	910
TRIDENT MEDICAL CENTER	2	1,456	372	1,417	382	1,429	370
TOTAL	11	4,971	2,648	4,831	2,422	4,889	2,464
			<u>x 2</u>		<u>x 2</u>		<u>x 2</u>
			5,296		4,844		4,928
			4,971		4,831		4,889
			<u>+ 5,296</u>		<u>+ 4,844</u>		<u>+ 4,928</u>
			10,267		9,675		9,817
			/ 11		/ 11		/ 11
DIAGNOSTIC EQUIVALENTS/CATH LAB			933.4		879.6		892.5



C. Earl Hunter, Commissioner

Promoting and protecting the health of the public and the environment

May 27, 2010

Mr. Evan Ray
Chief Operating Officer
East Cooper Medical Center
2000 Hospital Drive
Mount Pleasant, SC 29464

Dear Mr. Ray:

We received your letter dated May 12, 2010, requesting a determination as to whether the Bon Secours St. Francis Hospital's cardiac catheterization laboratory should be included in the utilization calculations for the Charleston area under the Certificate of Need (CON) program. The hospital has not reported any utilization for this cath lab on its Joint Annual Report (JAR) since 2006. It appears that the minimum utilization requirement of 960 diagnostic equivalents per cath lab cannot be met if this cath lab is included in the 2008 calculations. However, removing the apparently unused cath lab from the total existing labs in the service area would generate a calculated average utilization of greater than 960 diagnostic equivalents for the remaining cath labs. This could potentially allow a new provider to enter the market.

Based on our review of the standards in the 2008-2009 South Carolina Health Plan and the CON law and regulations, we have determined that we do not currently have a mechanism in place that would allow the Department to discount the existence of the St. Francis cardiac cath lab when computing the average utilization for the service area. However, we do recognize that continuing to inventory a service that has remained idle for three years can negatively impact the ability of other providers to offer that service. The issue could also be relevant to other beds and services covered under the CON program. As we are currently drafting the 2010-2011 South Carolina Health Plan, this may be the appropriate place for all parties to discuss how the Department could potentially amend the standards to allow adjustments in the need calculations for "unused" beds or equipment.

Thank you for bringing this matter to our attention. If you have any further questions, please contact Les Shelton or me at (803) 545-4200.

Sincerely,

Beverly A. Brandt, Chief
Bureau of Health Facilities and Services Development

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

Health Regulation

2600 Bull Street • Columbia, SC 29201 • www.scdhec.gov

East Cooper CON 0256



Catherine E. Heigel, Director

Ensuring and protecting the health of the public and the environment

April 22, 2016

Ralph W. Barbier, Esquire
c/o Nexsen Pruet, LLC
1200 Main Street, Suite 700
Columbia, SC 29201

Re: Notification of Roper St. Francis as an "Affected Person" with regard to the Certificate of Need Application filed by East Cooper Medical Center for the addition of a cardiac cath lab at a total project cost of \$442,612.
CON File No.: 2253

Dear Mr. Barbier:

This letter acknowledges receipt of your letter dated April 20, 2016 regarding Roper St. Francis's "affected person" status in the above-referenced Certificate of Need application. We will provide you with notifications and the scheduling of any project review meeting regarding this application in accordance with Regulation 61-15 and S.C. Code Ann. §44-7-210(C), et seq.

If you have any questions, please contact me at eubanklw@dhec.sc.gov.

Sincerely,

Louis Eubank
Director
Certificate of Need Program

Enclosure

cc: Shannon Cantwell (by email)

Correspondence



Catherine E. Heigel, Director

March 15, 2016

VIA CERTIFIED MAIL

Jason Alexander
CEO
East Cooper Medical Center
2000 Hospital Drive
Mt. Pleasant, SC 29464

Article #: 92148969009997901404085164

Re: Establishment of a single diagnostic cardiac catheterization lab collocated with an existing interventional radiology lab at a total project cost of \$442,612.
East Cooper Medical Center
Matter: 2253

Dear Mr. Alexander:

This is to notify you the South Carolina Department of Health and Environmental Control ("Department") has determined the aforementioned project to be complete for purposes of review by the Certification of Need Program. Enclosed is an invoice for the required application fee. It may be paid by check made payable to the S.C. Department of Health and Environmental Control or by electronic check through the Department's website (www.scdhec.gov) using the "Pay Invoices" hyperlink at the bottom of each webpage. This is a secure website. If payment is not received within fifteen (15) days of your receipt of this invoice, the pending application will be considered withdrawn and this matter closed. Should this deadline fall on a weekend or State holiday, it will be extended to the next calendar day that is neither weekend nor holiday pursuant to Regulation 61-15, Section 303.

Should the Department receive your application fee within the fifteen (15) day deadline, the Department will render a decision no earlier than thirty (30) days, but no later than one-hundred (120) days from the date notice is provided to affected persons in the State Register, unless a public hearing is held pursuant to Regulation 61-15, Section 305.

The Department has determined the relative importance of the project review criteria, pursuant to Regulation 61-15, Section 304, which will be used to review your application. The specific criteria to be used is set forth below and are ranked according to their relative importance, with the most important being listed first. All other relevant criteria will be given equal importance.

- a. Compliance with the South Carolina Health Plan;
- b. Community Need Documentation;
- c. Distribution (Accessibility);
- d. Financial Feasibility;

Jason Alexander
March 15, 2016
Page 2

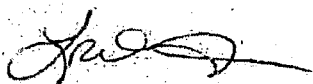
R1096

- e. Staff Resources;
- f. Adverse Effects on Other Facilities; and
- g. Record of the Applicant.

The aforementioned criteria are set forth in Regulation 61-15, Section 802. Should you wish to submit any additional information to the Department in support of your application, you have thirty (30) days from the receipt of this correspondence to do so.

If you have any questions, please contact me at 803.545.4200.

Sincerely,



Louis Eubank
Director
Certificate of Need Program

Enclosures: Application Fee Invoice

cc: David Levitt (via email)



INVOICE FOR SERVICES

Invoice No.

Bureau of Financial Management / Sims/Aycock Building
2600 Bull St, Columbia, South Carolina 29201

PC18031-5

Invoice To:

EAST COOPER MEDICAL CENTER
JASON ALEXANDER
2000 HOSPITAL DR
MOUNT PLEASANT, SC 29464

Ship To:

S.C. DHEC
Attention: Bureau of Financial Management
2600 Bull Street
Columbia, South Carolina 29201

Date:

3/15/2016

Terms:

DUE UPON RECEIPT

Department Name

Planning and Programs

Order Filled By:

SZATKOVIC

Description of Services: CERTIFICATE OF NEED APPLICATION FEE

Qty	Unit Description	Loc	Organ.	Fund	Account	Analytical	Unit Price	Amount
1	CON APPLICATION FEE (2253)	400	402011	428015	4486701	0000000	\$2,213.00	\$2,213.00
Total:								\$2,213.00

Payment can be made by credit card by completing the below form or by visiting www.scdhec.com and clicking on Invoice Payment under the Quick Links.

Name as it appears on credit card

Telephone Number

Mailing Address

Master Card / Visa / Discover

Type of card (circle one)

Credit Card Number

Expiration Date

Signature

East Cooper CON 0371

Note: Make checks payable to South Carolina Department of Health and Environmental Control, remit to above address to the Attention of: Bureau of Financial Management.

Decision



July 25, 2016

VIA CERTIFIED MAIL

Jason Alexander
Chief Executive Officer
East Cooper Medical Center
2000 Hospital Drive
Mount Pleasant, SC 29464

Re: **Decision Granting Application for a Certificate of Need
East Cooper Medical Center**

Establishment of a single diagnostic cardiac catheterization lab collocated with an existing interventional radiology lab at a total project cost of \$442,612.

Matter No.: 2253

Mount Pleasant, South Carolina

Dear Mr. Alexander:

The South Carolina Department of Health and Environmental Control (Department) has reviewed the application of East Cooper Medical Center (Applicant) to receive a Certificate of Need for the establishment of a single diagnostic cardiac catheterization lab collocated with an existing interventional radiology lab at a total project cost of \$442,612 (Project). Applicant has presented substantial evidence that the Project complies with the relevant project review criteria and is consistent with the *South Carolina Health Plan*, enacted August 13, 2015 (Plan). The Project satisfies the relevant requirements of Section 802 of Regulation 61-15 pertaining to Community Need Documentation, Distribution (Accessibility), Financial Feasibility, Staff Resources, Adverse Effects on Other Facilities, and Record of the Applicant. Accordingly, it is the decision of the Department that a Certificate of Need will be issued for this Project.

The Department's decision is based on the following findings:

Compliance with the Plan

In addition to the declarative Certificate of Need Standards #1 and #2 outlined in the Plan for cardiac catheterization services, the following Standards for the Project apply:

S.C. Department of Health and Environmental Control

East Cooper CON 0373

3. New diagnostic catheterization services, including mobile services; shall be approved only if all existing labs in the service area have performed a minimum of 500 diagnostic catheterization procedures per laboratory during the most recent year.

A review of relevant Joint Annual Report (JAR) data for all diagnostic catheterization labs within the 45-minute drive time service area showed that all diagnostic catheterization labs met or exceeded the 500 procedure threshold outlined in the Plan with one notable exception. The diagnostic cardiac catheterization lab located at Roper St. Francis Xavier Hospital in West Ashley performed no more than nine (9) procedures per year in any year from 2010 to 2014, according to available JAR data. The Department explained this inconsistency to both Roper St. Francis Xavier Hospital and the Applicant. Subsequently, Roper St. Francis Hospital - Berkeley submitted a CON application to the Department which contemplates the addition of diagnostic catheterization services at its new hospital location in Berkeley County (CON SC-16-01) and the closure of the underutilized diagnostic catheterization lab at Roper St. Francis Xavier Hospital. Roper St. Francis Xavier Hospital agreed to shutter its diagnostic catheterization lab upon approval of the aforementioned application, regardless of the timing of the transfer or any potential opposition to its application, thus allowing the department to discount the utilization figures of the lab at its current location. By decision dated July 25, 2016, the Department approved the Roper St. Francis Hospital - Berkeley application. As such, the Department concludes that other diagnostic catheterization labs within the service area operate at such a capacity as to not preclude the addition of the diagnostic catheterization lab contemplated by the Applicant.

4. An applicant for a fixed diagnostic service must project that the proposed service will perform a minimum of 500 diagnostic equivalent procedures annually within three years of initiation of services, without reducing the utilization of the existing diagnostic catheterization services in the service area below 500 diagnostic cardiac catheterization procedures per laboratory.

The Applicant projects a minimum of 514 procedures by the close of the third reporting year, and no evidence is provided which shows utilization at other existing diagnostic catheterization labs will drop below the 500 minimum procedure threshold as a result of approving the Project.

Certificate of Need Standards #5 and #6 do not apply to the contemplated Project as it is not an expansion of current cardiac catheterization services and is not a mobile diagnostic catheterization laboratory.

Accordingly, the Department concludes the Applicant has sufficiently complied with the Standards outlined in the Plan, Chapter VIII-4 and Chapter VIII-5.

Community Need Documentation

While the planning area for diagnostic catheterization services is defined as an area within a 45-minute, one-way drive from the Applicant's facility, the Applicant considers its primary service area to be Charleston and Berkeley counties. Within the planning area, there are a total of 11 existing catheterization labs which are open and able to perform the services contemplated by the Applicant's Project. With the notable exception discussed previously, all labs within the planning area operate between 79% and nearly 94% capacity.

Accordingly, the Department concludes Applicant has sufficiently projected Community Need to satisfy the requirements of Section 802.2, Reg. 61-15.

Distribution (Accessibility)

As outlined in Part C of the application, the applicant states that no admissions shall be restricted based on race, sex, creed, national origin, or ability to pay. Additionally, the applicant's parent company, Tenet Healthcare, maintains a compact with uninsured patients which further resolves to provide care regardless of insurance status. The applicant satisfactorily explained how patients will access the facility for the proposed services. Further, applicant has demonstrated that the location of the proposed lab at its hospital facility in Mt. Pleasant, SC will serve an area (opposite the Cooper River from other peninsula-based hospitals) where diagnostic catheterization services are needed. MUSC has agreed to transfer its Mt. Pleasant area-based diagnostic catheterization patients to the applicant's facility once it is online, thus mitigating any negative impact on that facility. The applicant does not foresee any negative impact on additional facilities, and no opposition to the applicant's plans has been raised by any affected persons.

Accordingly, the Department concludes Applicant has satisfied the requirements of Distribution (Accessibility) pursuant to Section 802.3, Reg. 61-15.

Financial Feasibility

Wes James, CFO of Southern Region for Tenet Healthcare, the applicant's parent company, attests that the project will be financed with cash-on-hand, and no financing tools will be utilized. Financial projections both with and without the contemplated project are positive and attest to the strong financial feasibility of the proposed project.

Accordingly, the Department concludes Applicant has satisfied the requirements of Financial Feasibility pursuant to Section 802.15, Reg. 61-15.

Staff Resources

The applicant provided a manpower budget as well as agreements with MUSC to provide the necessary medical staff for the contemplated service. The applicant's previous known track record suggests a satisfactory ability to provide necessary staff for its facilities and other services.

Accordingly, the Department concludes Applicant has satisfied the requirements of Staff Resources pursuant to Section 802.20, Reg. 61-15.

Adverse Effects on Other Facilities

As previously mentioned pursuant to Distribution (Accessibility), the applicant has secured the support of MUSC to allow its Mt. Pleasant area-based patients to seek diagnostic cardiac catheterization services in the applicant's facility, thus allowing the applicant to meet the minimum case threshold of 500 within three operational years. This fact mitigates any significant impact upon MUSC. Utilization of other diagnostic labs in the area is sufficiently high enough to protect against any modest impact the contemplated project may have upon them. These impacts, if any, will not prevent other facilities from maintaining a sufficiently high case load as needed to maintain provider acuity in the provision of diagnostic cardiac catheterizations.

Accordingly, the Department concludes Applicant has satisfied the requirements of Adverse Effects on Other Facilities pursuant to Section 802.23, Reg. 61-15.

Record of the Applicant

The applicant has no known citations or plans of correction on file with the department. A review of available records showed nothing which would prevent the applicant from being approved for the contemplated project based on its previous record with state and federal regulatory authorities.

Accordingly, the Department concludes Applicant has satisfied the requirements of Record of the Applicant pursuant to Section 802.13, Reg. 61-15.

The Department has determined the findings required by S.C. Code Reg. 61-15 §501 are not applicable to this Project.

The issuance of a Certificate of Need does not constitute approval for any proposed construction, licensing or certification changes. You should contact the following individuals for information concerning these and any other related issues: Bureau of Radiological Health, Mr. Aaron Gantt (803.545.4400); Division of Health Facilities Construction, Mr. William McCallum (803.545.4215); Division of Health Licensing, Ms. Gwendolyn Thompson, (803.545.4370); and Bureau of Certification, Ms. Mary Jo Roué (803.545.4293).

Sincerely,



Louis Eubank
Director, Certificate of Need Program
(803) 545-4200

cc: David Levitt (david.levitt@levitthealthcare.com)
Ralph Barbier (certified mail & email)
Shannon Cantwell (email)

South Carolina Board of Health and Environmental Control

Guide to Board Review

Pursuant to S.C. Code Ann. § 44-1-60

The decision of the South Carolina Department of Health and Environmental Control (Department) becomes the final agency decision fifteen (15) calendar days after notice of the decision has been mailed to the applicant, permittee, licensee and affected persons who have requested in writing to be notified, unless a written request for final review accompanied by a filing fee in the amount of \$100 is filed with Department by the applicant, permittee, licensee or affected person.

Applicants, permittees, licensees, and affected parties are encouraged to engage in mediation or settlement discussions during the final review process.

If the Board declines in writing to schedule a final review conference, the Department's decision becomes the final agency decision and an applicant, permittee, licensee, or affected person may request a contested case hearing before the Administrative Law Court within thirty (30) calendar days after notice is mailed that the Board declined to hold a final review conference. In matters pertaining to decisions under the South Carolina Mining Act, appeals should be made to the South Carolina Mining Council.

1. Filing of Request for Final Review

1. A written Request for Final Review (RFR) and the required filing fee of one hundred dollars (\$100) must be received by Clerk of the Board within fifteen (15) calendar days after notice of the staff decision has been mailed to the applicant, permittee, licensee, or affected persons. If the 15th day occurs on a weekend or State holiday, the RFR must be received by the Clerk on the next working day. RFRs will not be accepted after 5:00 p.m.
2. RFRs shall be in writing and should include, at a minimum, the following information:
 - The grounds for amending, modifying, or rescinding the staff decision;
 - a statement of any significant issues or factors the Board should consider in deciding how to handle the matter;
 - the relief requested;
 - a copy of the decision for which review is requested; and
 - mailing address, email address, if applicable, and phone number(s) at which the requestor can be contacted.
3. RFRs should be filed in person or by mail at the following address:

South Carolina Board of Health and Environmental Control
Attention: Clerk of the Board
2600 Bull Street
Columbia, South Carolina 29201

Alternatively, RFR's may be filed with the Clerk by facsimile (803-898-3393) or by electronic mail (boardclerk@dhec.sc.gov).
4. The filing fee may be paid by cash, check or credit card and must be received by the 15th day.
5. If there is any perceived discrepancy in compliance with this RFR filing procedure, the Clerk should consult with the Chairman or, if the Chairman is unavailable, the Vice-Chairman. The Chairman or the Vice-Chairman will determine whether the RFR is timely and properly filed and direct the Clerk to (1) process the RFR for consideration by the Board or (2) return the RFR and filing fee to the requestor with a cover letter explaining why the RFR was not timely or properly filed. Processing an RFR for consideration by the Board shall not be interpreted as a waiver of any claim or defense by the agency in subsequent proceedings concerning the RFR.
6. If the RFR will be processed for Board consideration, the Clerk will send an Acknowledgement of RFR to the Requestor and the applicant, permittee, or licensee, if other than the Requestor. All personal and financial identifying information will be redacted from the RFR and accompanying documentation before the RFR is released to the Board, Department staff or the public.
7. If an RFR pertains to an emergency order, the Clerk will, upon receipt, immediately provide a copy of the RFR to all Board members. The Chairman, or in his or her absence, the Vice-Chairman shall based on the circumstances, decide whether to refer the RFR to the RFR Committee for expedited review or to decline in writing to schedule a Final Review Conference. If the Chairman or Vice-Chairman determines review by the RFR Committee is appropriate, the Clerk will forward a copy of the RFR to Department staff and Office of General Counsel. A Department response and RFR Committee review will be provided on an expedited schedule defined by the Chairman or Vice-Chairman.
8. The Clerk will email the RFR to staff and Office of General Counsel and request a Department Response within eight (8) working days. Upon receipt of the Department Response, the Clerk will forward the RFR and Department Response to all Board members for review, and all Board members will confirm receipt of the RFR to the Clerk by email. If a Board member does not confirm receipt of the RFR within a twenty-four (24) hour period, the Clerk will contact the Board member and confirm receipt. If a Board member believes the RFR should be considered by the RFR Committee, he or she will

respond to the Clerk's email within forty-eight (48) hours and will request further review. If no Board member requests further review of the RFR within the forty-eight (48) hour period, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, stating the Board will not hold a Final Review Conference. Contested case guidance will be included within the letter.

NOTE: If the time periods described above end on a weekend or State holiday, the time is automatically extended to 5:00 p.m. on the next business day.

9. If the RFR is to be considered by the RFR Committee, the Clerk will notify the Presiding Member of the RFR Committee and the Chairman that further review is requested by the Board. RFR Committee meetings are open to the public and will be public noticed at least 24 hours in advance.
10. Following RFR Committee or Board consideration of the RFR, if it is determined no Conference will be held, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, stating the Board will not hold a Conference. Contested case guidance will be included within the letter.

II. Final Review Conference Scheduling

1. If a Conference will be held, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, informing the Requestor of the determination.
2. The Clerk will request Department staff provide the Administrative Record.
3. The Clerk will send Notice of Final Review Conference to the parties at least ten (10) days before the Conference. The Conference will be publically noticed and should:
 - include the place, date and time of the Conference;
 - state the presentation times allowed in the Conference;
 - state evidence may be presented at the Conference;
 - if the conference will be held by committee, include a copy of the Chairman's order appointing the committee; and
 - inform the Requestor of his or her right to request a transcript of the proceedings of the Conference prepared at Requestor's expense.
4. If a party requests a transcript of the proceedings of the Conference and agrees to pay all related costs in writing, including costs for the transcript, the Clerk will schedule a court reporter for the Conference.

III. Final Review Conference and Decision

1. The order of presentation in the Conference will, subject to the presiding officer's discretion, be as follows:
 - Department staff will provide an overview of the staff decision and the applicable law to include [10 minutes]:
 - Type of decision (permit, enforcement, etc.) and description of the program.
 - Parties
 - Description of facility/site
 - Applicable statutes and regulations
 - Decision and materials relied upon in the administrative record to support the staff decision.
 - Requestor(s) will state the reasons for protesting the staff decision and may provide evidence to support amending, modifying, or rescinding the staff decision. [15 minutes] *NOTE: The burden of proof is on the Requestor(s)*
 - Rebuttal by Department staff [15 minutes]
 - Rebuttal by Requestor(s) [10 minutes]

Note: Times noted in brackets are for information only and are superseded by times stated in the Notice of Final Review Conference or by the presiding officer.
2. Parties may present evidence during the conference; however, the rules of evidence do not apply.
3. At any time during the conference, the officers conducting the Conference may request additional information and may question the Requestor, the staff, and anyone else providing information at the Conference.
4. The presiding officer, in his or her sole discretion, may allow additional time for presentations and may impose time limits on the Conference.
5. All Conferences are open to the public.
6. The officers may deliberate in closed session.
7. The officers may announce the decision at the conclusion of the Conference or it may be reserved for consideration.
8. The Clerk will mail the written final agency decision (FAD) to parties within 30 days after the Conference. The written decision must explain the basis for the decision and inform the parties of their right to request a contested case hearing before the Administrative Law Court or in matters pertaining to decisions under the South Carolina Mining Act, to request a hearing before the South Carolina Mining Council. The FAD will be sent by certified mail, return receipt requested.
9. Communications may also be sent by electronic mail, in addition to the forms stated herein, when electronic mail addresses are provided to the Clerk.

The above information is provided as a courtesy; parties are responsible for complying with all applicable legal requirements.



Article #: 92148969009997901405693061

August 15, 2016

CERTIFIED MAIL, RETURN RECEIPT REQUESTED

Jason Alexander
Chief Executive Officer
East Cooper Medical Center
2000 Hospital Drive
Mount Pleasant, SC 29464

Re: **CON SC-16-47****Applicant:** East Cooper Community Hospital, Inc. d/b/a East Cooper Medical Center**Project:** Establishment of a single diagnostic cardiac catheterization lab collocated with an existing interventional radiology lab at a total project cost of \$442,612.**Application No.:** 2253

Dear Mr. Alexander:

Enclosed is the Certificate of Need granting approval of the above named project. This Certificate is valid for a period of twelve (12) months.

As required by Regulation No. 61-15, Section 607, you must submit quarterly progress reports from the date of issuance of this Certificate of Need documenting compliance with the timetable, which you submitted in your application. You must report on, if applicable:

Costs incurred on the project:

- a. Construction activity;
- b. Program or service activity; and
- c. Any deviations from the submitted application with supporting documentation.

The issuance of a Certificate of Need does not constitute approval for any proposed construction, licensing or certification changes. You should contact the following individuals for information concerning these related issues: Bureau of Radiological Health, Mr. Aaron Gantt (803.545.4400); Division of Health Facilities Construction, Mr. William McCallum (803.545.4215); Division of Health Licensing, Ms. Gwendolyn Thompson, (803.545.4370); and Bureau of Certification, Ms. Mary Jo Roue (803.545.4293).

East Cooper CON 0380

SC Department of Health and Environmental Control

Jason Alexander
Page 2
August 15, 2016

If this office can be of further service to you or if you have any questions concerning the above, feel free to contact me at (803) 545-4492.

Sincerely,

A handwritten signature in black ink, appearing to read "LE", followed by a horizontal line.

Louis Eubank
Director
Certificate of Need Program

Enclosures: Certificate of Need

South Carolina Department of Health
and Environmental Control

R1108



Certificate of Need

SC-16-47

IS HEREBY ISSUED TO: East Cooper Community Hospital, Inc. d/b/a East Cooper Medical Center

LOCATION: Charleston County

LICENSEE: East Cooper Medical Center

AGENT: Jason Alexander, Chief Executive Officer

FOR: Establishment of a single diagnostic cardiac catheterization lab collocated with an existing interventional radiology lab

TOTAL PROJECT COST: \$442,612

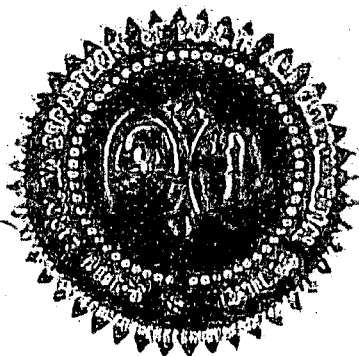
This Certificate is being issued in accordance with the Code of Laws of South Carolina.

In determining the need for this project, the South Carolina Department of Health and Environmental Control has taken into consideration the "Criteria for Project Review" and the South Carolina Health Plan as established in the "State Certification of Need and Health Facility Licensure Act," S.C. Code Ann. 44-7-110 et seq. and Regulation 61-15, "Certification of Need for Health Facilities and Services."

This Certificate of Need is valid until August 15, 2017 which is a period of twelve (12) months from the date of issuance unless the applicant receives an extension from the Department in accordance with applicable regulations.

Witness to this Certificate is confirmed by my signature and the seal of the Department of Health and Environmental Control this 15th day of August, 2016.

Louis W. Eubank
Director, Certificate of Need Program



East Cooper CON 0382

J02-097

Miscellaneous



INVOICE FOR SERVICES

Bureau of Financial Management / Sims/Aycock Building
2600 Bull St, Columbia, South Carolina 29201

Invoice No.

PC17804-6

Invoice To:

EAST COOPER MEDICAL CENTER
JASON ALEXANDER
2000 HOSPITAL DR
MOUNT PLEASANT, SC 29464

Ship To:

S.C. DHEC
Attention: Bureau of Financial Management
2600 Bull Street
Columbia, South Carolina 29201

Date:
2/8/2016

Terms:
DUE UPON RECEIPT

Department Name
Planning and Programs

Order Filled By:
SZATKOVIC

Description of Services: CERTIFICATE OF NEED INITIAL FILING FEE

Qty	Unit Description	Loc	Organ.	Fund	Account	Analytical	Unit Price	Amount
1	CON INITIAL FILING FEE (2253)	400	402011	428015	4486701	0000000	\$500.00	\$500.00
Total:								\$500.00

Payment can be made by credit card by completing the below form or by visiting www.scdhec.com and clicking on Invoice Payment under the Quick Links.

Name as it appears on credit card

Telephone Number

Mailing Address

Master Card / Visa / Discover

Type of card (circle one)

Credit Card Number

Expiration Date

Signature

East Cooper CON 0384

Note: Make checks payable to South Carolina Department of Health and Environmental Control, remit to above address to the Attention of: Bureau of Financial Management

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

NOTICE OF GENERAL PUBLIC INTEREST

In accordance with Section 44-7-200(D), Code of Laws of South Carolina, the public is hereby notified that a Certificate of Need application has been accepted for filing and publication February 26, 2016 for the following project(s). After the application is deemed complete, affected persons will be notified that the review cycle has begun. For further information, please contact Vonja Szatkowski, Certificate of Need Program, 2600 Bull Street, Columbia, SC 29201 at (803) 545-3028.

Affecting Abbeville County

PruittHealth Home Health, Inc. d/b/a PruittHealth Home Health – Abbeville
Establishment of a new Home Health Agency in Abbeville County at a total project cost of \$15,590.

Affecting Allendale County

Amedisys SC, LLC d/b/a Amedisys Home Health of Bluffton
Establishment of a new Home Health Agency in Allendale County at a total project cost of \$18,138.

Affecting Anderson County

PruittHealth Home Health, Inc. d/b/a PruittHealth Home Health – Anderson
Establishment of a new Home Health Agency in Anderson County at a total project cost of \$15,590.

Abbeville County Memorial Hospital d/b/a Health Related Home Care - Anderson County
Establishment of a new Home Health Agency in Anderson County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$15,200.

Amedisys Home Health, Inc. of South Carolina d/b/a Amedisys Home Health of Clinton
Establishment of a new Home Health Agency in Anderson County at a total project cost of \$18,138.

Affecting Barnwell County

Amedisys SC, LLC d/b/a Amedisys Home Health of Lexington
Establishment of a new Home Health Agency in Barnwell County at a total project cost of \$18,138.

Affecting Beaufort County

SS&J Associates, LLC d/b/a BrightStar Care Lowcountry - Beaufort County
Establishment of a new Home Health Agency in Beaufort County wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$5,000.

Affecting Charleston County

Gary Lesesne d/b/a Assurance Home Health Care
Establishment of a new Home Health Agency in Charleston County at a total project cost of \$0.

The Southeastern Spine Institute Ambulatory Surgery Center, LLC
Relocation and replacement of an Ambulatory Surgery Facility (ASF) with no increase in operating rooms (ORs) and for an additional three procedure rooms, for a total of 2 ORs and 3 Procedure Rooms at a total project cost of \$13,135,194.

20 NOTICES**East Cooper Community Hospital, Inc. d/b/a East Cooper Medical Center**

Establishment of Diagnostic Cardiac Catheterization Services at a total project cost of \$442,612.

Affecting Chesterfield County**McLeod Regional Medical Center of the Pee Dee, Inc. d/b/a McLeod Home Health**

Establishment of a new Home Health Agency in Chesterfield County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$0.

PruittHealth Home Health, Inc. d/b/a PruittHealth – Chesterfield

Establishment of a new Home Health Agency in Chesterfield County at a total project cost of \$17,099.

Affecting Clarendon County**PruittHealth Home Health, Inc. d/b/a PruittHealth – Clarendon**

Establishment of a new Home Health Agency in Clarendon County at a total project cost of \$17,099.

Georgetown Hospital Home Health, LLC d/b/a Amedisys Home Health Care

Establishment of a new Home Health Agency in Clarendon County at a total project cost of \$18,138.

Affecting Darlington County**PruittHealth Home Health, Inc. d/b/a PruittHealth – Darlington**

Establishment of a new Home Health Agency in Darlington County at a total project cost of \$17,099.

Affecting Dillon County**PruittHealth Home Health, Inc. d/b/a PruittHealth – Dillon**

Establishment of a new Home Health Agency in Dillon County at a total project cost of \$17,099.

Affecting Dorchester County**Presbyterian Home of South Carolina d/b/a Presbyterian Communities of South Carolina – The Village at Summerville**

Construction for the replacement of an existing 87-bed nursing facility and for the addition of one long term bed, for a total of 88 long term beds at a total project cost of \$28,400,134.

Affecting Edgefield County**PruittHealth Home Health, Inc. d/b/a PruittHealth Home Health – Edgefield**

Establishment of a new Home Health Agency in Edgefield County at a total project cost of \$15,590.

Affecting Florence County**PruittHealth Home Health, Inc. d/b/a PruittHealth – Florence**

Establishment of a new Home Health Agency in Florence County at a total project cost of \$17,099.

McLeod Regional Medical Center of the Pee Dee, Inc.

Addition of 8 medical/surgical beds for a total of 461 medical/surgical beds and the addition of 8 NICU Intensive Care bassinets for a total of 20 NICU Intensive Care bassinets, at a total project cost of \$995,000.00.

Affecting Georgetown County

Tidelands Georgetown County Memorial Hospital d/b/a Tidelands Georgetown Memorial Hospital
Renovation and expansion for the replacement of the Surgical Suite at a total project cost of \$44,068,689.

PruittHealth Home Health, Inc. d/b/a PruittHealth – Georgetown
Establishment of a new Home Health Agency in Georgetown County at a total project cost of \$17,099.

Affecting Greenville County

PruittHealth Home Health, Inc. d/b/a PruittHealth Home Health – Greenville
Establishment of a new Home Health Agency in Greenville County at a total project cost of \$15,590.

Abbeville County Memorial Hospital d/b/a Health Related Home Care - Greenville County
Establishment of a new Home Health Agency in Greenville County wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$15,200.

Affecting Greenwood County

PruittHealth Home Health, Inc. d/b/a PruittHealth Home Health – Greenwood
Establishment of a new Home Health Agency in Greenwood County at a total project cost of \$15,590.

Affecting Horry County

PruittHealth Home Health, Inc. d/b/a PruittHealth - Horry
Establishment of a new Home Health Agency in Horry County at a total project cost of \$17,099.

McLeod Loris Seacoast Hospital d/b/a McLeod Health Carolina Forest Campus
Construction of a new, off-Campus Emergency Department (ED) consisting of 12,995 sf located within an MOB currently under construction at a total project cost of \$9,575,662.77.

Affecting Jasper County

SS&J Associates, LLC d/b/a BrightStar Care Lowcountry - Jasper County
Establishment of a new Home Health Agency in Jasper County wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$5,000.

Affecting Lancaster County

Amedisys SC, LLC d/b/a Neighbors Care Home Health Agency, an Amedisys Company
Establishment of a new Home Health Agency in Lancaster County at a total project cost of \$18,138.

Affecting Laurens County

PruittHealth Home Health, Inc. d/b/a PruittHealth Home Health - Laurens
Establishment of a new Home Health Agency in Laurens County at a total project cost of \$15,590.

Affecting Marion County

PruittHealth Home Health, Inc. d/b/a PruittHealth – Marion
Establishment of a new Home Health Agency in Marion County at a total project cost of \$17,099.

22 NOTICES**Affecting Marlboro County****PruittHealth Home Health, Inc. d/b/a PruittHealth – Marlboro**

Establishment of a new Home Health Agency in Marlboro County at a total project cost of \$17,099.

Affecting McCormick County**PruittHealth Home Health, Inc. d/b/a PruittHealth Home Health – McCormick**

Establishment of a new Home Health Agency in McCormick County at a total project cost of \$15,590.

Affecting Newberry County**Abbeville County Memorial Hospital d/b/a Health Related Home Care**

Establishment of a new Home Health Agency in Newberry County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$17,200.

Affecting Oconee County**PruittHealth Home Health, Inc. d/b/a PruittHealth Home Health – Oconee**

Establishment of a new Home Health Agency in Oconee County at a total project cost of \$15,590.

Affecting Pickens County**PruittHealth Home Health, Inc. d/b/a PruittHealth Home Health – Pickens**

Establishment of a new Home Health Agency in Pickens County at a total project cost of \$15,590.

Affecting Saluda County**PruittHealth Home Health, Inc. d/b/a PruittHealth Home Health – Saluda**

Establishment of a new Home Health Agency in Saluda County at a total project cost of \$15,590.

Amedisys SC, LLC d/b/a Amedisys Home Health of Lexington

Establishment of a new Home Health Agency in Saluda County at a total Project cost of \$18,138.

Affecting Spartanburg County**PruittHealth Home Health, Inc. d/b/a PruittHealth Home Health – Spartanburg**

Establishment of a new Home Health Agency in Spartanburg County at a total project cost of \$15,590.

Amedisys Home Health, Inc. of South Carolina d/b/a Amedisys Home Health of Clinton

Establishment of a new Home Health Agency in Spartanburg County at a total Project cost of \$21,894.

Affecting Williamsburg County**PruittHealth Home Health, Inc. d/b/a PruittHealth – Williamsburg**

Establishment of a new Home Health Agency in Williamsburg County at a total project cost of \$17,099.

Affecting York County**Amedisys SC, LLC d/b/a Neighbors Care Home Health Agency, an Amedisys Company**

Establishment of a new Home Health Agency in York County at a total Project cost of \$21,894.

Brent Brady, R.Ph d/b/a Rock Hill Treatment Specialist

Establishment of a new Narcotic Treatment Program (NTP) in York County at a total project cost of \$141,400.

In accordance with Section 44-7-210(A), Code of Laws of South Carolina, and S.C. DHEC Regulation 61-15, the public and affected persons are hereby notified that for the following projects, applications have been deemed complete, and the review cycle has begun. A proposed decision will be made as early as 30 days, but no later than 120 days, from February 26, 2016. "Affected persons" have 30 days from the above date to submit requests for a public hearing to Vonja Szatkowski, Certificate of Need Program, 2600 Bull Street, Columbia, S.C. 29201. If a public hearing is timely requested, the Department's decision will be made after the public hearing, but no later than 150 days from the above date. For further information call (803) 545-3028.

Affecting Abbeville County

Renaissance Home Health, LLC

Establishment of a new Home Health Agency in Abbeville County at a total project cost of \$4,698.38.

Affecting Allendale County

PruittHealth Home Health d/b/a PruittHealth Home Health – Allendale

Establishment of a new Home Health Agency in Allendale County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$5,285.

Affecting Bamberg County

PruittHealth Home Health d/b/a PruittHealth Home Health – Bamberg

Establishment of a new Home Health Agency in Bamberg County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$5,285.

Affecting Barnwell County

PruittHealth Home Health d/b/a PruittHealth Home Health – Barnwell

Establishment of a new Home Health Agency in Barnwell County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$5,285.

Affecting Beaufort County

M&C Group, LLC d/b/a Home Helpers of Bluffton (Beaufort County)

Establishment of a Home Health Agency in Beaufort County wherein Licensee began operation during the period of time the CON Program was not operating at a total project cost of \$0.

Affecting Berkeley County

PruittHealth Home Health d/b/a PruittHealth Home Health – Berkeley

Establishment of a new Home Health Agency in Berkeley County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$5,285.

Affecting Calhoun County

PruittHealth Home Health d/b/a PruittHealth Home Health – Calhoun

Establishment of a new Home Health Agency in Calhoun County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$13,400.

24 NOTICES

Affecting Charleston County**PruittHealth Home Health d/b/a PruittHealth Home Health – Charleston**

Establishment of a new Home Health Agency in Charleston County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$5,285.

Medical University Hospital Authority d/b/a Medical University of South Carolina (Musculoskeletal Institute)

Construction of a new Ambulatory Surgical Facility (ASF) with six (6) Operating Rooms, two (2) Endoscopy Rooms, and an imaging platform including one (1) MRI and one (1) CT Scan at a total project cost of \$41,990,944.

Affecting Cherokee County**PruittHealth Home Health d/b/a PruittHealth Home Health – Cherokee**

Establishment of a new Home Health Agency in Cherokee County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$13,400.

Affecting Chester County**PruittHealth Home Health d/b/a PruittHealth Home Health – Chester**

Establishment of a new Home Health Agency in Chester County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$13,400.

Affecting Colleton County**PruittHealth Home Health d/b/a PruittHealth Home Health – Colleton**

Establishment of a new Home Health Agency in Colleton County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$5,285.

Affecting Dorchester County**PruittHealth Home Health d/b/a PruittHealth Home Health – Dorchester**

Establishment of a new Home Health Agency in Dorchester County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$5,285.

Affecting Fairfield County**PruittHealth Home Health d/b/a PruittHealth Home Health - Fairfield**

Establishment of a new Home Health Agency in Fairfield County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$13,400.

Affecting Hampton County**PruittHealth Home Health d/b/a PruittHealth Home Health - Hampton**

Establishment of a new Home Health Agency in Hampton County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$5,285.

Affecting Horry County**McLeod Loris Seacoast Hospital d/b/a McLeod Seacoast**

Renovation for the relocation of Cardiac Catheterization services from McLeod Loris to McLeod Seacoast at a total project cost of \$2,409,969.

Affecting Jasper County

PruittHealth Home Health d/b/a PruittHealth Home Health – Jasper

Establishment of a new Home Health Agency in Jasper County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$5,285.

Island Health Care, Inc.

Establishment of a new Home Health Agency in Jasper County wherein Licensee began operation during the time CON was not operating, at a total project cost of \$8,040.00.

M&C Group, LLC d/b/a Home Helpers of Bluffton (Jasper County)

Establishment of a new Home Health Agency in Jasper County at a total project cost of \$0.

Affecting Kershaw County

PruittHealth Home Health d/b/a PruittHealth Home Health – Kershaw

Establishment of a new Home Health Agency in Kershaw County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$13,400.

Affecting Lancaster County

PruittHealth Home Health d/b/a PruittHealth Home Health – Lancaster

Establishment of a new Home Health Agency in Lancaster County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$13,400.

Advanced Home Care, Inc. d/b/a Advanced Home Care

Establishment of a new Home Health Agency in Lancaster County at a total project cost of \$47,000.

Affecting Lee County

PruittHealth Home Health d/b/a PruittHealth Home Health – Lee

Establishment of a new Home Health Agency in Lee County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$13,400.

Affecting Lexington County

PruittHealth Home Health d/b/a PruittHealth Home Health – Lexington

Establishment of a new Home Health Agency in Lexington County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$13,400.

Affecting Newberry County

PruittHealth Home Health d/b/a PruittHealth Home Health – Newberry

Establishment of a new Home Health Agency in Newberry County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$13,400.

Affecting Orangeburg County

PruittHealth Home Health d/b/a PruittHealth Home Health - Orangeburg

Establishment of a new Home Health Agency in Orangeburg County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$5,285.

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Affecting Richland County**PruittHealth Home Health d/b/a PruittHealth Home Health – Richland**

Establishment of a new Home Health Agency in Richland County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$13,400.

Affecting Sumter County**PruittHealth Home Health d/b/a PruittHealth Home Health – Sumter**

Establishment of a new Home Health Agency in Sumter County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$13,400.

Affecting Union County**PruittHealth Home Health d/b/a PruittHealth Home Health – Union**

Establishment of a new Home Health Agency in Union County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$13,400.

Affecting York County**PruittHealth Home Health d/b/a PruittHealth Home Health - York**

Establishment of a new Home Health Agency in York County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$13,400.

Advanced Home Care, Inc. d/b/a Advanced Home Care

Establishment of a new Home Health Agency in York County at a total project cost of \$62,500.

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL**NOTICE OF GENERAL PUBLIC INTEREST****NOTICE OF CANCELLATION AND RESCHEDULING OF PUBLIC HEARING**

State Register Document 4642

The Department of Health and Environmental Control published a Notice of Proposed Regulation and Opportunity for Public Comment in the *State Register* on January 22, 2016, identified as Document 4642, to promulgate amendments of Regulation 61-24, *Licensed Midwives*. The aforementioned Notice scheduled a write-in public comment period that closed February 22, 2016, and gave notice of a Public Hearing scheduled before the Board of Health and Environmental Control for March 10, 2016.

The Public Hearing originally scheduled for March 10, 2016, has been cancelled and rescheduled before the Department's Board for April 7, 2016. The hearing will be held at the regularly-scheduled Board meeting on April 7, 2016, in the Peoples Auditorium, Third Floor, Aycock Building of the Department of Health and Environmental Control, 2600 Bull St., Columbia, SC. Please note, this public hearing will be held in the Peoples Auditorium, not the Board Room. Due to admittance procedures at the DHEC building, all visitors should enter through the Bull Street entrance and register at the front desk.

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DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

NOTICE OF GENERAL PUBLIC INTEREST

In accordance with Section 44-7-200(D), Code of Laws of South Carolina, the public is hereby notified that a Certificate of Need application has been accepted for filing and publication March 25, 2016 for the following project(s). After the application is deemed complete, affected persons will be notified that the review cycle has begun. For further information, please contact Vonja Szatkowski, Certificate of Need Program, 2600 Bull Street, Columbia, SC 29201 at (803) 545-3028.

Affecting Abbeville County**Tri-County Home Health Care & Services, Inc. d/b/a Tri-County Home Health Care & Services, Inc. - Abbeville County**

Establishment of a new Home Health Agency in Abbeville County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$8,100.

Affecting Anderson County**Tri-County Home Health Care & Services, Inc. d/b/a Tri-County Home Health Care & Services, Inc. - Anderson County**

Establishment of a new Home Health Agency in Anderson County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$8,100.

Affecting Barnwell County**Tri-County Home Health Care & Services, Inc. d/b/a Tri-County Home Health Care & Services, Inc. - Barnwell County**

Establishment of a new Home Health Agency in Barnwell County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$8,100.

Affecting Berkeley County**InCare Home Health, Inc. d/b/a InCare Home Health, Inc. - Berkeley County**

Establishment of a new Home Health Agency in Berkeley County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$8,100.

Affecting Cherokee County

Establishment of a new Home Health Agency in Cherokee County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$8,100.

Affecting Chesterfield County**InCare Home Health, Inc. d/b/a InCare Home Health, Inc. - Chesterfield County**

Establishment of a new Home Health Agency in Chesterfield County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$8,100.

Affecting Clarendon County**Tri-County Home Health Care & Services, Inc. d/b/a Tri-County Home Health Care & Services, Inc. - Clarendon County**

Establishment of a new Home Health Agency in Clarendon County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$8,100.

Affecting Colleton County

Tri-County Home Health Care & Services, Inc. d/b/a Tri-County Home Health Care & Services, Inc. - Colleton County

Establishment of a new Home Health Agency in Colleton County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$8,100.

Affecting Darlington County

InCare Home Health, Inc. d/b/a InCare Home Health, Inc. - Darlington County

Establishment of a new Home Health Agency in Darlington County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$8,100.

Affecting Dillon County

InCare Home Health, Inc. d/b/a InCare Home Health, Inc. - Dillon County

Establishment of a new Home Health Agency in Dillon County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$8,100.

Affecting Dorchester County

Tri-County Home Health Care & Services, Inc. d/b/a Tri-County Home Health Care & Services, Inc. - Dorchester County

Establishment of a new Home Health Agency in Dorchester County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$8,100.

Affecting Edgefield County

Tri-County Home Health Care & Services, Inc. d/b/a Tri-County Home Health Care & Services, Inc. - Edgefield County

Establishment of a new Home Health Agency in Edgefield County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$8,100.

Affecting Florence County

InCare Home Health, Inc. d/b/a InCare Home Health, Inc. - Florence County

Establishment of a new Home Health Agency in Florence County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$8,100.

Affecting Greenville County

Tri-County Home Health Care & Services, Inc. d/b/a Tri-County Home Health Care & Services, Inc. - Greenville County

Establishment of a new Home Health Agency in Greenville County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$8,100.

The Amendments Group, LLC d/b/a BrightStar Care Upstate

Establishment of a new Home Health Agency in Greenville County wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$5,000.

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Affecting Greenwood County

Tri-County Home Health Care & Services, Inc. d/b/a Tri-County Home Health Care & Services, Inc. - Greenwood County

Establishment of a new Home Health Agency in Greenwood County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$8,100.

Affecting Hampton County

Tri-County Home Health Care & Services, Inc. d/b/a Tri-County Home Health Care & Services, Inc. - Hampton County

Establishment of a new Home Health Agency in Hampton County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$8,100.

Affecting Jasper County

Tri-County Home Health Care & Services, Inc. d/b/a Tri-County Home Health Care & Services, Inc. - Jasper County

Establishment of a new Home Health Agency in Jasper County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$8,100.

Affecting Lee County

Tri-County Home Health Care & Services, Inc. d/b/a Tri-County Home Health Care & Services, Inc. - Lee County

Establishment of a new Home Health Agency in Lee County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$8,100.

Affecting Marion County

InCare Home Health, Inc. d/b/a InCare Home Health, Inc. - Marion County

Establishment of a new Home Health Agency in Marion County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$8,100.

Affecting Marlboro County

InCare Home Health, Inc. d/b/a InCare Home Health, Inc. - Marlboro County

Establishment of a new Home Health Agency in Marlboro County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$8,100.

Affecting McCormick County

Tri-County Home Health Care & Services, Inc. d/b/a Tri-County Home Health Care & Services, Inc. - McCormick County

Establishment of a new Home Health Agency in McCormick County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$8,100.

Affecting Pickens County

AnMed Health d/b/a AnMed Health Clemson

Construction for the purchase and installation of a CT Scanner at a total project cost of \$921,553.

Affecting Richland County**Palmetto Health d/b/a Palmetto Health Children's Hospital**

Renovation to an existing facility for the addition of a new 13 bed Rehabilitation Inpatient Unit at a total project cost of \$1,950,035.

Affecting Spartanburg County**Tri-County Home Health Care & Services, Inc. d/b/a Tri-County Home Health Care & Services, Inc. - Spartanburg County**

Establishment of a new Home Health Agency in Spartanburg County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$8,100.

The Amendments Group, LLC d/b/a BrightStar Care Upstate

Establishment of a new Home Health Agency in Spartanburg County wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$5,000.

Affecting Williamsburg County**InCare Home Health, Inc. d/b/a InCare Home Health, Inc. - Williamsburg County**

Establishment of a new Home Health Agency in Williamsburg County, wherein the Licensee began operations during the period of time the CON Program was not operating, at a total project cost of \$8,100.

In accordance with Section 44-7-210(A), Code of Laws of South Carolina, and S.C. DHEC Regulation 61-15, the public and affected persons are hereby notified that for the following projects, applications have been deemed complete, and the review cycle has begun. A proposed decision will be made as early as 30 days, but no later than 120 days, from March 25, 2016. "Affected persons" have 30 days from the above date to submit requests for a public hearing to Vonja Szatkowski, Certificate of Need Program, 2600 Bull Street, Columbia, S.C. 29201. If a public hearing is timely requested, the Department's decision will be made after the public hearing, but no later than 150 days from the above date. For further information call (803) 545-3028.

Affecting Bamberg County**The Regional Medical Center d/b/a Home Care of the Regional Medical Center**

Establishment of a new Home Health Agency in Bamberg County at a total project cost of \$0.

Affecting Berkeley County**Lowcountry Nursing Group LLC d/b/a Interim Healthcare - Berkeley County**

Establishment of a new Home Health Agency in Berkeley County at a total project cost of \$9,950.

Affecting Charleston County**Lowcountry Nursing Group LLC d/b/a Interim Healthcare - Charleston County**

Establishment of a new Home Health Agency in Charleston County wherein Licensee began operation during the time CON was not operating, at a total project cost of \$9,950.

The Southeastern Spine Institute Ambulatory Surgery Center, LLC

Relocation and replacement of an Ambulatory Surgery Facility (ASF) with no increase in operating rooms (ORs) and for an additional three procedure rooms, for a total of 2 ORs and 3 Procedure Rooms at a total project cost of \$13,135,194.

NOTICES

East Cooper Community Hospital, Inc. d/b/a East Cooper Medical Center

Establishment of Diagnostic Cardiac Catheterization Services at a total project cost of \$442,612.

Affecting Dorchester County

Lowcountry Nursing Group LLC d/b/a Interim Healthcare -Dorchester County

Establishment of new Home Health Agency in Dorchester County at a total project cost of \$9,950.

Presbyterian Home of South Carolina d/b/a Presbyterian Communities of South Carolina – The Village at Summerville

Construction for the replacement of an existing 87 bed nursing facility and for the addition of one long term bed, for a total of 88 long term beds at a total project cost of \$28,400,134.

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

NOTICE OF GENERAL PUBLIC INTEREST

Statutory Authority: S.C. Code Sections 48-1-10 et seq.

In accordance with South Carolina Regulation 61-62.1, Section (II)(B)(6), a facility may request an exemption from the requirement to obtain a construction permit for modifications to existing equipment, including the reconstruction, relocation, and replacement of existing equipment.

The Department has developed a guidance document, in the form of a memo, to be used by Bureau of Air Quality (BAQ) staff in making the determinations of when a facility may receive an exception from obtaining a construction permit. This guidance will be maintained by the Department and periodically published in the *South Carolina State Register*. Additionally, this guidance will be maintained on the DHEC website at: <http://www.scdhec.gov/Environment/AirQuality/Training>.

If you have questions or comments, please contact Steve McCaslin, Division of Engineering Services, at (803) 898-4123.

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

NOTICE OF GENERAL PUBLIC INTEREST

Statutory Authority: S.C. Code Sections 48-1-10 et seq.

South Carolina Regulation 61-62.5, Standard No. 7, Prevention of Significant Deterioration, Section (k)(2), requires that facilities requesting a Prevention of Significant Deterioration (PSD) construction permit submit a "source impact analysis" demonstrating "that allowable emissions increases from the proposed source or modification, in conjunction with all other applicable emissions increases or reductions (including secondary emissions), would not cause or contribute to air pollution in violation of ... any applicable maximum allowable increase over the baseline concentration in any area." The maximum allowable increases over the baseline concentration are also known as the PSD increments. Previously, the Department has requested that all facilities in areas where a baseline concentration has been set submit information to demonstrate that these facilities' emissions would not cause an exceedance of the applicable PSD increments. The Department has revised the guidance outlining how non-PSD facilities will comply with this requirement. This guidance will be maintained by the Department and will be posted on the DHEC website at: <http://www.scdhec.gov/Environment/docs/Std7PSDIncrementGuidance.pdf>.

Implementation