STATE HEALTH PLANNING BOARD

ELECTIVE ANGIOPLASTY WITHOUT ON-SITE CARDIAC SURGERY BACK-UP DEMONSTRATION PROJECTS

July 10, 2008

DEPARTMENT STAFF SUMMARIES

DEPARTMENT OF HEALTH AND SENIOR SERVICES
DIVISION OF HEALTH FACILITIES EVALAUTION AND LICENSING
OFFICE OF CERTIFICATE OF NEED AND HEALTHCARE FACILITY LICENSURE

STATE HEALTH PLANNING BOARD

ELECTIVE ANGIOPLASTY WITHOUT ON-SITE CARDIAC SURGERY BACK-UP DEMONSTRATION PROJECT SUMMARIES

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Hackensack, Ridgewood Hospital Market Area

1. Chilton Memorial Hospital
2. Holy Name Hospital

STATE HEALTH PLANNING BOARD
CERTIFICATE OF NEED PROJECT SUMMARY
ELECTIVE ANGIOPLASTY WITHOUT ON-SITE SURGERY BACK-UP
DEMONSTRATION PROJECT

Applicant:	Chilton Memorial Hospital (Chilton)
CN Number:	FR 071225-14-01
Location:	Pompton Plains, Morris County
Project Cost:	$0

PROJECT DESCRIPTION:
Applicant is proposing to provide elective PCI without back-up surgery on-site and further proposes to participate in the Atlantic C-PORT, Elective Angioplasty Study, a multi-state demonstration trial to assess safety, quality and cost of elective PCI offered at community hospitals that do not offer cardiac surgery services on site. There are no construction or project costs associated with this project. The applicant proposes to contract with Morristown Memorial Hospital as the participating cardiac surgery center.

I. SUMMARY OF THE APPLICANT'S REPRESENTATIONS

A. APPLICANT JUSTIFICATION

Chilton states that it meets the criteria for participation and is capable of providing high quality cardiac care to the community it serves, including primary and elective PCI. Chilton further states that its patient population is representative of the diverse regions in the State, namely its suburban populations. Chilton is committed to meeting health care needs of the medically underserved in the region and states that its projected case volume is sufficient to meet the requirements of the proposed trial. Further, approval of Chilton's application would enhance access for the more than 200 patients who require this intervention each year.

B. STATUTORY CRITERIA

a. The availability of facilities or services that may serve as alternatives or substitutes.

The applicant states that there four other hospitals, Morristown Memorial Hospital (Morristown), PBI Regional Medical Center, Saint Joseph's Hospital and Valley Hospital in the Chilton service area which provide elective angioplasty. Chilton acknowledges that all four hospitals anticipate some impact as a result of Chilton's participation in the study. Chilton states that these four hospitals performed 6,076 interventional procedures in 2006, and that Chilton's 153 anticipated elective PCIs in 2010 represent only 2.5% of that total. Morristown has agreed to participate with Chilton as the cardiac surgery center. Additionally, Chilton assumes that recent trends of volume increases will offset any impact to existing providers.

b. The need for special equipment and services in the area.

The applicant indicates that there is no additional equipment needed for the project.

c. The adequacy of financial resources and sources of present and future revenues.

The applicant states it has the financial resources to implement this project.

d. The availability of sufficient staff in the several professional disciplines involved.

The applicant states that 1 FTE nurse, 0.5 FTE technician, and 1 FTE clerical would be added to support the program. Six interventionalists already practice at Chilton, who would support the program.

e. The project is necessary to provide required health care in the region.

The applicant states that the November 5, 2007 CN call for elective angioplasty without on-site surgery back-up defines the need for the health care service in the state. The applicant further establishes its eligibility to participate in the project in its service area.

f. The project will not have an adverse impact on access to health care services in the region or Statewide.

As stated by the applicant, it made 210 cardiac surgery and PCI referrals in 2006 with the following impact: 101 or 48% were referred to Morristown Memorial Hospital; 52 or 24.8% to St. Joseph's Medical Center, and 46 or 21.9% to St. Mary's Hospital-Passaic. *Morristown's PCI volume was 2,648 in 2006 and the impact of 75% of Chilton's referrals being lost would account for 2.9% of Morristown's volume. St. Joseph's PCI volume was 1,265 in 2006 and the impact of 75% of Chilton's referrals being lost would account for 3.1% of St. Joseph's volume. St. Mary's PCI volume was 593 in 2006 and the impact of 75% of Chilton's referrals being lost would account for 5.8% of St. Mary's volume assuming all the referrals were for angioplasty. The above calculations assume all referrals were for PCI.*

Department analysis of 2006 UB discharge data indicates the percentage of each cardiac surgery center's PCI cases which came from each applicant's service area. Service area is defined as those zip codes that comprise 75% of an applicant's discharges, using 2006 UB discharge data, reported by the applicants in completeness responses. The impact is as follows: 5.1% of Morristown's; 15.1% of St. Joseph's Hospital; 4.5% of St. Mary's Passaic and 7.1% of Valley Hospital's PCI cases came from Chilton's service area in 2006.

C. DEMONSTRATION PROJECT CRITERIA AT N.J.A.C. 8:33-3.11(e)

For the most part, the applicant has sufficiently documented the ability to satisfy demonstration project eligibility criteria at N.J.A.C. 8:33-3.11(e)4 and the Atlantic C-PORT-E trial site inclusion criteria, including: (a) how the applicant will satisfy the patient selection criteria specified in the Atlantic C-PORT-E protocol, which is designed to assure informed consent and appropriate randomization, as provided in the Manual

*of Operations (N.J.A.C. 8:33-3.11(e)6iii); (b) approval of the study protocol by the applicant's Institutional Review Board, and if approval is pending, the status of that application (N.J.A.C. 8:33-3.11(e)6iv); (c) how the applicant will meet the target volume specified in the Atlantic C-PORT-E protocol of primary and elective angioplasties performed at the applicant's site, after randomization (that is, 100 PCI cases in year one and 200 cases in year two and each year thereafter) (N.J.A.C. 8:33-3.11(e)6v)**; (d) the applicant's compliance with the criteria for performance of primary PCI at N.J.A.C. 8:33E-2.16, 2.16(b) and N.J.A.C. 8:43G-7 (N.J.A.C. 8:33-3.11(e)6vi); and (e) documentation of the applicant's willingness to report elective PCI data to the Department separate from data collected as part of the study protocol, to support the Department's ongoing monitoring of cardiac services pursuant to N.J.A.C. 8:33E-1.9 and 2.10 (N.J.A.C. 8:33-3.11(e)6vii).*

**Staff Note: The applicant has <u>not</u> sufficiently documented the ability to satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol of performing at least 200 angioplasties per year.*

a. C-PORT-E Study Site Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6i):

The applicant has documented how it would satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol, including: (1) capability of performing a minimum volume of diagnostic cardiac catheterizations per year (N.J.A.C. 8:33-3.11(e)6i(1)); (2) agreement to complete an elective PCI development program (N.J.A.C. 8:33-3.11(e)6i(2)); (3) agreement to abide by physician, patient and device selection criteria defined in the study's Manual of Operations (N.J.A.C. 8:33-3.11(e)6i(3)); (4) agreement to collect and transmit study data in a timely fashion (N.J.A.C. 8:33-3.11(e)6i(4)); (5) agreement to perform elective PCI only via the study protocol and only while cases are being enrolled in the study (N.J.A.C. 8:33-3.11(e)6i(5)); and (6) agreement to develop and maintain a quality and error management program, including a weekly interventional conference and monthly quality and error management review (N.J.A.C. 8:33-3.11(e)6i(6)).

b. Participating Interventional Cardiologist Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6ii):

The applicant has documented that its participating interventional cardiologists have agreed to: (1) be in compliance and continue to be in compliance with minimum annual statewide interventional volume standards as set forth at N.J.A.C. 8:33E-2.16(b)6 (N.J.A.C. 8:33-3.11(e)6ii(1)); (2) practice in accordance with Atlantic C-PORT-E trial defined device and patient selection criteria (N.J.A.C. 8:33-3.11(e)6ii(2)); (3) obtain necessary informed consent for patient participation in the demonstration including the identity and location of the participating cardiac surgery center(s) that are to receive randomized study patients (N.J.A.C. 8:33-3.11(e)6ii(3));

Participating Interventional Cardiologist Performance Criteria:

1. The applicant states that all interventionalists will comply with Atlantic C-PORT-E criteria, including its minimum physician volume standard (in accordance with N.J.A.C. 8:33E-2.16(b)6).

2. *Listed below are participating physicians and their respective 2006 angioplasty PCI case volumes. Staff Note: Department staff found that five of six interventional cardiologists met the 75 case annual interventional volume standard for 2006.*

Physician Name	All cardiac centers where physician performs angioplasties
Blitz, Lawrence R. (1)	Morristown Memorial Hospital *(116)*
Doss, Emile F. (1)	St. Joseph's Hospital: St. Mary's- Passaic *(84)*
Duvvuri, Krishna (1)	St. Joseph's Hospital *(73)*
Hupart, Preston A. (1)	St. Mary's- Passaic *(130)*
Skolnick, Bruce A. (1)	St. Mary's- Passaic: St. Joseph's Hospital: The Valley Hospital *(105)*
Williams, Raashan C. (1)	St. Mary's- Passaic *(75)*

Source: Chilton Memorial Hospital Department Database and Logbooks and NJDOH Cardiac Registry
(1) Credentialed
(2) Not currently credentialed

c. Additional Demonstration Project Evaluative Criteria (N.J.A.C. 8:33-3.11(e)7i.-iv.):

i. Ability to offer a high quality program.

a. Licensure:

Chilton was conditionally licensed on December 31, 2007 for failure to achieve compliance with N.J.A.C. 8:33E-2.16(b)6, whereby each operator performing primary PCI must perform at least 75 PCI cases each year. Chilton has satisfied all conditional licensure requirements and maintains a target date of compliance of January 1, 2009.

b. Outcomes:

Chilton's Diagnostic Cardiac Catheterization Outcomes

	2005		*2006*	
	# of Cases	*% of Total*	*# of Cases*	*% of Total*
Total Cases	*373*	*n/a*	*466*	*n/a*
Death in Hospital	*4*	*1.07%*	*7*	*1.50%*
Death in Lab	*0*	*0%*	*2*	*.42%*
All In lab Complications	*4*	*1.07%*	*12*	*2.58%*

Source: NJDHSS Cardiac Data Registry (unaudited data)

In 2005, the Department recorded 4 complications in 2006 while Chilton reported one complication in its application. In 2006, the Department reported 466 cases, seven deaths in hospital, and twelve complications, while Chilton reported 467 cases, five deaths in hospital and five complications.

ii. Representation of State's diverse regions and urban/suburban/rural population.

Chilton is located in the Morris County, in the Northeast region of the state. The 2000 U.S. Census Bureau table titled "Urban and Rural Population: New Jersey, Counties and Municipalities" reports a small population residing in rural areas in Bloomingdale, Ringwood, Wanaque and West Milford while the remainder of Chilton's service area is considered to be urban.

iii. Potential to increase access to care for minorities and medically underserved.

As presented below, Chilton's total service area population is comprised of 6.9% non-white and the over age 45 population is comprised of 4.9% non-white, based on 2000 Census data. *Chilton's percentage of diagnostic cardiac catheterization caseload performed on non-white patients was 5.1% in 2005; and 3% in 2006. Chilton's minority use rate of diagnostic cardiac catheterization is comparable to the % of non-white residents in the service area population in 2005 and 2006.*

Chilton's Service Area Population by Race

Age	Total	White	Non-white	% of Non-White to Total Population
< 45	112,738	103,677	9,061	8.0%
45 - 64	45,790	43,195	2,595	5.7%
65-74	11,836	11,402	434	3.7%
75-84	7,624	7,384	240	3.1%
85+	2,779	2,691	88	3.2%
Total	180,767	168,349	12,418	6.9%

Source: 2000 US Census

Chilton's Diagnostic Cardiac Catheterization by Race

	White Non-Hispanic	*Black Non-Hispanic*	*Hispanic*	*Asian & Pacific Islander*	*Other*	*% of Non-White Cases*
2005	*94.9%*	*1.6%*	*1.6%*	*.3%*	*1.6%*	*5.1%*
2006	*97%*	*.6%*	*1.3%*	*.6%*	*.4%*	*3%*

Source: NJDHSS Cardiac Catheterization Data Registry

iv. Projected demonstration project elective angioplasty case volume

Based on the average 430 cardiac catheterizations performed between 2005 and 2007, a 30% conversion rate would result in 129 patients, of which a maximum of 75%, or 97, would be randomized to be eligible to participate in the research project at Chilton, assuming they all met the patient eligibility criteria of the research study and gave informed consent. Chilton performed 63 primary PCIs in 2007. Total annual volume of angioplasties projected would be 160, below the annual 200 case minimum C-PORT-E demonstration project requirement.

Chilton projects 202 PCI procedures in 2009 and 207 PCI procedures in 2010 In its completeness response, Chilton states that it does not anticipate any impact from the closure of Muhlenberg Regional Medical Center.

II. FINANCIAL

Department staff reviewed and found that the applicant has documented adequate financial resources to implement and maintain the project.

STATE HEALTH PLANNING BOARD
CERTIFICATE OF NEED PROJECT SUMMARY
ELECTIVE ANGIOPLASTY WITHOUT ON-SITE SURGERY BACK-UP
DEMONSTRATION PROJECT

Applicant:	Holy Name Hospital (Holy Name)
CN Number:	FR 071213-02-01
Location:	Teaneck, Bergen County
Project Cost:	$ 0

PROJECT DESCRIPTION:
Applicant is proposing to provide elective PCI without back-up surgery on-site and further proposes to participate in the Atlantic C-PORT, Elective Angioplasty Study, a multi-state demonstration trial to assess safety, quality and cost of elective PCI offered at community hospitals that do not offer cardiac surgery services on site. Holy Name is a current participant in the Atlantic C-PORT-E trial, having been CN approved in 2005 and licensed by the Department in 2006. There are no construction or project costs associated with this project. The applicant proposes to contract with Hackensack University Medical Center, Valley Hospital, and St. Joseph's Hospital & Medical Center as participating cardiac surgery centers.

I. SUMMARY OF THE APPLICANT'S REPRESENTATIONS

A. APPLICANT JUSTIFICATION

Holy Name states that it meets the criteria for participation in the Atlantic C-PORT, Elective Angioplasty Study and is capable of providing high quality cardiac care to the community it serves, including primary and elective PCI. Located in suburban Teaneck, Holy Name is also located within 5.5 miles of the George Washington Bridge, thereby serving both urban and suburban populations. Holy Name states it is committed to meeting health care needs of the medically underserved in the region and that its projected case volume is sufficient to meet the requirements of the proposed trial. The applicant argues that approval of Holy Name's application would enhance access for patients who require this intervention.

Holy Name states that it is a full-service community hospital located in a densely populated county that has five cardiac surgery providers within 12 miles, three of which (i.e., Hackensack Medical Center, Valley Hospital, St. Joseph's Hospital & Medical Center) have submitted letters of support and agreement to collaborate with Holy Name in the Atlantic C-PORT, Elective Angioplasty Trial. The remaining two cardiac surgery centers in the region are Englewood Hospital and Columbia Presbyterian in New York.

B. STATUTORY CRITERIA

a. The availability of facilities or services that may serve as alternatives or substitutes.

"Holy Name Hospital is the sole hospital in Bergen County that is not licensed to perform cardiac surgery in Bergen County; thus, if Bergen County is to be

represented in the C-PORT-E Demonstration Project, there are no alternatives/applicants other than Holy Name Hospital."

The applicant states that it is important that Bergen County be represented because:

- Bergen is New Jersey's most populous county;
- Bergen is home to various minorities;
- If Bergen is excluded, the northeastern portion of the state will not be represented; and
- Access issues and outmigration could be studied in Bergen County.

b. The need for special equipment and services in the area.

There are no construction or equipment costs associated with this demonstration project.

c. The adequacy of financial resources and sources of present and future revenues.

Holy Name indicates that it has adequate resources to initiate and maintain the program.

d. The availability of sufficient staff in the several professional disciplines involved.

Holy Name states that it has had no difficulty in staffing its cath lab in compliance with the C-PORTE project and is in the process of adding three additional interventionalists.

e. The project is necessary to provide required health care in the region.

Holy Name indicates that its demonstration application is submitted in response to a statewide call issued by the Department for hospitals wishing to participate in a multi-state demonstration project to assess the safety, quality and cost of elective angioplasty offered at community hospitals that do not also offer cardiac surgery services on-site.

f. The project will not have an adverse impact on access to health care services in the region or Statewide.

As stated by the applicant in completeness response tables 2 and 3, it made 151 cardiac surgery and PCI referrals in 2006 with the following impact: 121 or 80% were referred to Hackensack University Medical Center and 30 or 19.8% were referred to Englewood Hospital. *Hackensack's angioplasty volume was 3,083 in 2006 and the impact of 75% of Holy Name's referrals being lost would account for 2.9% of Hackensack's volume, assuming all the referrals were for angioplasty.*

Department analysis of 2006 UB discharge data indicate the percentage of each cardiac surgery center's PCI cases which came from each applicant's service area. Service area is defined as those zip codes that comprise 75% of an applicant's discharges using 2006 UB discharge data reported by the applicants in completeness responses. The

impact is as follows: 45.6% of Englewood Hospital's, 32.7% of Hackensack University Medical Center's, 11.6% of St. Mary's Hospital-Passaic's, 13.8% of Valley Hospital's and 5.6% of Jersey City Medical Center's PCI cases came from Holy Name's service area in 2006.

C. DEMONSTRATION PROJECT CRITERIA AT N.J.A.C. 8:33-3.11(e)

*For the most part, the applicant has sufficiently documented the ability to satisfy demonstration project eligibility criteria at N.J.A.C. 8:33-3.11(e)4 and the Atlantic C-PORT-E trial site inclusion criteria, including: (a) how the applicant will satisfy the patient selection criteria specified in the Atlantic C-PORT-E protocol, which is designed to assure informed consent and appropriate randomization, as provided in the Manual of Operations (N.J.A.C. 8:33-3.11(e)6iii); (b) approval of the study protocol by the applicant's Institutional Review Board, and if approval is pending, the status of that application (N.J.A.C. 8:33-3.11(e)6iv); (c) how the applicant will meet the target volume specified in the Atlantic C-PORT-E protocol of primary and elective angioplasties performed at the applicant's site, after randomization (that is, 100 PCI cases in year one and 200 cases in year two and each year thereafter) (N.J.A.C. 8:33-3.11(e)6v)*****; (d) the applicant's compliance with the criteria for performance of primary PCI at N.J.A.C. 8:33E-2.16, 2.16(b) and N.J.A.C. 8:43G-7 (N.J.A.C. 8:33-3.11(e)6vi); and (e) documentation of the applicant's willingness to report elective PCI data to the Department separate from data collected as part of the study protocol, to support the Department's ongoing monitoring of cardiac services pursuant to N.J.A.C. 8:33E-1.9 and 2.10 (N.J.A.C. 8:33-3.11(e)6vii).*

**Staff Note: The applicant has <u>not</u> sufficiently documented the ability to satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol of performing at least 200 angioplasties per year.*

a. C-PORT-E Study Site Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6i):

The applicant has documented how it would satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol, including: (1) capability of performing a minimum volume of diagnostic cardiac catheterizations per year (N.J.A.C. 8:33-3.11(e)6i(1)); (2) agreement to complete an elective PCI development program (N.J.A.C. 8:33-3.11(e)6i(2)); (3) agreement to abide by physician, patient and device selection criteria defined in the study's Manual of Operations (N.J.A.C. 8:33-3.11(e)6i(3)); (4) agreement to collect and transmit study data in a timely fashion (N.J.A.C. 8:33-3.11(e)6i(4)); (5) agreement to perform elective PCI only via the study protocol and only while cases are being enrolled in the study (N.J.A.C. 8:33-3.11(e)6i(5)); and (6) agreement to develop and maintain a quality and error management program, including a weekly interventional conference and monthly quality and error management review (N.J.A.C. 8:33-3.11(e)6i(6)).

b. Participating Interventional Cardiologist Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6ii):

The applicant has documented that its participating interventional cardiologists have agreed to: (1) be in compliance and continue to be in compliance with minimum annual statewide interventional volume standards as set forth at N.J.A.C. 8:33E-2.16(b)6 (N.J.A.C. 8:33-3.11(e)6ii(1)); (2) practice in accordance with Atlantic C-PORT-E trial defined device and patient selection criteria (N.J.A.C. 8:33-3.11(e)6ii(2)); (3) obtain necessary informed consent for patient participation in the demonstration including the identity and location of the participating cardiac surgery center(s) that are to receive randomized study patients (N.J.A.C. 8:33-3.11(e)6ii(3));

Participating Interventional Cardiologist Performance Criteria:

1. The applicant states that all interventionalists will comply with Atlantic C-PORT-E criteria, including its minimum physician volume standard (in accordance with N.J.A.C. 8:33E-2.16(b)6).

2. *Listed below are participating physicians and their respective 2006 angioplasty PCI case volumes. Staff Note: Department staff found that eight of nine interventionalists met the 75 case minimum. There may be mitigating factors regarding physician volume that have not been brought to the Department's attention.*

Physician Name	All Facilities Where Physician Performs Angioplasties
Admani, Irfan [C]	Hackensack Univ. MC *(63)*
Andrews, Paul [C]	Hackensack Univ. MC *(110)*
Angeli, Steven [C]	Hackensack Univ. MC, Englewood *(100)*
DiVagno, Leonardo [C]	Hackensack Univ. MC *(83)*
Kim, Steve [C] [2008]	Hackensack Univ. MC, Englewood *(108)*
Landers, David [C]	Hackensack Univ. MC, Valley Hospital *(83)*
Mulkay, Angel [C]	Hackensack Univ. MC *(175)*
Segovia, Fernando [C]	Hackensack Univ. MC *(234)*
Sharma, Atul [C]	Hackensack Univ. MC *(139)*

[C] Credentialed
[2008] New MD credentialed in January 2008
Source: Holy Name's completeness response Table 4 and NJDOH Cardiac Registry

c. Additional Demonstration Project Evaluative Criteria (N.J.A.C. 8:33-3.11(e)7i.-iv.):

i. Ability to offer a high quality program.

a. Licensure: *Holy Name is unconditionally licensed.*

b. Outcomes:

Holy Name's Diagnostic Cardiac Catheterization Outcomes

	2005		*2006*	
	# of Cases	*% of Total*	*# of Cases*	*% of Total*
Total Cases	*437*	*n/a*	*477*	*n/a*
Death in Hospital	*0*	*0*	*2*	*.42%*
Death in Lab	*0*	*0*	*0*	*0*
All In lab Complications	*0*	*0%*	*0*	*0%*

Source: NJDHSS Cardiac Data Registry (unaudited data)

In 2006, the Department recorded 437 cases in 2005, while Holy Name reported 436 in its application. In 2006, the Department reported 477 cases two deaths in hospital and zero complications, while Holy Name reported479 cases one death in hospital and one complication in its application.

ii. Representation of State's diverse regions and urban/suburban/rural population.

Holy Name is located in Bergen County, in the Northeast region of the state. The 2000 U.S. Census Bureau table titled "Urban and Rural Population: New Jersey, Counties and Municipalities" reports Holy Name's service area as urban.

Holy Name states that it "was founded by the Sisters of St. Joseph of Peace (a Roman Catholic Order) in Teaneck, a town where today the number of synagogues equal the number of churches, and where a thriving mosque exists as well." The applicant also states that, not only is it located in suburban Teaneck, but its location is also within 5.5 miles of the George Washington Bridge, thereby serving both urban and suburban populations. It is also stated that "We provide care through our ER and outpatient clinics to a significant number of patients who are undocumented aliens, a category of patients that is poorly accounted for in published data and not accounted for in charity care totals, given the lack of documentation from these persons."

iii. Potential to increase access to care for minorities and medically underserved.

As presented below, Holy Name's total service area population is comprised of 31% non-white. The over 45 population is 26.4% non-white*. As calculated by the Department, Holy Name's diagnostic cardiac catheterization patient population percentage of non-white patients was 33.4% in 2005 and 34.0% in 2006. Holy Name's minority use rate of diagnostic cardiac catheterization is above the % of non-white residents in the service area population in 2005 and 2006.*

Holy Name's Service Area Population by Race

Age Category	White	Non-White	Total	% of Non-White to Total Population
Under 45	286,837	144,274	431,111	33%
45-64	106,807	49,935	156,742	32%
65-74	40,977	10,879	51,856	21%
75-84	30,259	5,659	35,918	16%
85 +	10,949	1,473	12,422	12%
Total	475,829	212,220	688,049	31%

Source: Holy Name Completeness Question Responses

Holy Name's Diagnostic Cardiac Catheterization by Race

	White Non-Hispanic	*Black Non-Hispanic*	*Hispanic*	*Asian & Pacific Islander*	*Other*	*% of Non-White Cases*
2005	*66.6%*	*11.2%*	*12.1%*	*7.3%*	*2.7%*	*33.4%*
2006	*66.0%*	*12.6%*	*11.3%*	*8.0%*	*2.1%*	*34.0%*

Source: NJDHSS Cardiac Catheterization Data Registry

iv. Projected demonstration project elective angioplasty case volume

Based on the average of 442 cardiac catheterizations performed between 2005 and 2007, a 30% conversion rate would result in 133 patients, of which a maximum of 75%, or 99, would be randomized to be eligible to participate in the research project at Holy Name, assuming they all met the patient eligibility criteria of the research study and gave informed consent. In addition to the 99 elective angioplasties anticipated, Holy Name performed 45 primary angioplasties in 2007. Total annual volume of angioplasties projected based on past performance would be 144, which is below the annual 200 case minimum volume C-PORT-E demonstration project requirement.

In response to completeness questions, Holy Name stated that it does not expect any effect from the closing of Muhlenberg Regional Medical Center.

III.FINANCIAL

Department staff reviewed and found that the applicant has documented adequate financial resources to implement and maintain the project.

Newark/Jersey City Hospital Market Area

1. Bayonne Medical Center
2. Christ Hospital
3. Clara Maass Medical Center
4. Mountainside Hospital
5. Trinitas Hospital

STATE HEALTH PLANNING BOARD
CERTIFICATE OF NEED PROJECT SUMMARY
ELECTIVE ANGIOPLASTY WITHOUT ON-SITE SURGERY BACK-UP
DEMONSTRATION PROJECT

Applicant:	Bayonne Medical Center (Bayonne)
CN Number:	FR 071226-09-01
Location:	Bayonne, Hudson County
Project Cost:	$ 0

PROJECT DESCRIPTION
Applicant is proposing to provide elective PCI without back-up surgery on-site and further proposes to participate in the Atlantic C-PORT, Elective Angioplasty Study, a multi-state demonstration trial to assess safety, quality and cost of elective PCI offered at community hospitals that do not offer cardiac surgery services on site. Bayonne is a current participant in the Atlantic C-PORT-E trial, having been CN approved in 2005 and licensed by the Department in 2006. There are no construction or project costs associated with this project. The applicant proposes to contract with Newark Beth Israel Medical Center as the participating cardiac surgery center.

I. SUMMARY OF THE APPLICANT'S REPRESENTATIONS

A. APPLICANT JUSTIFICATION

Bayonne states that over the past several years it has demonstrated an ability to expand its cardiology services to meet the existing and increasing healthcare requirements of its community. From its initiation of a low risk cardiac catheterization laboratory, its designation as a full service laboratory in 2003, to its subsequent approvals for primary PCI and participation in the Atlantic C-PORT-E trial, Bayonne has provided a high-quality, safe and effective program that reflects the medical; center's commitment to its patients and the community.

Bayonne completed 187 PCIs in the first 12 months of the Atlantic C-PORT-E trial, with growth during the second 12 month period slowed due in part to litigation regarding certificate of need regulations and concerns over the hospital's financial situation and potential and subsequent bankruptcy in April, 2007. Bayonne indicates that once a transfer of ownership has been completed, it will embark on a public relations effort to ensure the community, physicians, employees and EMS services that Bayonne will continue to provide patients with excellent medical care. (Note: A transfer of ownership of Bayonne Medical Center to Opco, a wholly owned subsidiary of IJKG, LLC, a newly formed, for-profit limited liability company – CN# 071203-09-01 – was approved on January 9, 2008. On February 5, 2008, in response to completeness questions, a letter was submitted to the Department confirming that IJKG Opco LLC, the new owner of Bayonne Medical Center, fully approves and supports management's filing of the certificate of need application.)

Bayonne also indicates that its patient population is representative of the diverse regions in the State, namely its urban and suburban populations; Bayonne is committed to meeting health care needs of the medically underserved in the region and, if re-approved, its projected case volume is sufficient to meet the requirements of the proposed trial within 12 months of re-approval.

The applicant states that there are no additional construction or renovation costs for the project. Further, the applicant indicates that approval of Bayonne's application would enhance access for the more than 200 inpatients and emergency patients who require this intervention each year.

B. STATUTORY CRITERIA

a. The availability of facilities or services that may serve as alternatives or substitutes.

Bayonne and its medical staff considered the availability of services carefully, deciding that it was not appropriate to transfer emergency acute myocardial infarction patients and over 200 inpatients each year to other facilities. The applicant states that "BMC was (and is currently) in a position to provide these patients with high quality and effective cardiac care." Bayonne indicates that participation in the Atlantic C-PORT-E trial would bring leading edge cardiac treatment to an inner city hospital and provide its patients with an improved level of care and service.

b. The need for special equipment and services in the area.

The applicant states that Bayonne received certificate of need approval for participation in the Atlantic C-PORT-E trial in October, 2005, which in its view validates the need for this service within the hospital's service area. The applicant states further that Bayonne has demonstrated "an ability to provide a high-quality, safe effective level of care to patients requiring elective PCI and welcomes the opportunity to continue to serve its communities health care needs."

c. The adequacy of financial resources and sources of present and future revenues.

The applicant refers to Exhibit A of its application (*Staff note: correct reference is Exhibit D*), which is Bayonne's audited financial statements, in response to this criterion.

d. The availability of sufficient staff in the several professional disciplines involved.

Bayonne states that no additional staff is required to continue Bayonne's participation in the Atlantic C-PORT-E trial. Should a need arise for additional staff in the future, Bayonne will recruit to ensure that all positions required to provide a high-quality and safe program are filled.

e. The project is necessary to provide required health care in the region.

As indicated in "b" above, the applicant states that Bayonne received certificate of need approval for participation in the Atlantic C-PORT-E trial in October, 2005, which in its view validates the need for this service within the hospital's service area. The applicant states further that Bayonne has demonstrated "an ability to provide a high-quality, safe effective level of care to patients requiring elective PCI and welcomes the opportunity to continue to serve its communities health care needs."

f. The project will not have an adverse impact on access to health care services in the region or Statewide.

As stated by the applicant in completeness response tables 2 and 3, Newark Beth Israel Medical Center is Bayonne's primary referral center (153 or 100% of Bayonne's angioplasty and cardiac surgery referrals in 2006). Newark Beth Israel's angioplasty volume was 1,468 in 2006 and the impact of 100% of Bayonne's referrals being lost would account for only 10.4% of Newark Beth Israel Medical Center's volume, assuming all the referrals were for angioplasty.

Department of Health and Senior Services (Department) analysis of 2006 UB discharge data indicates the percentage of each cardiac surgery center's PCI cases which came from each applicant's service area. Service area is defined as those zip codes that comprise 75% of an applicant's discharges, using 2006 UB discharge data, reported by the applicants in completeness responses. The impact is as follows: 20.1% of Jersey City Medical Center's and 18.4% of Newark Beth Israel Medical Center's PCI cases came from Bayonne's service area in 2006.

Bayonne indicates that the impact on surrounding facilities that provide elective PCI has been negligible. A total of 187 PCI procedures were completed at Bayonne in the first 12 months of program participation (May, 2006 – April, 2007). During this time, cardiac volume at neighboring facilities has remained stable or increased. Bayonne believes that this is indicative of the need to maintain (if not further expand) the availability of elective PCI. Bayonne is the only hospital in Hudson County participating in the Atlantic C-PORT-E trial.

C. DEMONSTRATION PROJECT CRITERIA AT N.J.A.C. 8:33-3.11(e)

For the most part, the applicant has sufficiently documented the ability to satisfy demonstration project eligibility criteria at N.J.A.C. 8:33-3.11(e)4 and the Atlantic C-PORT-E trial site inclusion criteria, including: (a) how the applicant will satisfy the patient selection criteria specified in the Atlantic C-PORT-E protocol, which is designed to assure informed consent and appropriate randomization, as provided in the Manual of Operations (N.J.A.C. 8:33-3.11(e)6iii); (b) approval of the study protocol by the applicant's Institutional Review Board, and if approval is pending, the status of that application (N.J.A.C. 8:33-3.11(e)6iv); (c) how the applicant will meet the target volume specified in the Atlantic C-PORT-E protocol of primary and elective angioplasties performed at the applicant's site, after randomization (that is, 100 PCI cases in year one

and 200 cases in year two and each year thereafter) (N.J.A.C. 8:33-3.11(e)6v); (d) the applicant's compliance with the criteria for performance of primary PCI at N.J.A.C. 8:33E-2.16, 2.16(b) and N.J.A.C. 8:43G-7 (N.J.A.C. 8:33-3.11(e)6vi); and (e) documentation of the applicant's willingness to report elective PCI data to the Department separate from data collected as part of the study protocol, to support the Department's ongoing monitoring of cardiac services pursuant to N.J.A.C. 8:33E-1.9 and 2.10 (N.J.A.C. 8:33-3.11(e)6vii).

Staff Note: As noted below, the applicant has <u>not</u> sufficiently documented the ability to satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol of performing at least 200 angioplasties per year (N.J.A.C. 8:33-3.11(e)6v).

a. C-PORT-E Study Site Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6i):

The applicant has documented how it would satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol, including: (1) capability of performing a minimum volume of diagnostic cardiac catheterizations per year (N.J.A.C. 8:33-3.11(e)6i(1)); (2) agreement to complete an elective PCI development program (N.J.A.C. 8:33-3.11(e)6i(2)); (3) agreement to abide by physician, patient and device selection criteria defined in the study's Manual of Operations (N.J.A.C. 8:33-3.11(e)6i(3)); (4) agreement to collect and transmit study data in a timely fashion (N.J.A.C. 8:33-3.11(e)6i(4)); (5) agreement to perform elective PCI only via the study protocol and only while cases are being enrolled in the study (N.J.A.C. 8:33-3.11(e)6i(5)); and (6) agreement to develop and maintain a quality and error management program, including a weekly interventional conference and monthly quality and error management review (N.J.A.C. 8:33-3.11(e)6i(6)).

b. Participating Interventional Cardiologist Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6ii):

The applicant has documented that its participating interventional cardiologists have agreed to: (1) be in compliance and continue to be in compliance with minimum annual statewide interventional volume standards as set forth at N.J.A.C. 8:33E-2.16(b)6 (N.J.A.C. 8:33-3.11(e)6ii(1)); (2) practice in accordance with Atlantic C-PORT-E trial defined device and patient selection criteria (N.J.A.C. 8:33-3.11(e)6ii(2)); (3) obtain necessary informed consent for patient participation in the demonstration including the identity and location of the participating cardiac surgery center(s) that are to receive randomized study patients (N.J.A.C. 8:33-3.11(e)6ii(3));

Participating Interventional Cardiologist Performance Criteria:

1. The applicant states that all interventionalists have met the annual statewide interventional volume standard of 75 cases in 2006 and that its participating physicians will continue to meet this standard in accordance with N.J.A.C. 8:33E-2.16(b)6.

2. *Listed below are participating physicians and their respective 2006 angioplasty case volumes. Staff Note: Department staff found that all four interventionalists met the 75 case minimum.*

Physician Name	All Facilities Where Physician Performs Angioplasties (CY 2006 volume)
Asif, Mohammed	Newark Beth Israel Medical Center, Bayonne Medical Center *(187 cases)*
Hefferan, James	Newark Beth Israel Medical Center, Saint Barnabas MC, Bayonne Medical Center *(81 cases)*
Wasty, Najam	Newark Beth Israel Medical Center, Bayonne Medical Center *(168 cases)*
Wong, Peter	Newark Beth Israel Medical Center, Bayonne MC, Jersey City MC *(178 cases)*

Source: Applicant's completeness response and NJDOH Cardiac Registry

c. Additional Demonstration Project Evaluative Criteria (N.J.A.C. 8:33-3.11(e)7i.-iv.):

i. Ability to offer a high quality program;

a. Licensure: Licensure: *Bayonne's primary PCI program is conditionally licensed effective July 1, 2008 for failure to achieve compliance with facility and physician volume standards).*

Bayonne reported a violation of the Atlantic C-PORT-E study protocol involving an inappropriate enrollment of a patient that had been previously enrolled in the study.

b. Outcomes:

Bayonne's Diagnostic Cardiac Catheterization Outcomes

	2005		*2006*	
	# of Cases	*% of Total*	*# of Cases*	*% of Total*
Total Cases	*506*	*n/a*	*667*	*n/a*
Death in Hospital	*0*	*0*	*0*	*0*
Death in Lab	*0*	*0*	*0*	*0*
All in lab Complications	*0*	*0*	*0*	*0*

Source: NJDHSS Cardiac Data Registry (unaudited data)

The Department and the applicant found no complications reported in 2005 and 2006.

ii. Representation of State's diverse regions and urban/suburban/rural population

Bayonne is located in Hudson County, in the Northeast region of the state. The 2000 U.S. Census Bureau table titled "Urban and Rural Population: New Jersey, Counties and Municipalities" reports all of Bayonne's service area as urban.

Bayonne indicates that it has a history of supporting the indigent of its community and indigent families from neighboring communities. Bayonne cites the Department's prior certificate of need approval to participate in the Atlantic C-PORT-E trial. The Department's assessment at that time was that Bayonne's approval would increase access to care in Hudson County, a densely populated area with a very high percentage of minority and medically underserved residents. Bayonne's new ownership, IJKG Opco LLC, concurs with this assessment and has committed in writing and various public forums its intent to maintain and build upon the range of services offered to the

community. Bayonne also emphasizes the need for hospitals in the area to work to adequately respond to all healthcare needs of the residents of southern Hudson County due to the closure of nearby Greenville Hospital.

iii. Potential to increase access to care for minorities and medically underserved.

The needs of the medically underserved are cared for through Bayonne's Family Health Center and educational and screening offerings provided on-site through the hospital's Community Crossings program. Bayonne is also in discussions with the City of Bayonne and Horizon Federally Qualified Health Center as a means of offering more comprehensive services and serving more patients. "A future focus on disease management to better serve indigent members of our community with chronic diseases is of interest to our new owners."

As presented below, Bayonne's total service area population is comprised of 48.3% non-white and the over age 45 population is comprised of 34.66% non-white based on 2000 Census data. *As calculated by the Department, Bayonne's diagnostic cardiac catheterization patient population percentage of non-white patients was 40.9% in 2005 and 38.8% in 2006. Bayonne's minority use rate of diagnostic cardiac catheterization was comparable to the % of non-white residents in the service area population in 2005 and 2006.*

Bayonne's Service Area Population By Race And Age Distribution

Age	Total	White	Non-White	% of Non-White to Total Population
<45	77,700	34,310	43,390	55.8%
45-64	26,211	15,244	10,967	41.8%
65-74	8,334	5,884	2,450	29.4%
75-84	6,334	5,232	1,102	17.4%
85+	1,896	1,591	305	16.1%
Total	120,475	62,261	58,214	48.3%

Source: 2000 US Census

Bayonne's Diagnostic Cardiac Catheterization by Race

	White Non-Hispanic	*Black Non-Hispanic*	*Hispanic*	*Asian & Pacific Islander*	*Other*	*% of Non-White Cases*
2005	*59.1%*	*13.8%*	*16.4%*	*7.3%*	*3.4%*	*40.9%*
2006	*61.2%*	*17.8%*	*9.7%*	*7.2%*	*4.0%*	*38.8%*

Source: NJDHSS Cardiac Catheterization Data Registry

iv. Projected demonstration project elective angioplasty case volume.

Based on the average 588 cardiac catheterizations performed between 2005 and 2007, a 30% conversion rate would be 177 patients, of which a maximum of 75%, or 132, would be randomized to be eligible to participate in the research project at Bayonne, assuming they all met the patient eligibility criteria of the research study and gave informed consent. In addition to the 132 elective angioplasties anticipated, Bayonne performed 21 primary PCIs in 2007. Total annual volume of angioplasties projected based on past performance would be 153, below the 200 annual minimum C-PORT-E demonstration project requirement. Bayonne also predicts further increases in volume based on population growth and anticipated referral changes.

As a participant in the Atlantic C-PORT-E trial, Bayonne has performed a total of 107 elective PCI cases from May through December, 2006 and 124 cases during CY 2007, for a total of 231 elective PCI cases (ranking third highest in volume of the nine participants or 15% of total New Jersey C-PORT-E enrollees). There have been no reported deaths and one complication among Bayonne's elective PCI cases.

Bayonne Medical Center has performed 37 primary PCIs during CY2006 and 21 primary PCIs in CY 2007.

Bayonne anticipates no impact resulting from the closure of Muhlenberg Regional Medical Center, since there is no service area overlap.

Staff Note: The applicant has <u>not</u> sufficiently documented the ability to satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol of performing at least 200 angioplasties per year (N.J.A.C. 8:33-3.11(e)6v). The applicant was able to document its ability to timely implement the original CN approval of an elective PCI demonstration program in 2006. The applicant has performed 231 elective PCI cases from its initial Atlantic C-PORT-E patient enrollment on May 15, 2006 through December 31, 2007.

I. FINANCIAL

Department staff reviewed and found that the applicant has documented adequate financial resources to implement and maintain the project.

STATE HEALTH PLANNING BOARD
CERTIFICATE OF NEED PROJECT SUMMARY
ELECTIVE ANGIOPLASTY WITHOUT ON-SITE SURGERY BACK-UP
DEMONSTRATION PROJECT

Applicant:	Christ Hospital (Christ)
CN Number:	FR 071223-09-01
Location:	Jersey City, Hudson County
Project Cost:	$ 0

PROJECT DESCRIPTION:
Applicant is proposing to provide elective PCI without back-up surgery on-site and further proposes to participate in the Atlantic C-PORT, Elective Angioplasty Study, a multi-state demonstration trial to assess safety, quality and cost of elective PCI offered at community hospitals that do not offer cardiac surgery services on site. There are no costs associated with this project. The applicant proposes to contract with Jersey City Medical Center as the participating cardiac surgery center for the Atlantic C-PORT-E study.

I. SUMMARY OF THE APPLICANT'S REPRESENTATIONS

A. APPLICANT JUSTIFICATION

Christ Hospital is a major provider of health care in Jersey City and Hudson County – it shares with Jersey City Medical Center the highest patient volume in the county – and it is the site of the most active cardiovascular services in the area. Christ Hospital's application is enhanced by three important elements: 1) the continuing restructuring of health care services in Hudson County that presents an unprecedented opportunity for new institutional relationships and area wide cardiac care coordination, 2) data confirming that only one in every four Hudson residents who underwent angioplasty did so in the county, and 3) the willingness of the Department and Atlantic C-PORT-E study staff to increase the number of participants and flow of data in the study.

Christ Hospital indicates that it's service area not only is comprised of 42 percent minority patients, as its previous certificate of need submission documented, but also includes communities in the northern portion of Hudson County where there is no angioplasty program. The 2000 census found 608,975 people living in Hudson county, including 240,055 in Jersey City, 61,842 in Bayonne, and a higher combined total of 307,078 people in the 10 other municipalities in the county. Christ Hospital, which is centrally-located, draws more patients from those central and northern communities than either Jersey City Medical Center or Bayonne Medical Center, the two current providers of elective angioplasty in Hudson County.

Christ Hospital argues that in 2006 the three full service cardiac catheterization providers (i.e., Christ Hospital, Jersey City Medical Center, Bayonne Medical Center) and two low risk cardiac catheterization providers (i.e., Meadowlands Hospital, Palisades General Hospital) served a total of 3,470 cases. While that total was mainly diagnostic cases, it included 457 interventional cases with 348 undertaken at Jersey

City Medical Center and 107 at Bayonne Medical Center. The 457 cases represented only 22 percent of the 2007 interventional cases among Hudson County residents in 2006. The remaining 78 percent were distributed among more than a dozen hospitals in Essex, Bergen and Passaic Counties and across the state.

Christ Hospital states that a survey of its five most active interventionalists indicate that during 2007 the number of catheterization and referred angioplasty cases totaled nearly 800. This potential caseload would greatly exceed the criteria for participation in Atlantic C-PORT-E. The arrival in July, 2008 of a 64-slice CT will also provide an expanded diagnostic tool that is likely to increase the number of patients who will benefit from PCI. Christ Hospital further states that its proposal provides for a significant number of new patients drawn largely from a minority and underserved patient population that is representative of the diverse regions in the State, namely its inner city and urban populations.

B. STATUTORY CRITERIA

a. The availability of facilities or services that may serve as alternatives or substitutes.

Christ Hospital indicates that it is located in Hudson County where Jersey City Medical Center is the only cardiac surgery center and Bayonne Medical Center was the only non-cardiac surgery center providing elective PCI in the county. Christ Hospital also indicates that the future of Bayonne Medical Center is clouded but Christ Hospital's participation in the Atlantic C-PORT-E study should bring new volume into the study and should not adversely affect Bayonne Medical Center.

b. The need for special equipment and services in the area.

Christ Hospital indicates that Hudson County is the most densely populated county in New Jersey and with 65 percent of its population classified as minorities, it is also the most diverse county in the state. With the highest concentration of medically underserved residents in New Jersey, elective angioplasty exists at two institutions in the county, but 3 out of every four residents who receive PCI do so out of county, a pattern that a Christ Hospital program will reverse.

c. The adequacy of financial resources and sources of present and future revenues.

Christ Hospital indicates that it has adequate resources to initiate and maintain the demonstration project. There are no additional costs associated with this study.

d. The availability of sufficient staff in the several professional disciplines involved.

No additional staff would be required to implement this demonstration project. If recruitment is necessary to ensure that positions are filled, Christ Hospital will utilize its extensive, ongoing recruitment and retention efforts.

e. The project is necessary to provide required health care in the region.

Christ Hospital indicates that this application to participate in the Atlantic C-PORT-E demonstration project is intended to assess the safety, quality and effectiveness of elective PCI offered at community hospitals that do not offer cardiac surgery services on site.

f. The project will not have an adverse impact on access to health care services in the region or Statewide.

As stated by the applicant, it made 184 cardiac surgery and PCI referrals in 2006 with the following impact: 37 or 20.1% were referred to Jersey City Medical Center, 40 or 21.7% to St. Mary's Hospital, Passaic, and 50 or 27.2% to St. Michael's Medical Center. *Jersey City's PCI volume was 504 in 2006 and the impact of 75% of Christ's referrals being lost would account for 5.5% of Jersey City's PCI volume. St. Mary's PCI volume was 593 in 2006 and the impact of 75% of Christ's referrals being lost would account for 5.1% of St. Mary's PCI volume. St. Michael's PCI volume was 1,882 in 2006 and the impact of 75% of Christ's referrals being lost would account for 2.0% of Saint Michael's PCI volume. The above calculations assume all referrals were for PCI.*

Department of Health and Senior Services (Department) analysis of 2006 UB discharge data indicates the percentage of each cardiac surgery center's PCI cases which came from each applicant's service area. Service area is defined as those zip codes that comprise 75% of an applicant's discharges using 2006 UB discharge data, reported by the applicants in completeness responses. The impact is as follows: 58% of Jersey City Medical Center's, 8.9% of St. Mary's Hospital Passaic, 7.2% of University Hospital's, 6.6% of St. Michael's Medical Center's, 5.3% of Newark Beth Israel's, 4.5% of Hackensack University Medical Center's and 3.7% of Englewood Hospital's PCI cases came from Christ Hospital's service area in 2006.

C. DEMONSTRATION PROJECT CRITERIA AT N.J.A.C. 8:33-3.11(e)

For the most part, the applicant has sufficiently documented the ability to satisfy demonstration project eligibility criteria at N.J.A.C. 8:33-3.11(e)4 and the Atlantic C-PORT-E trial site inclusion criteria, including: (a) how the applicant will satisfy the patient selection criteria specified in the Atlantic C-PORT-E protocol, which is designed to assure informed consent and appropriate randomization, as provided in the Manual of Operations (N.J.A.C. 8:33-3.11(e)6iii); (b) approval of the study protocol by the applicant's Institutional Review Board, and if approval is pending, the status of that application (N.J.A.C. 8:33-3.11(e)6iv); (c) how the applicant will meet the target volume specified in the Atlantic C-PORT-E protocol of primary and elective angioplasties performed at the applicant's site, after randomization (that is, 100 PCI cases in year one and 200 cases in year two and each year thereafter) (N.J.A.C. 8:33-3.11(e)6v); (d) the applicant's compliance with the criteria for performance of primary PCI at N.J.A.C. 8:33E-2.16, 2.16(b) and N.J.A.C. 8:43G-7 (N.J.A.C. 8:33-3.11(e)6vi); and (e) documentation of the applicant's willingness to report elective PCI data to the

Department separate from data collected as part of the study protocol, to support the Department's ongoing monitoring of cardiac services pursuant to N.J.A.C. 8:33E-1.9 and 2.10 (N.J.A.C. 8:33-3.11(e)6vii).

Staff Note: As noted below, the applicant has <u>not</u> sufficiently documented the ability to satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol of performing at least 200 angioplasties per year (N.J.A.C. 8:33-3.11(e)6v).

a. C-PORT-E Study Site Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6i):

The applicant has documented how it would satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol, including: (1) capability of performing a minimum volume of diagnostic cardiac catheterizations per year (N.J.A.C. 8:33-3.11(e)6i(1)); (2) agreement to complete an elective PCI development program (N.J.A.C. 8:33-3.11(e)6i(2)); (3) agreement to abide by physician, patient and device selection criteria defined in the study's Manual of Operations (N.J.A.C. 8:33-3.11(e)6i(3)); (4) agreement to collect and transmit study data in a timely fashion (N.J.A.C. 8:33-3.11(e)6i(4)); (5) agreement to perform elective PCI only via the study protocol and only while cases are being enrolled in the study (N.J.A.C. 8:33-3.11(e)6i(5)); and (6) agreement to develop and maintain a quality and error management program, including a weekly interventional conference and monthly quality and error management review (N.J.A.C. 8:33-3.11(e)6i(6)).

b. Participating Interventional Cardiologist Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6ii):

The applicant has documented that its participating interventional cardiologists have agreed to: (1) be in compliance and continue to be in compliance with minimum annual statewide interventional volume standards as set forth at N.J.A.C. 8:33E-2.16(b)6 (N.J.A.C. 8:33-3.11(e)6ii(1)); (2) practice in accordance with Atlantic C-PORT-E trial defined device and patient selection criteria (N.J.A.C. 8:33-3.11(e)6ii(2)); (3) obtain necessary informed consent for patient participation in the demonstration including the identity and location of the participating cardiac surgery center(s) that are to receive randomized study patients (N.J.A.C. 8:33-3.11(e)6ii(3));

Participating Interventional Cardiologist Performance Criteria:

1. The applicant states that all interventionalists have met the annual statewide interventional volume standard of 75 cases in 2006 and that its participating physicians will continue to meet this standard in accordance with N.J.A.C. 8:33E-2.16(b)6.

2. *Listed below are participating catheterization lab physicians at Christ and their respective 2006 angioplasty case volumes. Staff Note: Department staff found that five of nine interventionalists met the 75 case minimum. The Department could not verify volume of two physicians. There may be mitigating factors*

regarding physician volume that have not been brought to the Department's attention.

Physician Name	All facilities where physician performs angioplasties.
Benz, M	St Michael's, Christ Hospital *(unavailable)*
Goldstein, Jonathan	St Michael's, Clara Maass, Christ Hospital *(354 cases)*
Hannallah, Benyamin	SJHMC, JCMC *(72 cases)*
Hupart, Preston	St Mary - Passaic, JCMC, Chilton, Christ Hospital *(130 cases*)
Javed, M	Christ Hospital, JCMC *(96 cases)*
Kahan, F	UMDNJ, Christ Hospital *(unavailable)*
Kelly, Dennis III	Christ Hospital, Hackensack *(52 cases)*
Williams, Raashan	St Mary-Passaic, BI-Passaic, Chilton, Christ Hospital *(75 cases*)
Wong, Peter	Bayonne, Newark Beth Israel, Christ Hospital *(178 cases)*

c. Additional Demonstration Project Evaluative Criteria (N.J.A.C. 8:33-3.11(e)7i.-iv.):

i. Ability to offer a high quality program.

a. Licensure: *Christ Hospital cardiac catheterization service was licensed unconditionally through May 31, 2008. Christ Hospital was granted CN approval for a full service cardiac catheterization service on June 9, 2004 (CN# 040501-09-01) and was granted CN approval to provide primary angioplasty on October 3, 2005 (CN# 050703-09-01).*

b. Outcomes:

Christ's Diagnostic Cardiac Catheterization Outcomes

	2005		*2006*	
	# of Cases	*% of Total*	*# of Cases*	*% of Total*
Total Cases	*522*	*n/a*	*526*	*n/a*
Death in Hospital	*0*	*0*	*0*	*0*
Death in Lab	*0*	*0*	*0*	*0*
All In lab Complications	*1*	*0.19%*	*2*	*.38%*

Source: NJDHSS Cardiac Data Registry (unaudited data)

In 2005, the Department found 522 cases and one death in hospital, while Christ reported 521 cases and zero deaths in hospital. In 2006, the Department found 526 cases and zero deaths in hospital, while Christ reported 520 cases and one death in hospital.

ii. Representation of State's diverse regions and urban/suburban/rural population.

Christ is located in Hudson County, in the Northeast region of the state. The 2000 U.S. Census Bureau table titled "Urban and Rural Population: New Jersey, Counties and Municipalities" reports all of Christ's service area as urban.

Hudson County has the highest concentration of medically underserved residents in the State, and Christ Hospital notes that elective angioplasty is available at only two institutions in the County. Selection of Christ Hospital would therefore help to determine the effectiveness of such services to medically underserved populations and help to enhance a service that has historically been underutilized by medically underserved populations. The extensive outmigration of county residents for PCI would also be reduced.

iii. Potential to increase access to care for minorities and medically underserved.

As presented below, Christ's total service area population is comprised of 59.25% non-white and the over age 45 population is comprised of 48.3% non-white. As calculated by the Department, Christ's diagnostic cardiac catheterization patient population percentage of non-white patients was 72.4% in 2005 and 70.7% in 2006. Christ's minority use rate of diagnostic cardiac catheterization is above the % of non-white residents in the service area population in 2005 and 2006.

Christ Hospital's Service Area Population by Race

Age Category	White	Non-White	% of Non-White to Total Population
Under 45	79,500	140,866	63.92%
45-64	27,899	34,340	55.17%
65-74	10,277	6,988	40.47%
75-84	7,501	3,128	29.43%
85 +	2,876	853	22.87%
Total	128,053	186,175	59.25%

Source: Christ Hospital Completeness Questions, #8c.

Christ Hospital's Diagnostic Cardiac Catheterization by Race

	White Non-Hispanic	*Black Non-Hispanic*	*Hispanic*	*Asian & Pacific Islander*	*Other*	*% of Non-White Cases*
2005	*27.6%*	*28.5%*	*25.5%*	*18.0%*	*0%*	*72.4%*
2006	*29.3%*	*23.4%*	*31.6%*	*14.8%*	*0%*	*70.7%*

Source: NJDHSS Cardiac Catheterization Data Registry

The needs of the medically underserved are cared for through Christ Hospital's strategic alliance with North Hudson Community Action Corporation to supplement and administer care to the medically underserved population within Christ Hospital's service area. North Hudson is designated as Federally Qualified Health Center that provides primary health care at a site that is in close proximity to Christ Hospital. Patients who require consultations with a cardiologist are referred to a service panel of cardiologists

on staff at Christ Hospital and subsequently scheduled for a cardiac workup regardless of their ability to pay for services.

iv. Projected demonstration project elective angioplasty case volume

Based on the average 489 cardiac catheterizations performed between 2005 and 2007, a 30% conversion rate would result in 147 patients, of which 75%, or 110, would be randomized to be eligible to participate in the research project at Christ, assuming they all met the patient eligibility criteria of the research study and gave informed consent. In addition to the 110 elective angioplasties anticipated, Christ performed 26 primary PCIs in 2007. Total annual volume of PCIs projected would be 136, below the 200 annual minimum C-PORT-E demonstration project requirement. Christ Hospital predicts further increases in volume based on population growth and anticipated referral changes due to the availability of elective PCI.

Christ Hospital anticipates no impact resulting from the closure of Muhlenberg Regional Medical Center, since there is no service area overlap.

Staff Note: The applicant has not sufficiently documented the ability to satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol of performing at least 200 angioplasties per year (N.J.A.C. 8:33-3.11(e)6v).

II. FINANCIAL

Department staff reviewed and found that the applicant has documented adequate financial resources to implement and maintain the project.

STATE HEALTH PLANNING BOARD
CERTIFICATE OF NEED PROJECT SUMMARY
ELECTIVE ANGIOPLASTY WITHOUT ON-SITE SURGERY BACK-UP
DEMONSTRATION PROJECT

Applicant:	Clara Maass Medical Center (Clara Maass)
CN Number:	FR 071217-07-01
Location:	Belleville, Essex County
Project Cost:	$ 0

PROJECT DESCRIPTION:
The applicant is proposing to provide elective PCI without back-up surgery on-site and further proposes to participate in the Atlantic C-PORT, Elective Angioplasty Study, a multi-state demonstration trial to assess safety, quality and cost of elective PCI offered at community hospitals that do not offer cardiac surgery services on site. There are no construction or project costs associated with this project. The applicant proposes to contract with Newark Beth Israel Medical Center and Saint Barnabas Medical Center as participating cardiac surgery centers.

I. SUMMARY OF THE APPLICANT'S REPRESENTATIONS

A. APPLICANT JUSTIFICATION

Clara Maass indicates that it meets the criteria for participation and is capable of providing high quality cardiac care to the community it serves. Clara Maass further states that its patient population is extraordinarily diverse, racially and ethnically, thereby being representative of the diverse regions in the State. The service area includes northern Essex, southern Passaic, southern Bergen and western Hudson County, with minorities constituting a growing percentage of the population. Clara Maass is also committed to meeting health care needs of the medically underserved in the region and has been successful in reaching many of these high-risk populations. That success is reflected in its cardiac catheterization performance data and its potential to meet the requirements of the Department and the Atlantic C-PORT-E study.

Clara Maass indicates that it has the staff, cardiology, support services and the facilities to provide elective PCI. Since Clara Maass already provides high quality cardiac catheterization services and primary PCI services, the addition of elective angioplasty will not require any additional capital or construction costs.

Clara Maass emphasizes its institutional commitment to quality as demonstrated by its consistent ranking above the ninetieth percentile for treatment of heart attack, pneumonia and congestive heart failure in the New Jersey 2006 Hospital Performance Report and achieving the second highest composite index score in the 2007 Report for treatment of heart attack, pneumonia, congestive heart failure and surgical infection prevention.

The interventional team at Clara Maass would consist of five physicians, all of whom are board certified in cardiology and meet regulatory requirements for cardiac catheterization and PCI. A sixth physician has applied for privileges and is being monitored and a seventh physician has expressed interest in practicing at Clara Maass. Clara Maass brings the clinical and operational expertise of its staff and that of its St. Barnabas Health Care System affiliate, the Heart Hospital of New Jersey, located at both Newark Beth Israel Medical Center and St. Barnabas Medical Center. Every facet of cardiac care, from cardiac catheterizations and angioplasties to cardiac surgery and cardiac transplantation, is provided at the Heart Hospital of New Jersey.

B. STATUTORY CRITERIA

a. The availability of facilities or services that may serve as alternatives or substitutes.

Clara Maass also indicates that its demonstration project application is submitted in response to a statewide call issued by the Department of Health and Senior Services (Department) for hospitals wishing to participate in a multi-state demonstration project to assess the safety, quality and cost of elective angioplasty offered at community hospitals that do not also offer cardiac surgery services on-site.

b. The need for special equipment and services in the area.

Clara Maass indicates that the need for the proposed project is based on the Department's call for certificates of need from hospitals throughout the State with an interest in participating in the proposed multi-state elective angioplasty trial. The applicant further states that its application "demonstrates that: (1) Clara Maass Medical Center is fully capable of providing a high quality program (2) its patient population is representative of the diverse regions of the state (3) Clara Maass Medical Center is committed to meeting the health care needs of the medically underserved in the region, and (4) its projected case volume is sufficient to meet the requirements of the proposed trial."

c. The adequacy of financial resources and sources of present and future revenues.

Clara Maass indicates that it has adequate resources to initiate and maintain the program.

d. The availability of sufficient staff in the several professional disciplines involved.

Clara Maass indicates that sufficient personnel are available in the various disciplines required. When necessary, recruitment would ensure all needed positions are filled. As part of the St. Barnabas Health Care System, Clara Maass has extensive ongoing recruitment and retention efforts. Efforts have included advertising in area newspapers and national journals, internet advertising, the system's nursing website, and contacts with the job placement offices at local schools. Other efforts include job fairs, open interview days and foreign recruitment. Nursing students are provided with

scholarships, and loan forgiveness programs are also offered to students. One of the most successful recruitment tools has been employee referrals of potential new employees. The many retention efforts, such as the newly restructured orientation program and employee initiatives, such as flexible scheduling, rate and shift differentials and recognition programs, serve to ensure that we attract and then retain the newly recruited staff person as well as our experienced staff.

e. The project is necessary to provide required health care in the region.

The applicant states that the November 5, 2007 CN call for elective angioplasty without on-site surgery back-up defines the need for the health care service in the state. Clara Maass also indicates that approval of its application will enhance access for the more than 200 patients who require this intervention each year.

f. The project will not have an adverse impact on access to health care services in the region or Statewide.

As stated by the applicant in completeness response tables 2 and 3, St. Michael's Medical Center (representing 164, or 63.6% of Clara Maass' angioplasty and cardiac surgery referrals in 2006) and St. Barnabas Medical Center (representing 75, or 29.1% of Clara Maass' angioplasty and cardiac surgery referrals in 2006) are Clara Maass' primary referral centers. *St. Michael's angioplasty volume was 1,882 in 2006, and the impact of 75% of Clara Maass' referrals being lost would account for 6.5% of St. Michael's volume, assuming all the referrals were for angioplasty. Similarly, St. Barnabas' angioplasty volume was 961 in 2006, and the impact of 75% of Clara Maass' referrals being lost would account for 5.9% of St. Barnabas' volume, assuming all the referrals were for angioplasty.*

Department analysis of 2006 UB discharge data reports the percentage of each cardiac surgery center's PCI cases which came from each applicant's service area. Service area is defined as those zip codes that comprise 75% of an applicant's discharges using 2003 UB discharge data reported by the applicants in completeness responses. The impact is as follows: 11.8% of St. Michael's Medical Center's, 3.1% of St Barnabas Medical Center, 9.6% of St. Mary's/Passaic Beth Israel Regional Medical Center's, 2.2% of Newark Beth Israel Medical Center's, 3.1% of St. Joseph's Medical Center's, and 3.3% of University Hospital's and 5.1% of Hackensack University Medical Center's PCI cases came from Clara Maass' service area in 2006.

C. DEMONSTRATION PROJECT CRITERIA AT N.J.A.C. 8:33-3.11(e)

For the most part, the applicant has sufficiently documented the ability to satisfy demonstration project eligibility criteria at N.J.A.C. 8:33-3.11(e)4 and the Atlantic C-PORT-E trial site inclusion criteria, including: (a) how the applicant will satisfy the patient selection criteria specified in the Atlantic C-PORT-E protocol, which is designed to assure informed consent and appropriate randomization, as provided in the Manual of Operations (N.J.A.C. 8:33-3.11(e)6iii); (b) approval of the study protocol by the

applicant's Institutional Review Board, and if approval is pending, the status of that application (N.J.A.C. 8:33-3.11(e)6iv); (c) how the applicant will meet the target volume specified in the Atlantic C-PORT-E protocol of primary and elective angioplasties performed at the applicant's site, after randomization (that is, 100 PCI cases in year one and 200 cases in year two and each year thereafter) (N.J.A.C. 8:33-3.11(e)6v); (d) the applicant's compliance with the criteria for performance of primary PCI at N.J.A.C. 8:33E-2.16, 2.16(b) and N.J.A.C. 8:43G-7 (N.J.A.C. 8:33-3.11(e)6vi); and (e) documentation of the applicant's willingness to report elective PCI data to the Department separate from data collected as part of the study protocol, to support the Department's ongoing monitoring of cardiac services pursuant to N.J.A.C. 8:33E-1.9 and 2.10 (N.J.A.C. 8:33-3.11(e)6vii).

Staff Note: As noted below, the applicant has <u>not</u> sufficiently documented the ability to satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol of performing at least 200 angioplasties per year (N.J.A.C. 8:33-3.11(e)6v).

a. C-PORT-E Study Site Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6i):

The applicant has documented how it would satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol, including: (1) capability of performing a minimum volume of diagnostic cardiac catheterizations per year (N.J.A.C. 8:33-3.11(e)6i(1)); (2) agreement to complete an elective PCI development program (N.J.A.C. 8:33-3.11(e)6i(2)); (3) agreement to abide by physician, patient and device selection criteria defined in the study's Manual of Operations (N.J.A.C. 8:33-3.11(e)6i(3)); (4) agreement to collect and transmit study data in a timely fashion (N.J.A.C. 8:33-3.11(e)6i(4)); (5) agreement to perform elective PCI only via the study protocol and only while cases are being enrolled in the study (N.J.A.C. 8:33-3.11(e)6i(5)); and (6) agreement to develop and maintain a quality and error management program, including a weekly interventional conference and monthly quality and error management review (N.J.A.C. 8:33-3.11(e)6i(6)).

b. Participating Interventional Cardiologist Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6ii):

The applicant has documented that its participating interventional cardiologists have agreed to: (1) be in compliance and continue to be in compliance with minimum annual statewide interventional volume standards as set forth at N.J.A.C. 8:33E-2.16(b)6 (N.J.A.C. 8:33-3.11(e)6ii(1)); (2) practice in accordance with Atlantic C-PORT-E trial defined device and patient selection criteria (N.J.A.C. 8:33-3.11(e)6ii(2)); (3) obtain necessary informed consent for patient participation in the demonstration including the identity and location of the participating cardiac surgery center(s) that are to receive randomized study patients (N.J.A.C. 8:33-3.11(e)6ii(3));

Participating Interventional Cardiologist Performance Criteria*:*

1. The applicant states that all interventionalists have met the annual statewide interventional volume standard of 75 cases in 2006 and that its participating

physicians will continue to meet this standard in accordance with N.J.A.C. 8:33E-2.16(b)*6.*

2. *Listed below are participating physicians at Clara Maass and their respective 2006 angioplasty case volumes. Staff Note: Department staff found that seven of twelve interventional cardiologists met the 75 case annual interventional volume standard. There may be mitigating factors regarding physician volume that have not been brought to the Department's attention.*

Physician Name	All facilities where physician performs angioplasties (CY 2006 volume)
Amato, James, Jr.	CMMC/SMMC/Trinitas Hosp/Mountainside Hosp. *(95 cases)*
Campanile, Giovanni	SBMC/Valley Hosp/Lenox Hill Hosp. *(71 cases)*
Chaaban, Fadi	N/A
Chakhtoura, Elie	CMMC/SMMC/SBMC *(192 cases)*
DeLaCruz, Catalino	N/A
Fusilli, Louis	N/A
Haik, Bruce	CMMC/SBMC/SMMC/Raritan Bay Med. Center *(256 cases*)
Hawthorne, Keith	CMMC/SBMC/SMMC *(137 cases)*
Quinn, James	N/A
Saeed, Qaisra	NBIMC/SMMC/UMDNJ/SBMC *(81 cases)*
Shehadeh, Abbas	NBIMC/SMMC/UMDNJ/SBMC *(169 cases*)
Torre, Sabino	CMMC/SBMC/SMMC *(247 cases)*

Source: Clara Maass completeness response Table 4 and NJDOH Cardiac Registry

c. Additional Demonstration Project Evaluative Criteria (N.J.A.C. 8:33-3.11(e)7i.-iv.):

i. Ability to offer a high quality program.

a. *Licensure: Clara Maass is licensed unconditionally through January 31, 2009. Clara Maass was granted CN approval to provide primary angioplasty on February 17, 2005 (CN# 041203-07-01) and became licensed on June 3, 2005.*

b. Outcomes:

Clara Maass' Diagnostic Cardiac Catheterization Outcomes

	2005		*2006*	
	# of Cases	*% of Total*	*# of Cases*	*% of Total*
Total Cases	*428*	*n/a*	*622*	*n/a*
Death in Hospital	*1*	*.23%*	*2*	*.32%*
Death in Lab	*1*	*.23%*	*1*	*.16%*
All In lab Complications	*3*	*.70%*	*4*	*.64%*

Source: NJDHSS Cardiac Data Registry (unaudited data)

The applicant's outcome data agreed with the Department's tables.

In addition to its laboratory and physician performance measures, Clara Maass emphasizes its continued strong compliance with the quality core measure indicators and its excellent patient satisfaction results as reflective of the quality of its cardiac services.

ii. Representation of State's diverse regions and urban/suburban/rural population.

Clara Maass is located in Essex County, in the Northeast region of the state. The 2000 U.S. Census Bureau table titled "Urban and Rural Population: New Jersey, Counties and Municipalities" reports all of Clara Maass' service area as urban.

Clara Maass indicates that its patient population is extraordinarily diverse, racially and ethnically, thereby being highly representative of the diverse regions in the State. The service area includes northern Essex, southern Passaic, southern Bergen and western Hudson County, with minorities constituting a growing percentage of the population. The service area "is a densely populated urban area that may be considered a microcosm of urban New Jersey…one can easily observe the diversity of this population by examining the racial/ethnic mix across the municipalities within the primary service area."

iii. Potential to increase access to care for minorities and medically underserved.

As presented below, Clara Maass' total service area population is comprised of 47.5% non-white and the over age 45 population is comprised of 36.3% non-white. *As calculated by the Department, Clara Maass' diagnostic cardiac catheterization patient population percentage of non-white patients was 42.5% in 2005 and 45.3% in 2006. Clara Maass' minority use rate of diagnostic cardiac catheterization is comparable to the % of non-white residents in the service area population in 2005 and 2006.*

Clara Maass' Service Area Population by Race

Age Category	White	Non-White	% of Non-White to Total Population
Under 45	142,652	161,663	53.1%
45-64	57,822	41,249	41.6%
65-74	19,352	9,152	32.1%
75-84	16,031	4,506	21.9%
85 +	5,608	1,472	20.8%
Total	241,465	218,042	47.5%

Source: Clara Maass completeness response

Clara Maass' Diagnostic Cardiac Catheterization by Race

	White Non-Hispanic	*Black Non-Hispanic*	*Hispanic*	*Asian & Pacific Islander*	*Other*	*% of Non-White Cases*
2005	*57.5%*	*19.2%*	*20.3%*	*2.1%*	*0.9%*	*42.5%*
2006	*54.7%*	*17.2%*	*24.3%*	*3.1%*	*0.8%*	*45.3%*

Source: NJDHSS Cardiac Catheterization Data Registry

Clara Maass indicates that it has a strong history of providing care to the underprivileged. In 2006, 8% of its cardiac catheterization cases and 7% of its primary PCIs were self pay or charity care. Clara Mass states that it works with the local communities to reach the impoverished and underserved residents and will expand efforts to include access to elective angioplasty.

iv. Projected demonstration project elective angioplasty case volume

Based on the average 559 cardiac catheterizations performed between 2005 and 2007, a 30% conversion rate would result in 168 patients, of which 75%, or 126, would be randomized to be eligible to participate in the research project at Clara Maass, assuming they all met the patient eligibility criteria of the research study and gave informal consent. In addition to the 126 elective angioplasties anticipated, Clara Maass performed 37 primary angioplasties in 2007. Total annual volume of angioplasties projected based on past performance would be163, below the 200 annual minimum C-PORT-E demonstration project requirement.

Clara Maass projects further increases in volume based on population growth and anticipated referral changes that would, in its view, achieve compliance with the volume standards by the second full year of operation. Further, Clara Maass anticipates that the closing of Muhlenberg Regional Medical Center will have a minor impact on Clara Maass' projected cases. In 2006, approximately 2.6% of Clara Maass' adult patients originated from Union County and only one inpatient for cardiac catheterization. Clara Maass states further that it would have no difficulty with receiving patients from the Muhlenberg service area.

Staff Note: The applicant has <u>not</u> sufficiently documented the ability to satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol of performing at least 200 angioplasties per year (N.J.A.C. 8:33-3.11(e)6v).

II. FINANCIAL

Department staff reviewed and found that the applicant has documented adequate financial resources to implement and maintain the project.

STATE HEALTH PLANNING BOARD
CERTIFICATE OF NEED PROJECT SUMMARY
ELECTIVE ANGIOPLASTY WITHOUT ON-SITE SURGERY BACK-UP
DEMONSTRATION PROJECT

Applicant:	Mountainside Hospital (Mountainside)
CN Number:	FR 071228-07-01
Location:	Montclair, Essex County
Project Cost:	$0

PROJECT DESCRIPTION:
Mountainside Hospital (Mountainside) is proposing to provide elective PCI without back-up surgery on-site and further proposes to participate in the Atlantic C-PORT, Elective Angioplasty Study (Atlantic C-PORT-E), a multi-state demonstration trial to assess safety, quality and cost of elective PCI offered at community hospitals that do not offer cardiac surgery services on site. There are no capital costs associated with this project, although $228,000 in minor moveable equipment is being purchased to implement the project. The applicant proposes to contract with St. Michael's Medical Center in Newark as the participating cardiac surgery center.

I. SUMMARY OF THE APPLICANT'S REPRESENTATIONS

A. APPLICANT JUSTIFICATION

Mountainside indicates that it is best positioned to serve a diverse population residing in the communities in the north and northwest area of Essex County. Under its new leadership, Mountainside has established a cooperative partnership with a broad spectrum of community and government organizations with the objective of: achieving effective community outreach for preventive services, collaborative education programs, making services more accessible to all residents and coordinating the efforts of partner organizations and hence maximizing impact. The Mountainside coordination includes: Townships, Health Departments, community organizations including churches, primary care centers, senior day care providers, and Medicare Advantage Organizations that offer managed care coverage for the Medicare eligible population.

Mountainside emphasizes that it has an extensive and dedicated staff of physicians, nurses, cardiac technicians, and community health educators who are known for the quality of their service to patients. Mountainside's location makes access to care easier for the elderly and minority populations in its service area and surrounding communities – patients for whom access to angioplasty is an important service. Mountainside's cardiac catheterization service provides high quality cardiac catheterization services as documented by an independent external review that cites cardiologists, staff and the technology in the catheterization laboratory.

B. STATUTORY CRITERIA

a. The availability of facilities or services that may serve as alternatives or substitutes.

Mountainside's traditional service area includes the north and northwest area of Essex County. No hospitals in Mountainside's service area provide elective angioplasty. The closest, St. Barnabas Medical Center is located in Livingston and during rush hour and other high traffic hours can be up to an hour drive from the communities in north and northwest Essex County. In addition to St. Barnabas Medical Center, there are three other cardiac surgery centers in Essex County (Newark Beth Israel Medical Center, St. Michael's Medical Center, and University Hospital). The development of an elective angioplasty program at Mountainside will have minimal affect on any of these programs.

b. The need for special equipment and services in the area.

Mountainside is a current provider of full service cardiac catheterization services and primary PCI services. There are no capital costs associated with this project, although $228,000 in minor moveable equipment is being purchased from available cash to implement the demonstration project.

c. The adequacy of financial resources and sources of present and future revenues.

Merit Health has invested in Mountainside and its community since assuming ownership on June 1, 2007. Merit Health (Merit) has sufficient access to capital to allow additional investment in services to the benefit of the community. Merit has brought in an experienced management team and has moved quickly to improve the quality of care provided at Mountainside by bringing in new radiology and anesthesia groups.

d. The availability of sufficient staff in the several professional disciplines involved.

Mountainside operates two cardiac catheterization laboratories which have state-of-the-art flat panel imaging systems. Once Mountainside exceeds 100 PCIs, staffing will need to be increased by two full-time RNs and two full-time CVTs, and some of the increased staffing costs will be offset by lower on call staffing.

e. The project is necessary to provide required health care in the region.

Since Merit Health assumed ownership of Mountainside in June, 2007, the focus of the new ownership has been to improve the quality of care, increase healthcare access for the service area residents, and become a full service community hospital. Mountainside has initiated a revitalization of the commitment to the community after a decade long period of inattention by the former owner that concentrated its efforts on other system hospitals to the detriment of the community served by Mountainside. Mountainside has developed relationships with a broad range of community groups, including health centers, senior adult day care centers, faith-based organizations and public health departments, which it sees as a new approach to reduce health disparities among at-risk populations.

The need for this demonstration project is reflected in the demonstrated outmigration by approximately 300 residents to cardiac surgery centers in Bergen, Essex and Passaic Counties (NJ Inpatient Data) and the projections of Mountainside cardiologists of the cases that can be performed at Mountainside. Since Mountainside cannot perform elective angioplasties, residents must travel greater distances to receive care and this delay can discourage patients from seeking care (as cited in professional journal articles).

f. The project will not have an adverse impact on access to health care services in the region or Statewide.

As stated by the applicant, it made 133 cardiac surgery and PCI referrals in 2006 with the following impact: 24 or 18% were referred to Hackensack University Medical Center, 13 or 9.8% were referred to Columbia Presbyterian in New York, 56 or 42.1% to Saint Barnabas Medical Center, and 23 or 17.3% to Valley Hospital. *St. Barnabas' PCI volume was 961 in 2006 and the impact of 75% of Mountainside's referrals being lost would account for 4.4% of St. Barnabas' PCI volume assuming all referrals were for PCI.*

Department analysis of 2006 UB discharge data indicates the percentage of each cardiac surgery center's PCI cases which came from each applicant's service area. Service area is defined as those zip codes that comprise 75% of an applicant's discharges, using 2006 UB discharge data, reported by the applicants in completeness responses. The impact is as follows: 16.2% of St. Michael's Medical Center, 12.2% of Hackensack University Medical Center's, 10.3% of Newark Beth Israel Medical Center's, 26% of St. Barnabas Medical Center's, 9.7% of St. Joseph's Hospital and 3.3% of University Hospital's PCI cases came from Mountainside service area in 2006.

As indicated in "a" above, no hospitals in Mountainside's service area provides elective angioplasty. The closest, St. Barnabas Medical Center is located in Livingston and during rush hour and other high traffic hours can be up to an hour drive from the communities in north and northwest Essex County. In addition to St. Barnabas Medical Center, there are three other cardiac surgery centers in Essex County (Newark Beth Israel Medical Center, St. Michael's Medical Center, and University Hospital). The development of an elective angioplasty program at Mountainside will have minimal affect on any of the existing centers.

C. DEMONSTRATION PROJECT CRITERIA AT N.J.A.C. 8:33-3.11(e)

For the most part, the applicant has sufficiently documented the ability to satisfy demonstration project eligibility criteria at N.J.A.C. 8:33-3.11(e)4 and the Atlantic C-PORT-E trial site inclusion criteria, including: (a) how the applicant will satisfy the patient selection criteria specified in the Atlantic C-PORT-E protocol, which is designed to assure informed consent and appropriate randomization, as provided in the Manual of Operations (N.J.A.C. 8:33-3.11(e)6iii); (b) approval of the study protocol by the applicant's Institutional Review Board, and if approval is pending, the status of that application (N.J.A.C. 8:33-3.11(e)6iv); (c) how the applicant will meet the target volume

*specified in the Atlantic C-PORT-E protocol of primary and elective angioplasties performed at the applicant's site, after randomization (that is, 100 PCI cases in year one and 200 cases in year two and each year thereafter) (N.J.A.C. 8:33-3.11(e)6v)**; (d) the applicant's compliance with the criteria for performance of primary PCI at N.J.A.C. 8:33E-2.16, 2.16(b) and N.J.A.C. 8:43G-7 (N.J.A.C. 8:33-3.11(e)6vi); and (e) documentation of the applicant's willingness to report elective PCI data to the Department separate from data collected as part of the study protocol, to support the Department's ongoing monitoring of cardiac services pursuant to N.J.A.C. 8:33E-1.9 and 2.10 (N.J.A.C. 8:33-3.11(e)6vii).*

**Staff Note: The applicant has not sufficiently documented the ability to satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol of performing at least 200 angioplasties per year.*

a. C-PORT-E Study Site Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6i):

The applicant has documented how it would satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol, including: (1) capability of performing a minimum volume of diagnostic cardiac catheterizations per year (N.J.A.C. 8:33-3.11(e)6i(1)); (2) agreement to complete an elective PCI development program (N.J.A.C. 8:33-3.11(e)6i(2)); (3) agreement to abide by physician, patient and device selection criteria defined in the study's Manual of Operations (N.J.A.C. 8:33-3.11(e)6i(3)); (4) agreement to collect and transmit study data in a timely fashion (N.J.A.C. 8:33-3.11(e)6i(4)); (5) agreement to perform elective PCI only via the study protocol and only while cases are being enrolled in the study (N.J.A.C. 8:33-3.11(e)6i(5)); and (6) agreement to develop and maintain a quality and error management program, including a weekly interventional conference and monthly quality and error management review (N.J.A.C. 8:33-3.11(e)6i(6)).

b. Participating Interventional Cardiologist Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6ii):

The applicant has documented that its participating interventional cardiologists have agreed to: (1) be in compliance and continue to be in compliance with minimum annual statewide interventional volume standards as set forth at N.J.A.C. 8:33E-2.16(b)6 (N.J.A.C. 8:33-3.11(e)6ii(1)); (2) practice in accordance with Atlantic C-PORT-E trial defined device and patient selection criteria (N.J.A.C. 8:33-3.11(e)6ii(2)); (3) obtain necessary informed consent for patient participation in the demonstration including the identity and location of the participating cardiac surgery center(s) that are to receive randomized study patients (N.J.A.C. 8:33-3.11(e)6ii(3));

Participating Interventional Cardiologist Performance Criteria:

1. The applicant states that all interventionalists will comply with Atlantic C-PORT-E criteria, including its minimum physician volume standard (in accordance with N.J.A.C. 8:33E-2.16(b)6).

2. *Listed below are participating physicians and their respective 2006 angioplasty PCI case volumes. Staff Note: Department staff found that six of ten interventionalists met the 75 case minimum, one physician's volume could not be verified by the Department. There may be mitigating factors regarding physician volume that have not been brought to the Department's attention.*

Physician Name	All facilities where physician performs Angioplasties
Amato Jr. , James	Mountainside Hospital, Clara Maass Hospital *(95 cases*)
Brown, Elliot	Mountainside Hospital, Passaic Beth Israel *(unavailable)*
Campanile, Giovanni	Mountainside Hospital, Valley Hospital, Clara Maass Hospital, Lenox Hill Hospital, St. Barnabas Hospital *(71 cases)*
DeGregorio, Joseph	Mountainside Hospital, Hackensack University Medical Center, St. Barnabas Hospital, St. Michael's Hospital, Clara Maass Hospital, Lenox Hill Hospital *(716 cases)*
Gupta, Ajay	Mountainside Hospital, St. Joseph's Hospital, St. Mary's Hospital *(66 cases*)
Mahdi, Lawrence	Mountainside Hospital, Newark Beth Israel *(117 cases)*
Miller, Kenneth	Mountainside Hospital, St. Barnabas Hospital *(70 cases)*
Narang, Ravinder	Mountainside Hospital, Passaic Beth Israel *(105 cases)*
Skolnick, Bruce	Mountainside Hospital, St. Mary's Hospital, Hackensack University Medical Center, St. Joseph's Hospital, Valley Hospital *(105 cases)*
Stoupakis, George	Mountainside Hospital, Hackensack University Medical Center, Holy Name *(106 cases)*

Footnote: Mountainside anticipates that St. Michael's/Columbus doctors may participate
Source: Mountainside's completeness response Table 4 and NJDOH Cardiac Registry

c. Additional Demonstration Project Evaluative Criteria (N.J.A.C. 8:33-3.11(e)7i.-iv.):

i. Ability to offer a high quality program.

a. Licensure:

Mountainside is conditionally licensed effective May 1, 2008 for failure to achieve compliance with the annual adult diagnostic cardiac catheterization facility volume requirement and director volume requirement. Mountainside was also conditionally licensed on May 1, 2007 for failure to achieve compliance with the annual adult diagnostic cardiac catheterization facility volume requirement and the primary PCI physician volume requirement.

b. Outcomes:

Mountainside's Diagnostic Cardiac Catheterization Outcomes

Year	*2005*		*2006*	
	# of Cases	*% of Total*	*# of Cases*	*% of Total*
Total Cases	*481*	*n/a*	*397*	*n/a*
Death in Hospital	*2*	*.42%*	*5**	*1.26%*
Death in Lab	*0*	*0%*	*1*	*.25%*
All in Lab Complications	*2*	*.42%*	*0*	*0%*

Source: NJDHSS Cardiac Data Registry (unaudited data)

In 2005, Mountainside reports 483 cases while the Department reports 481 cases. In 2006, the Department reports 397 cases, five deaths in hospital, one death in lab and zero complications, Mountainside reports 401 cases, 4 deaths in hospital, one death in lab and one complication.

* Mountainside cites Dr. Wharton's external review report-Conclusion-3rd paragraph: "All in-hospital deaths occurred in patients with acute myocardial infarction that were very critically ill or in cardiogenic shock, all with severe co-morbidities such as very advanced age, hemodialysis, sepsis, and/or with lesions that were extremely challenging. Otherwise, the rates of major complications (death, MI, CVA, groin complication requiring intervention) were within accepted benchmark limits for all operators. There were no complications that required emergency transfer to a surgical hospital."

ii. Representation of State's diverse regions and urban/suburban/rural population.

Mountainside is located in Essex County, in the Northeast region of the state. The 2000 U.S. Census Bureau table titled "Urban and Rural Population: New Jersey, Counties and Municipalities" reports all of Mountainside's service area as urban.

Mountainside's primary service area consists of older suburban communities in north and northwest Essex County. "These communities consist of working class populations, middle and upper middle-class populations and many have lived in the area for many generations and Mountainside is "their hospital"…The southeastern section of Mountainside's primary service area has seen significant changes in its population demographics. These primarily ethnic working class neighborhoods contiguous to the north ward of Newark and East Orange have seen a significant increase in the number of African-American and Latino populations. The changing demographics of Mountainside's service area is illustrative that Mountainside can provide a broad patient selection from a community that is representative of urban and suburban populations of the state from the upper-middle class to the low-income.

iii. Potential to increase access to care for minorities and medically underserved.

As presented below, Mountainside's total service area population is comprised of 37.3% non-white and the 45 and over population is comprised of 31.3% non-white based on 2000 Census data. *Mountainside's percentage of diagnostic cardiac catheterization caseload performed on non-white patients was 20.0% in 2005; and 21.4% in 2006. Mountainside's minority use rate of diagnostic cardiac catheterization is below the % of non-white residents in the service area population in 2005 and 2006.*

Mountainside's Service Area Population by Race

Age Category	White	Non-White	% of Non-White to Total Population
Under 45	168,846	115,638	40.6%
45-64	67,938	28,150	29.3%
65-74	20,527	13,444	39.6%
75-84	16,502	7,150	30.2%
85 +	6,807	2,269	25.0%
Total	280,620	166,651	37.3%

Source: Mountainside Completeness Questions, #7b & 7c.

Mountainside Diagnostic Cardiac Catheterization by Race

	White Non-Hispanic	*Black Non-Hispanic*	*Hispanic*	*Asian & Pacific Islander*	*Other*	*% of Non-White Cases*
2005	*80.0%*	*14.8%*	*2.1%*	*2.3%*	*0.8%*	*20.0%*
2006	*78.6%*	*15.9%*	*3.0%*	*2.0%*	*0.5%*	*21.4%*

Source: NJDHSS Cardiac Catheterization Data Registry

iv. Projected demonstration project elective angioplasty case volume

Based on the average 413 cardiac catheterizations performed between 2005 and 2007, a 30% conversion rate would be 124 patients, of which a maximum of 75%, or 93, would be randomized to be eligible to participate in the research project at Mountainside, assuming they all met the patient eligibility criteria of the research study and gave informed consent. In addition to the 93 elective angioplasties anticipated, Mountainside performed 33 primary PCIs in 2007. Total annual volume of angioplasties projected based on past performance would be 126, below the 200 annual minimum C-PORT-E demonstration project requirement. Mountainside also predicts further increases in volume based on population growth and anticipated referral changes.

Staff Note: As indicated above, the applicant has not sufficiently documented the ability to satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol of performing at least 200 angioplasties per year.

In its completeness response, Mountainside states that the closure of Muhlenberg Regional Medical Center may cause physicians and patients to migrate to Mountainside and positively impact its potential patient population.

II. FINANCIAL

Department staff reviewed and found that the applicant has documented adequate financial resources to implement and maintain the project.

STATE HEALTH PLANNING BOARD
CERTIFICATE OF NEED PROJECT SUMMARY
ELECTIVE ANGIOPLASTY WITHOUT ON-SITE SURGERY BACK-UP
DEMONSTRATION PROJECT

Applicant:	Trinitas Hospital (Trinitas)
CN Number:	FR 071209-20-01
Location:	Elizabeth City, Union County
Project Cost:	$ 0

PROJECT DESCRIPTION
The applicant is proposing to provide elective PCI without back-up surgery on-site and further proposes to participate in the Atlantic C-PORT, Elective Angioplasty Study, a multi-state demonstration trial to assess safety, quality and cost of elective PCI offered at community hospitals that do not offer cardiac surgery services on site. Trinitas is a current participant in the Atlantic C-PORT-E trial, having been CN approved in 2005 and licensed by the Department in 2006. There are no construction or project costs associated with this project. The applicant proposes to contract with Saint Michael's Medical Center as the participating cardiac surgery center.

I. SUMMARY OF THE APPLICANT'S REPRESENTATIONS

A. APPLICANT JUSTIFICATION

Trinitas Hospital (Trinitas) indicates that it is the sole remaining acute care institution in the Greater Elizabeth area and is an essential safety-net institution that provides the sixth highest level of charity care among New Jersey's hospitals. "As a participant in the first year of the demonstration, Trinitas successfully met all required state and demonstration volume levels, reporting schedules and other project criteria and provided the study with a hospital whose care in a stressed urban area allowed extensive participation of minorities, at-risk populations, and the medically underserved."

Trinitas continues to maintain a high volume cardiology service and a comprehensive cardiac diagnostic program that was able to provide, through its participation as a C-PORT-E demonstration site, both elective and primary angioplasty to the Greater Elizabeth region – the last highly populated area in New Jersey without either a cardiac surgery or elective angioplasty program.

St. Michael's Medical Center (St. Michael's) has agreed to continue as the receiving cardiac surgery center required by the Department's call and the C-PORT-E study. Both Trinitas and St. Michael's have agreed to adhere to all state and C-PORT-E conditions, including treatment protocols, data collection and reporting requirements.

Trinitas has an Institutional Review Board consisting of 13 members that meets bi-monthly and has endorsed continued participation in the C-PORT-E study.

B. STATUTORY CRITERIA

a. The availability of facilities or services that may serve as alternatives or substitutes.

The applicant states that there is no cardiac surgery center located in Union County and the only elective PCI services that are available in the county are the Atlantic C-PORT-E demonstration sites at Trinitas and Muhlenberg Regional Medical Center in Plainfield. *Department staff notes that Muhlenberg has withdrawn its application for this elective angioplasty without on-site surgery backup demonstration project CN batch and has also filed a CN to close its facility.*

b. The need for special equipment and services in the area.

Trinitas indicates that since it is already successfully performing primary and elective PCI, the equipment and resources necessary to continue participation as an elective PCI demonstration project are already in place.

c. The adequacy of financial resources and sources of present and future revenues.

Trinitas indicates that it has adequate resources to continue to maintain the demonstration project.

d. The availability of sufficient staff in the several professional disciplines involved.

Trinitas indicates that since it is already successfully performing primary and elective PCI, the equipment and resources, including the required staff necessary to perform elective PCI, are already in place.

e. The project is necessary to provide required health care in the region.

Trinitas indicates that there are no other providers of elective angioplasty services located in Union County other than the Trinitas and Muhlenberg *(see above staff note regarding Muhlenberg)* demonstration projects. The Department's original certificate of need approval of Trinitas as an elective angioplasty demonstration sites demonstrates that a need exists in the region to evaluate the safety and effectiveness of elective PCI without the availability of cardiac surgery on-site.

f. The project will not have an adverse impact on access to health care services in the region or Statewide.

As stated by the applicant in completeness response tables 2 and 3, Trinitas made 258 PCI and cardiac surgery referrals in 2006 with the following impact: 61 or 23.6% were referred to St. Michael's Medical Center, 17 or 6.6% were referred to University Hospital and 171 or 66% were not identified by facility. The applicant states that these patients were not transferred directly to a facility; therefore, the referral could not be tracked. St. Michael's PCI volume was 1,882 in 2006 and the impact of 75% of Trinitas' referrals

being lost would account for 2.4% of St. Michael's volume assuming all the referrals were for PCI.

Department of Health and Senior Services (Department) analysis of 2006 UB discharge data reports the percentage of cardiac surgery center's PCI cases which came from the applicant's service area. Service area is defined as those zip codes that comprise 75% of an applicant's discharges using 2006 UB discharge data, which is reported by the applicants in completeness responses. The impact is as follows: 2.1% of St. Michael's Medical Center's and 7.4% of University Hospital's PCI cases came from Trinitas' service area in 2006.

C. DEMONSTRATION PROJECT CRITERIA AT N.J.A.C. 8:33-3.11(e)

For the most part, the applicant has sufficiently documented the ability to satisfy demonstration project eligibility criteria at N.J.A.C. 8:33-3.11(e)4 and the Atlantic C-PORT-E trial site inclusion criteria, including: (a) how the applicant will satisfy the patient selection criteria specified in the Atlantic C-PORT-E protocol, which is designed to assure informed consent and appropriate randomization, as provided in the Manual of Operations (N.J.A.C. 8:33-3.11(e)6iii); (b) approval of the study protocol by the applicant's Institutional Review Board, and if approval is pending, the status of that application (N.J.A.C. 8:33-3.11(e)6iv); (c) how the applicant will meet the target volume specified in the Atlantic C-PORT-E protocol of primary and elective angioplasties performed at the applicant's site, after randomization (that is, 100 PCI cases in year one and 200 cases in year two and each year thereafter) (N.J.A.C. 8:33-3.11(e)6v); (d) the applicant's compliance with the criteria for performance of primary PCI at N.J.A.C. 8:33E-2.16, 2.16(b) and N.J.A.C. 8:43G-7 (N.J.A.C. 8:33-3.11(e)6vi); and (e) documentation of the applicant's willingness to report elective PCI data to the Department separate from data collected as part of the study protocol, to support the Department's ongoing monitoring of cardiac services pursuant to N.J.A.C. 8:33E-1.9 and 2.10 (N.J.A.C. 8:33-3.11(e)6vii).

Staff Note: As noted below, the applicant has <u>not</u> sufficiently documented the ability to satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol of performing at least 200 angioplasties per year (N.J.A.C. 8:33-3.11(e)6v).

a. C-PORT-E Study Site Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6i):

The applicant has documented how it would satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol, including: (1) capability of performing a minimum volume of diagnostic cardiac catheterizations per year (N.J.A.C. 8:33-3.11(e)6i(1)); (2) agreement to complete an elective PCI development program (N.J.A.C. 8:33-3.11(e)6i(2)); (3) agreement to abide by physician, patient and device selection criteria defined in the study's Manual of Operations (N.J.A.C. 8:33-3.11(e)6i(3)); (4) agreement to collect and transmit study data in a timely fashion (N.J.A.C. 8:33-3.11(e)6i(4)); (5) agreement to perform elective PCI only via the study protocol and only while cases are being enrolled in the study (N.J.A.C. 8:33-3.11(e)6i(5)); and (6) agreement to develop and maintain a quality and error

management program, including a weekly interventional conference and monthly quality and error management review (N.J.A.C. 8:33-3.11(e)6i(6)).

b. Participating Interventional Cardiologist Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6ii):

The applicant has documented that its participating interventional cardiologists have agreed to: (1) be in compliance and continue to be in compliance with minimum annual statewide interventional volume standards as set forth at N.J.A.C. 8:33E-2.16(b)6 (N.J.A.C. 8:33-3.11(e)6ii(1)); (2) practice in accordance with Atlantic C-PORT-E trial defined device and patient selection criteria (N.J.A.C. 8:33-3.11(e)6ii(2)); (3) obtain necessary informed consent for patient participation in the demonstration including the identity and location of the participating cardiac surgery center(s) that are to receive randomized study patients (N.J.A.C. 8:33-3.11(e)6ii(3));

Participating Interventional Cardiologist Performance Criteria:

1. The applicant states that all interventionalists have met the annual statewide interventional volume standard of 75 cases in 2006 and that its participating physicians will continue to meet this standard in accordance with N.J.A.C. 8:33E-2.16(b)6.
2. *Listed below are participating physicians at Trinitas and their respective 2006 angioplasty case volumes. Staff Note: Department staff found that ten of 15 interventional cardiologists met the 75 case annual interventional volume standard. The Department could not verify the case volume of one physician. There may be mitigating factors regarding physician volume that have not been brought to the Department's attention.*

Physician Name	All facilities where physician performs angioplasties
Amato, James	Clara Maass Hospital, SMMC, Trinitas *(95 Cases*)
Cholankeril, Mathew	SMMC, Trinitas *(76 Cases)*
Dailey-Sterling, Felix	SMMC, Trinitas *(128 Cases)*
Doskow, Jeffery	SMMC, St. Barnabas Hospital, Trinitas *(23 Cases)*
Gold, Jeffery	SMMC, St. Barnabas Hospital, Trinitas *(29 Cases)*
Hamirani, Kamran	UMDNJ, Trinitas *(160 Cases*)
Karpenos, Alexander	JFK, Muhlenberg, RWJUH, SMMC, Trinitas *(96 Cases)*
Katdare, Umesh	SMMC, Trinitas *(118 Cases)*
Lenchur, Peter	NBU, SMMC, UMDNJ, Staten Island, Trinitas *(34 Cases)*
Patel, Sanjiv	SMMC, Trinitas *(unavailable)*
Pinnelas, David	Trinitas, Ocean, Jersey Shore *(93 Cases)*
Randhawa, Preet	NBU, Trinitas, UMDNJ *(273 Cases)*
**Richard, Merwin	UMDNJ, Trinitas, Jersey City (*327 Cases*)
Shamoon, Fayez	SMMC, Trinitas *(429 Cases)*
Younan, Shaddy	Jersey Shore, RWJUH, SMMC, Trinitas (*62 Cases)*

Source: Trinitas completeness response Table 4 and NJDOH Cardiac Registry

c. Additional Demonstration Project Evaluative Criteria (N.J.A.C. 8:33-3.11(e)7i.-iv.)

i. Ability to offer a high quality program.

a. *Licensure: Trinitas' full service diagnostic cardiac catheterization program is currently licensed unconditionally through August 31, 2008. Trinitas was licensed to perform primary PCI on October 15, 2003 and was granted certificate of need approval (CN# 020705-20-01) on October 1, 2002.*

b. Outcomes:

Trinitas' Diagnostic Cardiac Catheterization Outcomes

	2005		*2006*	
	# of Cases	*% of Total*	*# of Cases*	*% of Total*
Total Cases	*563*	*n/a*	*629*	*n/a*
Death in Hospital	*2*	*.36%*	*2*	*.32%*
Death in Lab	*0*	*0*	*1*	*.16%*
All In lab Complications	*0*	*0%*	*1*	*.16%*

Source: NJDHSS Cardiac Data Registry (unaudited data)

In 2005, the Department reported two deaths in hospital and zero complications, while Trinitas reported three deaths in hospital and five complications. In 2006, the Department reported 629 cases, two deaths in hospital and one complication, while Trinitas reported 630 cases, four deaths in hospital and four complications.

ii. Representation of State's diverse regions and urban/suburban/rural population.

Trinitas is located in Union County, in the Northeast region of the state. The 2000 U.S. Census Bureau table titled "Urban and Rural Population: New Jersey, Counties and Municipalities" reports all of Trinitas' service area as urban.

Trinitas states that it "serves a much larger African-American and Hispanic population than most hospitals in New Jersey. Both of those patient populations, holding other factors constant, are at a higher risk of developing heart disease. ..A total of 211,604 African-Americans and Hispanics, live in Union County, according to the latest census. Fully 163,398 of these individuals reside in the Trinitas primary service area. Trinitas presently serves more than double the minority populations served by Muhlenberg Hospital or Overlook Hospital, both located in less populated areas of the county."

iii. Potential to increase access to care for minorities and medically underserved.

As presented below, Trinitas' total service area population is comprised of 40.82% non-white and the 45 and over population is comprised of 28.9% non-white*. As calculated by the Department, Trinitas' diagnostic cardiac catheterization patient population percentage of non-white patients was 75.1% in 2005 and 70.4% in 2006. Trinitas' minority use rate of diagnostic cardiac catheterization exceeded the % of non-white residents in the service area population in 2005 and 2006.*

Trinitas' Service Area Population by Race

Age	Total	White	Non-white	% of Non-White to Total Population
< 45	173,273	91,949	81,324	46.93%
45 - 64	54,669	35,533	19,136	35.00%
65-74	16,486	12,464	4,022	24.40%
75-84	13,065	11,153	1,912	14.63%
85+	4,500	3,952	548	12.18%
Total	261,993	155,051	106,942	40.82%

Source: Trinitas Completeness Questions, #7c (US 2000 Census)

Trinitas' Diagnostic Cardiac Catheterization by Race

	White Non-Hispanic	*Black Non-Hispanic*	*Hispanic*	*Asian & Pacific Islander*	*Other*	*% of Non-White Cases*
2005	*24.9%*	*30.2%*	*40.1%*	*3.4%*	*0.4%*	*75.1%*
2006	*29.6%*	*26.1%*	*40.1%*	*3.8%*	*0.5%*	*70.4%*

Source: NJDHSS Cardiac Catheterization Data Registry

Trinitas emphasizes that its location is situated within two miles from three Elizabeth census tracts designated as "medically underserved areas" by the Secretary of Health and Human Services. Trinitas states that its provision of services to the indigent is apparent from the $40 million in charity care and hospital relief funds in 2006, a total that is four times that of Muhlenberg Regional Medical center and 20 times higher than the $2 million received by Overlook Hospital.

iv. Projected demonstration project elective angioplasty case volume

Based on the average 626 cardiac catheterizations performed between 2005 and 2007, a 30% conversion rate would result in 188 patients, of which 75%, or 141, would be randomized to be eligible to participate in the research project at Trinitas, assuming they all met the patient eligibility criteria of the research study and gave informed consent. In addition to the 141 elective angioplasties anticipated, Trinitas performed 58 primary angioplasties in 2007. Total annual volume of angioplasties projected based on past performance would be199, which is slightly below the 200 annual minimum C-PORT-E demonstration project requirement.

Trinitas predicts further increases in volume based on population growth, the closure of two hospitals in Union County (Union Hospital, Muhlenberg Regional Medical Center), and anticipated referral changes.

Trinitas anticipates that the closing of Muhlenberg Regional Medical Center will have little impact on Trinitas' continued participation in Atlantic C-PORT-E. Trinitas drew just over 1% of its admissions from the Muhlenberg service area and just 1 PCI case. Trinitas states further that it will make every effort to ensure that anyone from the Muhlenberg service area needing PCI will be provided full access to Trinitas.

Staff Note: The applicant has <u>not</u> sufficiently documented the ability to satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol of performing at least 200 angioplasties per year (N.J.A.C. 8:33-3.11(e)6v).

II. FINANCIAL

Department staff reviewed and found that the applicant has documented adequate financial resources to implement and maintain the project.

Morristown Hospital Market Area

1. Overlook Hospital

2. Saint Clare's Hospital/Denville Campus

STATE HEALTH PLANNING BOARD
CERTIFICATE OF NEED PROJECT SUMMARY
ELECTIVE ANGIOPLASTY WITHOUT ON-SITE SURGERY BACK-UP
DEMONSTRATION PROJECT

Applicant:	Overlook Hospital (Overlook)
CN Number:	FR 071220-12-01
Location:	Summit, Union County
Project Cost:	$ 0

PROJECT DESCRIPTION:
The Applicant is proposing to participate in the Atlantic C-PORT, Elective Angioplasty Study, to provide elective PCI without back-up surgery on-site and further proposes a multi-state demonstration trial to assess safety, quality and cost of elective PCI offered at community hospitals that do not offer cardiac surgery services on-site. There are no construction or project costs associated with this project. The applicant proposes to contract with Morristown Memorial Hospital as the participating cardiac surgery center.

I. SUMMARY OF THE APPLICANT'S REPRESENTATIONS

A. APPLICANT JUSTIFICATION

Experience: Overlook Hospital (Overlook) states that the quality of its cardiology program was recognized by its selection as the first and only New Jersey hospital to participate in the original multi-center C-PORT trial [of primary angioplasty]. The Overlook cardiac catheterization laboratory has performed over 25,000 cardiac catheterizations and close to 500 primary angioplasties.

Research: Overlook has been involved in significant research related to heart disease and its management since 1975. The Atlantic Health System (AHS) has a dedicated Cardiac research Department and provides an integrated system Institutional Review Board. In 2007, Overlook and its sister hospital, Morristown Memorial Hospital, were involved in 44 cardiac funded studies.

Accreditation: Overlook recently received accreditation as a Chest Pain Center by the Society of Chest Pain Centers, an international, professional organization that sets guidelines for quality chest pain center care.

Results: In recent experience, Overlook's median door to balloon time was 83 minutes compared to the national goal of 90 minutes.

Timeliness: Overlook is able to transport patients needing an emergency transfer in nine minutes to Morristown Memorial Hospital's emergency room. Emergency helicopter transfer is also "part of its emergency response continuum." Overlook also is committed to patient safety and its two cardiac catheterization laboratories have state-of-the-art flat plate digital equipment, which allows both increased image quality as well

as the ability to transmit electronically and without image degradation to Morristown surgeons when real time emergent consultation is required.

Teamwork: The AHS partnership insures that Overlook and Morristown Memorial Hospital physicians, nurses and allied professionals are cross-trained and cross-privileged. AHS has dedicated training facilities and can provide streamlined data collection and principal support.

B. STATUTORY CRITERIA

a. The availability of facilities or services that may serve as alternatives or substitutes.

The applicant indicates that there is limited elective angioplasty programs located in Union County.

b. The need for special equipment and services in the area.

The applicant indicates that there is no cost involved for Overlook's participation in this demonstration project.

c. The availability of sufficient staff in the several professional disciplines involved.

The project represents an extension of the Atlantic Health System Cardiac Surgery Program. It is anticipated that quality improvements in the overall program would result from comparisons between methods and procedures seen as improvements in each of the various centers. Any additional manpower/personnel required at Overlook Hospital to undertake the elective angioplasty program would be in place prior to commencement of the program.

d. The adequacy of financial resources and sources of present and future revenues.

Overlook states that Atlantic Health System has the financial capacity to implement the project.

e. The project is necessary to provide required health care in the region.

Overlook indicates that there are limited providers of elective angioplasty services located in Union County and that Overlook is ideally placed geographically within Union County to enhance access to care for the residents of the region. The Overlook program would work closely with the AHS cardiac program at Morristown Memorial Hospital. The extension of the angioplasty program of Overlook, carefully developed and nurtured through a decade of shared experiences among medical cardiology, interventional cardiology and transport staff would improve the access to cardiovascular programs for residents of Overlook's service areas.

f. The project will not have an adverse impact on access to health care services in the region or Statewide.

As stated by the applicant in completeness response tables 2 and 3, Morristown Memorial Hospital (99, or 94.3% of Overlook's angioplasty and cardiac surgery referrals in 2006) is Overlook's primary referral center. *Morristown Memorial Hospital's angioplasty volume was 2,648 in 2006 and the impact of 94.3% of Overlook's referrals being lost would account for 3.7% of Morristown Memorial Hospital's volume, assuming all the referrals were for angioplasty.*

Department analysis of 2006 UB discharge data indicates the percentage of each cardiac surgery center's PCI cases which came from each applicant's service area. Service area is defined as those zip codes that comprise 75% of an applicant's discharges using 2006 UB discharge data reported by the applicants in completeness responses. The impact is as follows: 24.9% of University Hospital's, 10.5% of St. Michael Medical Center's, 16.0% of Newark Beth Israel Medical Center's, 16.4% of St. Barnabas Medical Center's, and 15.5% of Morristown Memorial Hospital's PCI cases came from Overlook's service area in 2006. In addition, 50.8% of Trinitas Hospital's PCI cases and 45.9% of Muhlenberg Regional Medical Center's PCI cases were derived from Overlook's service area in 2006.

C. DEMONSTRATION PROJECT CRITERIA AT N.J.A.C. 8:33-3.11(e)

For the most part, the applicant has sufficiently documented the ability to satisfy demonstration project eligibility criteria at N.J.A.C. 8:33-3.11(e)4 and the Atlantic C-PORT-E trial site inclusion criteria, including: (a) how the applicant will satisfy the patient selection criteria specified in the Atlantic C-PORT-E protocol, which is designed to assure informed consent and appropriate randomization, as provided in the Manual of Operations (N.J.A.C. 8:33-3.11(e)6iii); (b) approval of the study protocol by the applicant's Institutional Review Board, and if approval is pending, the status of that application (N.J.A.C. 8:33-3.11(e)6iv); (c) how the applicant will meet the target volume specified in the Atlantic C-PORT-E protocol of primary and elective angioplasties performed at the applicant's site, after randomization (that is, 100 PCI cases in year one and 200 cases in year two and each year thereafter) (N.J.A.C. 8:33-3.11(e)6v); (d) the applicant's compliance with the criteria for performance of primary PCI at N.J.A.C. 8:33E-2.16, 2.16(b) and N.J.A.C. 8:43G-7 (N.J.A.C. 8:33-3.11(e)6vi); and (e) documentation of the applicant's willingness to report elective PCI data to the Department separate from data collected as part of the study protocol, to support the Department's ongoing monitoring of cardiac services pursuant to N.J.A.C. 8:33E-1.9 and 2.10 (N.J.A.C. 8:33-3.11(e)6vii).

Staff Note: As noted below, the applicant has <u>not</u> sufficiently documented the ability to satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol of performing at least 200 angioplasties per year (N.J.A.C. 8:33-3.11(e)6v).

a. C-PORT-E Study Site Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6i):

The applicant has documented how it would satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol, including: (1) capability of performing a minimum volume of diagnostic cardiac catheterizations per year (N.J.A.C. 8:33-3.11(e)6i(1)); (2) agreement to complete an elective PCI development program (N.J.A.C. 8:33-3.11(e)6i(2)); (3) agreement to abide by physician, patient and device selection criteria defined in the study's Manual of Operations (N.J.A.C. 8:33-3.11(e)6i(3)); (4) agreement to collect and transmit study data in a timely fashion (N.J.A.C. 8:33-3.11(e)6i(4)); (5) agreement to perform elective PCI only via the study protocol and only while cases are being enrolled in the study (N.J.A.C. 8:33-3.11(e)6i(5)); and (6) agreement to develop and maintain a quality and error management program, including a weekly interventional conference and monthly quality and error management review (N.J.A.C. 8:33-3.11(e)6i(6)).

b. Participating Interventional Cardiologist Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6ii):

The applicant has documented that its participating interventional cardiologists have agreed to: (1) be in compliance and continue to be in compliance with minimum annual statewide interventional volume standards as set forth at N.J.A.C. 8:33E-2.16(b)6 (N.J.A.C. 8:33-3.11(e)6ii(1)); (2) practice in accordance with Atlantic C-PORT-E trial defined device and patient selection criteria (N.J.A.C. 8:33-3.11(e)6ii(2)); (3) obtain necessary informed consent for patient participation in the demonstration including the identity and location of the participating cardiac surgery center(s) that are to receive randomized study patients (N.J.A.C. 8:33-3.11(e)6ii(3));

Participating Interventional Cardiologist Performance Criteria:

1. The applicant states that all interventionalists have met the annual statewide interventional volume standard of 75 cases in 2006 and that its participating physicians will continue to meet this standard in accordance with N.J.A.C. 8:33E-2.16(b)6.

2. *Listed below are participating physicians at Overlook and their respective 2006 angioplasty case volumes. Staff Note: Department staff found that five of seven interventional cardiologists met the 75 case annual interventional volume standard. There may be mitigating factors regarding physician volume that have not been brought to the Department's attention.*

Physician Name	All cardiac centers where physicians perform angioplasty
Altszuler, Henry M.	Overlook Hospital, Morristown Memorial Hospital *(106 cases*)
Cohen, Barry M.	Overlook Hospital, Morristown Memorial Hospital *(173 cases)*
Krell Mark J.	Overlook Hospital, Morristown Memorial Hospital *(54 cases)*
Mich, Robert J.	Overlook Hospital, Morristown Memorial Hospital *(108 cases)*
Robbins, David	Overlook Hospital, Newark Beth Israel
Schwartz, Daniel	Overlook Hospital, Morristown Memorial Hospital *(127 cases)*
Weber, Vance J.	Overlook Hospital, Morristown Memorial Hospital *(99 cases)*

c. Additional Demonstration Project Evaluative Criteria (N.J.A.C. 8:33-3.11(e)7i.-iv.):

i. Ability to offer a high quality program.

a. *Licensure: Overlook's full service diagnostic cardiac catheterization program and primary PCI program is currently licensed unconditionally through April 30, 2009. Overlook was granted CN approval (CN #020402-20-01) on June 21, 2002 and licensed to perform primary PCI on May 1, 2003.*

b. Outcomes:

Overlook's Diagnostic Cardiac Catheterization Outcomes				
	2005		*2006*	
	# of Cases	*% of Total*	*# of Cases*	*% of Total*
Total Cases	*546*	*n/a*	*444*	*n/a*
Death in Hospital	*5*	*.92%*	*4*	*.90%*
Death in Lab	*0*	*0%*	*0*	*0*
All In lab Complications	*4*	*.73%*	*10*	*2.25%*

Source: NJDHSS Cardiac Data Registry (unaudited data)

In 2005, the Department reported 546 cases and five deaths in hospital and zero complications, while Overlook reported 545 cases and three deaths in hospital. In 2006, the Department reported four deaths in hospital and ten complications, while Trinitas reported six deaths in hospital and eleven complications.

ii. Representation of State's diverse regions and urban/suburban/rural population.

Overlook is located in Union County, in the Northeast region of the state. The 2000 U.S. Census Bureau table titled "Urban and Rural Population: New Jersey, Counties and Municipalities" reports a small population residing in rural area in Chatham, while the remainder of Overlook's service area is considered to be urban.

Overlook's service area for elective angioplasty is its primary and secondary service area, which encompasses Union County and surrounding communities from Morris, Somerset, Essex and Middlesex counties. Overlook has demonstrated its commitment to providing access to care for underserved communities in Union County by establishing a satellite emergency department (SED) at the site of the former Union Hospital in October, 2007. Overlook projects an additional 130 cardiac catheterizations and 45 elective interventions will be derived from the Union SED.

iii. Potential to increase access to care for minorities and medically underserved.

As presented below, Overlook's total service area population is comprised of 33.04% non-white and the 45 and over population is comprised of 23.4% non-white. *As calculated by the Department, Overlook's diagnostic cardiac catheterization patient population percentage of non-white patients was 7.7% in 2005 and 15.3% in 2006. Overlook's minority use rate of diagnostic cardiac*

catheterization was below the % of non-white residents in the service area population in 2005 and 2006.

Overlook's Service Area Population by Race

Age Category	White	Non-White	% of Non-White to Total Population
Under 45	301,026	189,448	38.63%
45-64	126,455	50,634	28.59%
65-74	42,595	9,958	18.95%
75-84	35,919	4,689	11.55%
85 +	13,031	1,385	9.61%
Total	519,026	256,114	33.04%

Source: Overlook Completeness Questions, #7c.

Overlook's Diagnostic Cardiac Catheterization by Race

	White Non-Hispanic	*Black Non-Hispanic*	*Hispanic*	*Asian & Pacific Islander*	*Other*	*% of Non-White Cases*
2005	*92.3%*	*7.0%*	*0.7%*	*0%*	*0%*	*7.7%*
2006	*84.7%*	*9.5%*	*1.6%*	*1.4%*	*2.9%*	*15.3%*

Source: NJDHSS Cardiac Catheterization Data Registry

Overlook indicates that all minorities comprise 46% of Overlook's primary and secondary service area in 2007 and that this percentage will increase to 51% by 2012. In addition, Overlook's establishment of a satellite emergency department (SED) at the former site of Union Hospital and the announced closure of Muhlenberg Regional Medical Center in Plainfield are expected to provide an additional 386 cardiac catheterization cases and 117 PCI cases annually based on service area overlap. Overlook notes that the minority population in the service area where the SED is located is 54%. Overlook also identifies women as an underserved and misdiagnosed population and has established a comprehensive Women's Heart Program.

iv. Projected demonstration project elective angioplasty case volume

Based on the average 463 cardiac catheterizations performed between 2005 and 2007, a 30% conversion rate would result in 139 patients, of which 75%, or 104, would be randomized to be eligible to participate in the research project at Overlook, assuming they all met the patient eligibility criteria of the research study and gave informed consent. In addition to the 104 elective angioplasties anticipated, Overlook performed 75 primary angioplasties in 2007. Total annual volume of angioplasties projected based on past performance would be 179, below the 200 annual minimum C-PORT-E demonstration project requirement.

Overlook predicts further increases in volume based on population growth, the closure of two hospitals in Union County (Union Hospital, Muhlenberg Regional Medical Center), and anticipated referral changes due to the availability of elective angioplasty. Overlook anticipates that the closing of Muhlenberg Regional Medical Center will provide an additional 256 cardiac catheterizations and 72 elective PCI cases based on service area and interventional physician overlap. Overlook also expects an additional 130 cardiac catheterizations and 45 elective PCI cases from Overlook's establishment of a satellite emergency department (SED) at the site of the former Union Hospital.

Staff Note: The applicant has <u>not</u> sufficiently documented the ability to satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol of performing at least 200 angioplasties per year (N.J.A.C. 8:33-3.11(e)6v).

II. FINANCIAL

Department staff reviewed and found that the applicant has documented adequate financial resources to implement and maintain the project.

STATE HEALTH PLANNING BOARD
CERTIFICATE OF NEED PROJECT SUMMARY
ELECTIVE ANGIOPLASTY WITHOUT ON-SITE SURGERY BACK-UP
DEMONSTRATION PROJECT

Applicant:	St. Clare's Hospital-Denville (St. Clare's)
CN Number:	FR 071210-14-01
Location:	Denville, New Jersey
Project Cost:	$8,000

PROJECT DESCRIPTION:
The applicant is proposing to provide elective PCI without back-up surgery on-site and further proposes to participate in the Atlantic C-PORT, Elective Angioplasty Study, a multi-state demonstration trial to assess safety, quality and cost of elective PCI offered at community hospitals that do not offer cardiac surgery services on site. There are project costs of $8,000 for major moveable equipment associated with this project. The applicant proposes to contract with Morristown Memorial Hospital (Morristown) as the participating cardiac surgery center.

I. SUMMARY OF THE APPLICANT'S REPRESENTATIONS

A. APPLICANT JUSTIFICATION

St. Clare's states that it bases the need for its participation in this demonstration project on its existing cardiac volume, reduction in mortality and morbidity in the service area, improved accessibility for patients, reduction in the need for ambulance transfers and improved continuity of care. The applicant states that it is geographically positioned to address the needs of the residents in the three county region of Northwest New Jersey. The applicant also states that it has surpassed all quality standards in clinical complications, door to balloon time and volume expectations in its emergency angioplasty program. The applicant provides services to the medically underserved that reside and/or work in its service area. The applicant also states that it would meet the minimum volume standards needed to participate in the C-PORT-E study as it projects 215 cases in the first year of the study.

B. STATUTORY CRITERIA

a. The availability of facilities or services that may serve as alternatives or substitutes.

The applicant states that there is one hospital, Morristown, in the St. Clare's service area which provides elective angioplasty. The interventional cardiologists who would participate in the C-PORT-E at St. Clare's are also on staff at Morristown. While some cases may shift to St. Clare's, the patients who shift will be the ones who currently utilize St. Clare's for their other healthcare needs and whose primary care physicians are on staff at St. Clare's and often not on staff at Morristown.

b. The need for special equipment and services in the area.

The applicant indicates that there four additional scanners will be purchased to participate in the study, as well as the software necessary for participation in the C-PORT-E demonstration project.

c. The adequacy of financial resources and sources of present and future revenues.

The applicant states it has the financial resources to implement this project.

d. The availability of sufficient staff in the several professional disciplines involved.

The applicant states that the specific staff to be recruited and/or designated to support the project include: 1 .2 FTE's RN, 1.5 FTE Data Analyst and 2.24 FTE of Cardiology current staff. Five interventionalists already practicing at St. Clare's would support the program.

e. The project is necessary to provide required health care in the region.

The applicant bases the need for its participation in this demonstration project on their existing and projected growth in cardiac volume, reduction in mortality and morbidity in the service area, improved accessibility for patients, reduction in the need for ambulance transfers and improved continuity of care.

f. The project will not have an adverse impact on access to health care services in the region or Statewide.

As stated by the applicant in completeness response tables 2 and 3, Morristown is St. Clare's primary referral center (212, or 99.5% of St. Clare's angioplasty and cardiac surgery referrals in 2006). *Morristown's angioplasty volume was 2,648 in 2006 and the impact of 75% of St. Clare's referrals being lost would account for only 6% of Morristown's volume assuming all the referrals were for angioplasty.*

Department analysis of 2006 UB discharge data indicates the percentage of each cardiac surgery center's PCI cases which came from each applicant's service area. Service area is defined as those zip codes that comprise 75% of an applicant's discharges using 2006 UB discharge data, reported by the applicants in completeness responses. The impact is as follows: 36.4% of Morristown's, and 6.6% of St. Barnabas Medical Center's PCI cases came from St. Clare's service area in 2006.

C. DEMONSTRATION PROJECT CRITERIA AT N.J.A.C. 8:33-3.11(e)

For the most part, the applicant has sufficiently documented the ability to satisfy demonstration project eligibility criteria at N.J.A.C. 8:33-3.11(e)4 and the Atlantic C-PORT-E trial site inclusion criteria, including: (a) how the applicant will satisfy the patient selection criteria specified in the Atlantic C-PORT-E protocol, which is designed to assure informed consent and appropriate randomization, as provided in the Manual

*of Operations (N.J.A.C. 8:33-3.11(e)6iii); (b) approval of the study protocol by the applicant's Institutional Review Board, and if approval is pending, the status of that application (N.J.A.C. 8:33-3.11(e)6iv); (c) how the applicant will meet the target volume specified in the Atlantic C-PORT-E protocol of primary and elective angioplasties performed at the applicant's site, after randomization (that is, 100 PCI cases in year one and 200 cases in year two and each year thereafter) (N.J.A.C. 8:33-3.11(e)6v)**; (d) the applicant's compliance with the criteria for performance of primary PCI at N.J.A.C. 8:33E-2.16, 2.16(b) and N.J.A.C. 8:43G-7 (N.J.A.C. 8:33-3.11(e)6vi); and (e) documentation of the applicant's willingness to report elective PCI data to the Department separate from data collected as part of the study protocol, to support the Department's ongoing monitoring of cardiac services pursuant to N.J.A.C. 8:33E-1.9 and 2.10 (N.J.A.C. 8:33-3.11(e)6vii).*

**Staff Note: The applicant has <u>not</u> sufficiently documented the ability to satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol of performing at least 200 angioplasties per year.*

a. C-PORT-E Study Site Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6i):

The applicant has documented how it would satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol, including: (1) capability of performing a minimum volume of diagnostic cardiac catheterizations per year (N.J.A.C. 8:33-3.11(e)6i(1)); (2) agreement to complete an elective PCI development program (N.J.A.C. 8:33-3.11(e)6i(2)); (3) agreement to abide by physician, patient and device selection criteria defined in the study's Manual of Operations (N.J.A.C. 8:33-3.11(e)6i(3)); (4) agreement to collect and transmit study data in a timely fashion (N.J.A.C. 8:33-3.11(e)6i(4)); (5) agreement to perform elective PCI only via the study protocol and only while cases are being enrolled in the study (N.J.A.C. 8:33-3.11(e)6i(5)); and (6) agreement to develop and maintain a quality and error management program, including a weekly interventional conference and monthly quality and error management review (N.J.A.C. 8:33-3.11(e)6i(6)).

b. Participating Interventional Cardiologist Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6ii):

The applicant has documented that its participating interventional cardiologists have agreed to: (1) be in compliance and continue to be in compliance with minimum annual statewide interventional volume standards as set forth at N.J.A.C. 8:33E-2.16(b)6 (N.J.A.C. 8:33-3.11(e)6ii(1)); (2) practice in accordance with Atlantic C-PORT-E trial defined device and patient selection criteria (N.J.A.C. 8:33-3.11(e)6ii(2)); (3) obtain necessary informed consent for patient participation in the demonstration including the identity and location of the participating cardiac surgery center(s) that are to receive randomized study patients (N.J.A.C. 8:33-3.11(e)6ii(3));

1. Participating Interventional Cardiologist Performance Criteria:

The applicant states that all interventionalists will comply with Atlantic C-PORT-E criteria, including its minimum physician volume standard (in accordance with N.J.A.C. 8:33E-2.16(b)6).

2. *Listed below are participating physicians and their respective 2006 angioplasty PCI case volumes. The Department found that four of the five interventionalists met the 75 case minimum. There may me mitigating factors regarding physician volume that have not been brought to the Department's attention.*

Physician Name	All facilities where physician performs angioplasties
DeRenzi, Paul D	Morristown Memorial Hospital, St. Clare's *(199)*
Fusman, Benjamin	Morristown Memorial Hospital, St. Clare's *(144)*
Lowell, Barry H	Morristown Memorial Hospital, St. Clare's *(394)*
Schalet, Bennett D.	Morristown Memorial Hospital, St. Clare's *(69)*
Wang, Robert L	Morristown Memorial Hospital, St. Clare's *(212)*

Source: Applicant's completeness response and NJDOH Cardiac Registry

c. Additional Demonstration Project Evaluative Criteria (N.J.A.C. 8:33-3.11(e)7i.-iv.):

i. Ability to offer a high quality program.

a. Licensure:
St. Clare's full service cardiac catheterization program and emergency PCI with off-site cardiac surgery back-up are licensed unconditionally through December 31, 2008.

b. Outcomes:

St. Clare's Diagnostic Cardiac Catheterization Outcomes

	2005		*2006*	
	# of Cases	*% of Total*	*# of Cases*	*% of Total*
Total Cases	*530*	*n/a*	*466*	*n/a*
Death in Hospital	*9*	*1.70%*	*4*	*.86%*
Death in Lab	*1*	*.18%*	*1*	*.21%*
All In lab Complications	*13*	*2.45%*	*11*	*2.36%*

Source: NJDHSS Cardiac Data Registry (unaudited data)

The Department recorded nine in hospital deaths and 13 complications in 2005 while St. Clare's reported eight in hospital deaths and 8 complications in its application. St. Clare's reported three in hospital deaths in 2006 while the Department had four recorded. St. Clare's reported twelve complications in its application while the Department reported eleven.

ii. Representation of State's diverse regions and urban/suburban/rural population.

St. Clare's is located in the Morris County, in the Northeast region of the state. The 2000 U.S. Census Bureau table titled "Urban and Rural Population: New Jersey, Counties and Municipalities" reports a small population residing in rural areas in Montville, Randolph and Hopatcong, while the remainder of St. Clare's service area is considered to be urban.

iii. Potential to increase access to care for minorities and medically underserved.

As presented below, St. Clare's total service area population is comprised of 13.5% non-white and the over age 45 population is comprised of 9.5% non-white based on 2000 Census data. *St. Clare's percentage of diagnostic cardiac catheterization caseload performed on non-white patients was 13.2% in 2005 and 11.4% in 2006. St. Clare's minority use rate of diagnostic cardiac catheterization was comparable to the % of non-white residents in the service area population in 2005 and 2006.*

St. Clare's Service Area Population by Race and Age Distribution

Age	Total	White	Non-white	% of Non-White to Total Population
< 45	248,612	209,555	39,057	15.7%
45 - 64	96,066	85,752	10,314	10.7%
65-74	22,177	20,386	1,791	8.1%
75-84	13,755	12,998	757	5.5%
85+	5,081	4,856	225	4.4%
Total	385,691	333,547	52,144	13.5%

Source: St. Clare's completeness response question 6c (2000 US Census)

St. Clare's Diagnostic Cardiac Catheterization by Race

	White Non-Hispanic	*Black Non-Hispanic*	*Hispanic*	*Asian & Pacific Islander*	*Other*	*% of Non-White Cases*
2005	*86.8%*	*3.2%*	*5.7%*	*3.4%*	*.9%*	*13.2%*
2006	*88.6%*	*1.5%*	*6.9%*	*2.1%*	*.9%*	*11.4%*

Source: NJDHSS Cardiac Catheterization Data Registry

iv. Projected demonstration project elective angioplasty case volume

Based on the average 473 cardiac catheterizations performed between 2005 and 2007, a 30% conversion rate would result in a maximum of 142 patients, of which 75%, or 106, would be randomized to be eligible to participate in the research project at St. Clare's, assuming they all met the patient eligibility criteria of the research study and gave informed consent. In addition to the 106 elective angioplasties anticipated, St. Clare's performed 61 primary angioplasties in 2007. Total annual volume of angioplasties projected based on past performance would be 167, below the annual 200 cases minimum C-PORT-E demonstration project requirement.

In its completeness response, St. Clare's states that it will not experience any impact form the closure of Muhlenberg Regional Medical Center.

II. FINANCIAL

Department staff reviewed and found that the applicant has documented adequate financial resources to implement and maintain the project.

New Brunswick Hospital Market Area

1. Hunterdon Medical Center l
2. JFK Medical Center
4. Raritan Bay Medical Center-Perth Amboy
5. Saint Peter's University Hospital
6. Somerset Medical Center
7. University Medical Center at Princeton

STATE HEALTH PLANNING BOARD
CERTIFICATE OF NEED PROJECT SUMMARY
ELECTIVE ANGIOPLASTY WITHOUT ON-SITE SURGERY BACK-UP
DEMONSTRATION PROJECT

Applicant:	Hunterdon Medical Center (Hunterdon)
CN Number:	FR 071219-10-01
Location:	Flemington, Hunterdon County
Project Cost:	$0

PROJECT DESCRIPTION:
Applicant is proposing to provide elective PCI without back-up surgery on-site and further proposes to participate in the Atlantic C-PORT, Elective Angioplasty Study, a multi-state demonstration trial to assess safety, quality and cost of elective PCI offered at community hospitals that do not offer cardiac surgery services on site. There are no project costs associated with this project. The applicant proposes to contract with Morristown Memorial Hospital as the participating cardiac surgery center.

I. SUMMARY OF THE APPLICANT'S REPRESENTATIONS

A. APPLICANT JUSTIFICATION

Hunterdon Medical Center states that its participation in the Atlantic C-PORT-E demonstration project would "positively contribute to the orderly development of health care services by increasing geographic access to area residents while having a minimum impact upon current cardiac surgical programs." Hunterdon Medical states that the expansion in cardiac services would increase access as it is the sole acute-care hospital which provides emergency PCI in northwestern NJ. Approval would reduce the need to refer patients who require elective PCI to out of area and out of state hospitals.

Hunterdon states that it has a unique focus on primary care whereby over 50% of the care provided is primary care which includes health promotion, education, diagnosis and treatment.

Hunterdon states that "elective PCI at HMC will help maintain and improve cardiology care at HMC, support the Medical Center's ability to sustain its emergency PCI program and retain cardiac interventionalists." HMC further states that it "initially found it difficult to initiate the emergency PCI program due to the limited availability of interventional cardiologists. The expansion of PCI capabilities will help ensure that our practicing cardiologists will want to stay and that area residents will have access to this vital service.

B. STATUTORY CRITERIA

a. The availability of facilities or services that may serve as alternatives or substitutes.

Hunterdon states that it is the sole provider of emergency PCI in Hunterdon and Warren Counties. Northwestern New Jersey residents must travel further then their counterparts seeking elective PCI in other areas of the state. The majority of Hunterdon's referred elective PCI cases go to Morristown Memorial Hospital, which has agreed to participate as Hunterdon's cardiac surgery center.

b. The need for special equipment and services in the area.

The applicant indicates that there is no additional equipment or services needed for the project.

c. The adequacy of financial resources and sources of present and future revenues.

The applicant states it has the financial resources to implement this project.

d. The availability of sufficient staff in the several professional disciplines involved.

The applicant states that the catheterization lab's staff consists of 8.8 FTE RNs, 1 FTE technician and 0.5 FTE unit coordinator. The lab would add an additional 0.5 FTE unit coordinator and a full-time research coordinator. Three interventionalists would support the program.

e. The project is necessary to provide required health care in the region.

The applicant states that the November 5, 2007 CN call for elective angioplasty without on-site surgery back-up defines the need for the health care service in the state.

f. The project will not have an adverse impact on access to health care services in the region or Statewide.

As stated by the applicant in completeness response tables 2 and 3, it made 253 cardiac surgery and PCI referrals in 2006 with the following impact: 241 or 95% were referred to Morristown Memorial Hospital and 12 or 5% were referred to Doylestown Hospital in Pennsylvania. *Morristown's angioplasty volume was 2,648 in 2006 and the impact of 75% (190 cases) of Hunterdon's referrals being lost would account for 7.2% of Morristown's volume, assuming all the referrals were for angioplasty.*

Department analysis of 2006 UB discharge data indicate the percentage of each cardiac surgery center's PCI cases which came from each applicant's service area. Service area is defined as those zip codes that comprise 75% of an applicant's discharges using 2006 UB discharge data reported by the applicants in completeness responses. The

impact is as follows: 6.2% of Morristown Memorial Hospital's PCI cases came from Hunterdon's service area in 2006.

Hunterdon states in its application that its participation in the Atlantic C-PORT-E clinical trial will have minimal impact on other facilities. The majority of Hunterdon's referrals go to Morristown Memorial Hospital, which agreed to participate in the study with Hunterdon as its surgical backup.

C. DEMONSTRATION PROJECT CRITERIA AT N.J.A.C. 8:33-3.11(e)

*For the most part, the applicant has sufficiently documented the ability to satisfy demonstration project eligibility criteria at N.J.A.C. 8:33-3.11(e)4 and the Atlantic C-PORT-E trial site inclusion criteria, including: (a) how the applicant will satisfy the patient selection criteria specified in the Atlantic C-PORT-E protocol, which is designed to assure informed consent and appropriate randomization, as provided in the Manual of Operations (N.J.A.C. 8:33-3.11(e)6iii); (b) approval of the study protocol by the applicant's Institutional Review Board, and if approval is pending, the status of that application (N.J.A.C. 8:33-3.11(e)6iv); (c) how the applicant will meet the target volume specified in the Atlantic C-PORT-E protocol of primary and elective angioplasties performed at the applicant's site, after randomization (that is, 100 PCI cases in year one and 200 cases in year two and each year thereafter) (N.J.A.C. 8:33-3.11(e)6v)*****; (d) the applicant's compliance with the criteria for performance of primary PCI at N.J.A.C. 8:33E-2.16, 2.16(b) and N.J.A.C. 8:43G-7 (N.J.A.C. 8:33-3.11(e)6vi); and (e) documentation of the applicant's willingness to report elective PCI data to the Department separate from data collected as part of the study protocol, to support the Department's ongoing monitoring of cardiac services pursuant to N.J.A.C. 8:33E-1.9 and 2.10 (N.J.A.C. 8:33-3.11(e)6vii).*

**Staff Note: The applicant has <u>not</u> sufficiently documented the ability to satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol of performing at least 200 angioplasties per year.*

a. C-PORT-E Study Site Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6i):

The applicant has documented how it would satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol, including: (1) capability of performing a minimum volume of diagnostic cardiac catheterizations per year (N.J.A.C. 8:33-3.11(e)6i(1)); (2) agreement to complete an elective PCI development program (N.J.A.C. 8:33-3.11(e)6i(2)); (3) agreement to abide by physician, patient and device selection criteria defined in the study's Manual of Operations (N.J.A.C. 8:33-3.11(e)6i(3)); (4) agreement to collect and transmit study data in a timely fashion (N.J.A.C. 8:33-3.11(e)6i(4)); (5) agreement to perform elective PCI only via the study protocol and only while cases are being enrolled in the study (N.J.A.C. 8:33-3.11(e)6i(5)); and (6) agreement to develop and maintain a quality and error management program, including a weekly interventional conference and monthly quality and error management review (N.J.A.C. 8:33-3.11(e)6i(6)).

b. Participating Interventional Cardiologist Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6ii):

The applicant has documented that its participating interventional cardiologists have agreed to: (1) be in compliance and continue to be in compliance with minimum annual statewide interventional volume standards as set forth at N.J.A.C. 8:33E-2.16(b)6 (N.J.A.C. 8:33-3.11(e)6ii(1)); (2) practice in accordance with Atlantic C-PORT-E trial defined device and patient selection criteria (N.J.A.C. 8:33-3.11(e)6ii(2)); (3) obtain necessary informed consent for patient participation in the demonstration including the identity and location of the participating cardiac surgery center(s) that are to receive randomized study patients (N.J.A.C. 8:33-3.11(e)6ii(3));

Participating Interventional Cardiologist Performance Criteria:

1. The applicant states that all interventionalists will comply with Atlantic C-PORT-E criteria, including its minimum physician volume standard (in accordance with N.J.A.C. 8:33E-2.16(b)6).

2. *Listed below are participating physicians and their respective 2006 angioplasty PCI case volumes. Department staff found that two of the three interventionalists met the 75 case minimum. The applicant did not provide proper documentation regarding case volume from out of state facilities.*

Physician Name	All facilities where physician performs angioplasties
Andrey Espinoza	Hunterdon, Morristown Memorial, Doylestown Hospital (PA) *(137 NJ)*
Barry Hunt Lowell	Hunterdon, St. Clare's, Morristown Memorial *(394 in NJ)*
Matthew R. Voss	Hunterdon, Morristown Memorial, Doylestown Hospital (PA) *(25 NJ)*

Source: Hunterdon's completeness response Table 4 and NJDOH Cardiac Registry

c. Additional Demonstration Project Evaluative Criteria (N.J.A.C. 8:33-3.11(e)7i.-iv.):

i. Ability to offer a high quality program.

a. Licensure:

Hunterdon's full service diagnostic cardiac catheterization program is currently licensed unconditionally through July 31, 2008. Hunterdon was licensed for primary PCI on October 27, 2005 and will be evaluated on July 31, 2008.

b. Outcomes:

Hunterdon's Diagnostic Cardiac Catheterization Outcomes

Year	*2005*		*2006*	
	# of Cases	*% of Total*	*# of Cases*	*% of Total*
Total Cases	*473*	*n/a*	*493*	*n/a*
Death in Hospital	*3*	*.63%*	*4*	*0.81%*

Death in Lab	*1*	*0.21%*	*1*	*0.20%*
All in Lab Complications	*3*	*.42%*	*15*	*3.04%*

Source: NJDHSS Cardiac Data Registry (unaudited data)

In 2005, the Department reported 473 cases, three deaths in hospital, one death in lab and three complications, while Hunterdon's application reported 478 cases, zero deaths in lab and zero deaths in hospital and zero complications. In 2006, the Department reported 493 cases, four deaths in hospital, one death in lab and fifteen complications, while Hunterdon reported 533 cases, zero deaths in hospital, zero deaths in lab and three complications.

ii. Representation of State's diverse regions and urban/suburban/rural population.

Hunterdon Medical Center is located in Flemington, Hunterdon County. The 2000 U.S. Census Bureau table titled "Urban and Rural Population: New Jersey, Counties and Municipalities" reports that over half of the county's population resides in rural areas.

iii. Potential to increase access to care for minorities and medically underserved.

As presented by the applicant in its tables below, Hunterdon's service area population is comprised of 6.3% non-white and the 45 and over population is comprised of 3.5% non-white. Hunterdon's diagnostic cardiac catheterization patient population percentage of non-white patients was 3.8% in 2005 and 4.1% in 2006. Hunterdon's minority use rate of diagnostic cardiac catheterization is comparable to the % of non-white residents in the service area population in 2005 and 2006.

Hunterdon's Service Area Population by Race

Age Category	White	Non-White	Total	% of Non-White to Total Population
Under 45	92,748	7,972	100,720	7.92%
45-64	39,431	1,677	41,108	4.08%
65-74	9323	256	9,579	2.67%
75-84	6179	127	6,306	2.01%
85 +	2119	38	2,157	1.76%
Total	149,800	10,070	159,870	6.30%

Source: Hunterdon Completeness Questions, #6 (US Census 2000)

Hunterdon's Diagnostic Cardiac Catheterization by Race

	White Non-Hispanic	*Black Non-Hispanic*	*Hispanic*	*Asian & Pacific Islander*	*Other*	*% of Non-White Cases*
2005	*96.2%*	*.8%*	*.6%*	*1.5%*	*0.8%*	*3.8%*
2006	*95.9%*	*1.2%*	*.4%*	*.2%*	*1.8%*	*4.1%*

Source: NJDHSS Cardiac Catheterization Data Registry

iv. Projected demonstration project elective angioplasty case volume

Based on the average 478 cardiac catheterizations performed between 2005 and 2007, a 30% conversion rate would result in 144 patients, of which a maximum of 75%, or 108, would be randomized to be eligible to participate in the research project at Hunterdon, assuming they all met the patient eligibility criteria of the research study and gave informed consent. Hunterdon Medical performed 51 primary PCIs in 2007. Total annual volume of projected angioplasties would be 159, below the annual 200 case minimum C-PORT-E demonstration project requirement.

The applicant projects 139 total PCIs in 2009 and 201 in 2010. Hunterdon reports that the closure of Muhlenberg Regional Medical Center will have a minimal impact on its program.

II. FINANCIAL

Department staff reviewed and found that the applicant has documented adequate financial resources to implement and maintain the project.

STATE HEALTH PLANNING BOARD
CERTIFICATE OF NEED PROJECT SUMMARY
ELECTIVE ANGIOPLASTY WITHOUT ON-SITE SURGERY BACK-UP
DEMONSTRATION PROJECT

Applicant:	JFK Medical Center (JFK)
CN Number:	FR 071215-12-01
Location:	Edison, Middlesex County
Project Cost:	$ 0

PROJECT DESCRIPTION:
JFK Medical Center (JFK), an affiliate of the Solaris Health System (SHS), is proposing to provide elective PCI without back-up surgery on-site and further proposes to participate in the Atlantic C-PORT, Elective Angioplasty Study, a multi-state demonstration trial to assess safety, quality and cost of elective PCI offered at community hospitals that do not offer cardiac surgery services on site. A major component of the application includes relocating the elective angioplasty team and program currently operational at Muhlenberg Regional Medical Center, an affiliate of SHS, in Plainfield to the JFK campus in Edison. There are no project costs associated with this project. The applicant proposes to contract with Newark Beth Israel Medical Center (NBI) in Newark, Robert Wood Johnson University Hospital (RWJUH) in New Brunswick, and St. Michael's Medical Center (St. Michael's) in Newark as participating cardiac surgery centers.

I. SUMMARY OF THE APPLICANT'S REPRESENTATIONS

A. APPLICANT JUSTIFICATION

The applicant states that it is well positioned clinically to implement an elective angioplasty program. The hospital operates a full service diagnostic catheterization laboratory and is licensed for primary PCI. The applicant has successfully operated the primary PCI program for more than a year and has met or exceeded all regulatory requirements related to the primary PCI program.

The elective PCI program at JFK would be led by an experienced and committed Director of Interventional Cardiology and staffed by the catheterization team from Muhlenberg Regional Medical Center, who is one of the nine successful hospital 2005 C-PORT-E demonstration projects, performing 241 successful elective PCI cases to date.

The applicant also has a Quality Improvement Plan already in place that contains a systematic process of monitoring and evaluating the quality and appropriateness of patient care, resolving identified problems and providing adherence to regulatory peer review requirements (N.J.A.C. 8:33E-1.6). The applicant stresses that "documented patient outcomes at JFK and Muhlenberg compare favorably with state and national benchmarks."

JFK argues that it is well positioned geographically to implement an elective PCI demonstration project. The applicant's location in the northern region of Middlesex County, and only 3 miles from the western border of Union County and the City of Plainfield, is 15 miles from the only cardiac surgery center (Robert Wood Johnson University Hospital in New Brunswick) in both counties.

The applicant emphasized its ability and commitment to increase access to care for minority and medically underserved populations. A comprehensive Community Outreach, Access and Prevention Plan (COAPP) was developed by SHS in 2002 as part of Muhlenberg Regional Medical Center's (Muhlenberg) primary PCI program. The plan was designed to increase access to care for high-risk populations in the SHS service area, including those that are indigent, Black and Hispanic. Over the past several years SHS implemented plan strategies, such as risk factor screenings, health education, community awareness campaigns, collaborative partnerships, a van transportation system, and establishment of an information system for tracking/retrieving patient data. The Plan was utilized in Atlantic C-PORT-E program at Muhlenberg in 2005, resulted in a 44.7 percent rate of minorities undergoing PCI, a percentage higher than other providers and more consistent with service area demographics. SHS plans to implement the same outreach plan for an elective PCI program at JFK and is confident it can further improve access to cardiac care for minority and medically underserved populations from the greater service area - for treatment on the Edison campus.

The applicant also employed two separate, "conservative" methodologies for projecting PCI volume at its two medical centers which estimated 266 PCI study cases at JFK (and 200 cases at Muhlenberg) using the "current referral pattern" methodology, and over 500 PCI cases using a "PCI use rate" methodology. In either case, JFK expects to exceed the minimum annual Atlantic C-PORT-E study PCI volume requirement.

B. STATUTORY CRITERIA

a. The availability of facilities or services that may serve as alternatives or substitutes.

The application for participation in the Atlantic C-PORT-E demonstration project is intended to assess the safety, quality and cost of elective PCI performed at hospitals that do not offer cardiac surgery services on-site.

b. The need for special equipment and services in the area.

The applicant states that since JFK Medical Center is already successfully performing primary PCI, the equipment and resources necessary to initiate participation in the elective PCI program are already in place.

c. The adequacy of financial resources and sources of present and future revenues.

There are no capital or project costs associated with this project and the application includes a financial feasibility study (Attachment 5) that indicates a modest surplus of revenue over expenses from the elective PCI program.

d. The availability of sufficient staff in the several professional disciplines involved.

JFK is confident that it will be able to assure the necessary staff required to perform elective PCI to participate in the demonstration project.

e. The project is necessary to provide required health care in the region.

The applicant points to the Department's issuance of a CN call that establishes the need for the demonstration projects and JFK Medical Center has made the case for its selection as one of the demonstration projects in its CN application.

f. The project will not have an adverse impact on access to health care services in the region or Statewide.

As indicated by the applicant in completeness response tables 2 and 3, Robert Wood Johnson University Hospital is JFK Medical Center's primary referral center (246 or 75% of JFK Medical Center's angioplasty and cardiac surgery referrals in 2006). Robert Wood Johnson University Hospital's angioplasty volume was 3,370 in 2006 and the impact of 75% of JFK Medical Center's referrals being lost would account for only 5.5% of Robert Wood Johnson University Hospital's volume, assuming all the referrals were for angioplasty. Newark Beth Israel Medical Center, on the other hand, received a total of 61 or 18.6% of JFK Medical Center's intervention referrals which would account for only 3.1% of Newark Beth Israel Medical Center's total PCI caseload of 1,468 in 2006.

Department of Health and Senior Services (Department) analysis of 2006 UB discharge data indicates the percentage of each cardiac surgery center's PCI cases which came from each applicant's service area. Service area is defined as those zip codes that comprise 75% of an applicant's discharges, using 2006 UB discharge data, reported by the applicants in completeness responses. The impact is as follows:
10.1% of University Hospital, 7.5% of Robert Wood Johnson University Hospital 7.2% of St. Michaels' Medical Center and 4.7% of Newark Beth Israel Medical Center's PCI cases came from JFK Medical Center's service area in 2006.

The applicant indicates that the CN application for participation in the Atlantic C-PORT-E demonstration project is intended to assess the safety, quality and cost of elective PCI performed at hospitals that do not offer cardiac surgery services on site. The applicant's Community Outreach, Access and Prevention Plan (COAPP – Attachment 7) reflects JFK Medical Center's strong commitment to improving access to its service area populations

C. DEMONSTRATION PROJECT CRITERIA AT N.J.A.C. 8:33-3.11(e)

The applicant has sufficiently documented the ability to satisfy demonstration project eligibility criteria at N.J.A.C. 8:33-3.11(e)4 and the Atlantic C-PORT-E trial site inclusion criteria, including: (a) how the applicant will satisfy the patient selection criteria specified in the Atlantic C-PORT-E protocol, which is designed to assure informed consent and appropriate randomization, as provided in the Manual of Operations (N.J.A.C. 8:33-3.11(e)6iii); (b) approval of the study protocol by the applicant's Institutional Review Board, and if approval is pending, the status of that application (N.J.A.C. 8:33-3.11(e)6iv); (c) how the applicant will meet the target volume specified in the Atlantic C-PORT-E protocol of primary and elective angioplasties performed at the applicant's site, after randomization (that is, 100 PCI cases in year one and 200 cases in year two and each year thereafter) (N.J.A.C. 8:33-3.11(e)6v); (d) the applicant's compliance with the criteria for performance of primary PCI at N.J.A.C. 8:33E-2.16, 2.16(b) and N.J.A.C. 8:43G-7 (N.J.A.C. 8:33-3.11(e)6vi); and (e) documentation of the applicant's willingness to report elective PCI data to the Department separate from data collected as part of the study protocol, to support the Department's ongoing monitoring of cardiac services pursuant to N.J.A.C. 8:33E-1.9 and 2.10 (N.J.A.C. 8:33-3.11(e)6vii).

a. C-PORT-E Study Site Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6i):

The applicant has documented how it would satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol, including: (1) capability of performing a minimum volume of diagnostic cardiac catheterizations per year (N.J.A.C. 8:33-3.11(e)6i(1)); (2) agreement to complete an elective PCI development program (N.J.A.C. 8:33-3.11(e)6i(2)); (3) agreement to abide by physician, patient and device selection criteria defined in the study's Manual of Operations (N.J.A.C. 8:33-3.11(e)6i(3)); (4) agreement to collect and transmit study data in a timely fashion (N.J.A.C. 8:33-3.11(e)6i(4)); (5) agreement to perform elective PCI only via the study protocol and only while cases are being enrolled in the study (N.J.A.C. 8:33-3.11(e)6i(5)); and (6) agreement to develop and maintain a quality and error management program, including a weekly interventional conference and monthly quality and error management review (N.J.A.C. 8:33-3.11(e)6i(6)).

b. Participating Interventional Cardiologist Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6ii):

The applicant has documented that its participating interventional cardiologists have agreed to: (1) be in compliance and continue to be in compliance with minimum annual statewide interventional volume standards as set forth at N.J.A.C. 8:33E-2.16(b)6 (N.J.A.C. 8:33-3.11(e)6ii(1)); (2) practice in accordance with Atlantic C-PORT-E trial defined device and patient selection criteria (N.J.A.C. 8:33-3.11(e)6ii(2)); (3) obtain necessary informed consent for patient participation in the demonstration including the identity and location of the participating cardiac surgery center(s) that are to receive randomized study patients (N.J.A.C. 8:33-3.11(e)6ii(3));

Participating Interventional Cardiologist Inclusion Criteria:

1. *The applicant states that all interventionalists have met the annual statewide interventional volume standard of 75 cases in 2006 and that its participating physicians will continue to meet this standard in accordance with N.J.A.C. 8:33E-2.16(b)6.*

2. *Listed below are participating physicians and their respective 2006 angioplasty case volumes. Staff Note: Department staff found that all six interventionalists met the 75 case minimum.*

Physician Name	All facilities where physician performs PCI	
Alam Mahmood	Muhlenberg Regional Medical Center	
	Newark Beth Israel Medical Center	
	Robert Wood Johnson University Hospital	
	Raritan Bay Medical Center- Perth Amboy	*(98 cases*)
Altszuler Henry M.	Muhlenberg Regional Medical Center	
	St. Joseph's Hospital	
	Morristown Memorial Hospital	*(106 cases)*
Husain Saleem	Muhlenberg Regional Medical Center	
	Newark Beth Israel Medical Center	*(189 cases)*
Karpenos Alexander G.	Muhlenberg Regional Medical Center	
	Robert Wood Johnson University Hospital	
	Trinitas Hospital	*(96 cases)*
Passi Rakesh K.	Muhlenberg Regional Medical Center	
	Robert Wood Johnson University Hospital	
	Raritan Bay Medical Center- Perth Amboy	*(434 cases)*
Schanzer Robert	Newark Beth Israel Medical Center	
	Robert Wood Johnson University Hospital	
	Muhlenberg Regional Medical Center	*(109 cases)*

Source: JFK's completeness response and NJDOH Cardiac Registry

c. Additional Demonstration Project Evaluative Criteria (N.J.A.C. 8:33-3.11(e)7i.-iv.):

i. The applicant's ability to offer a high quality program.

a. *Licensure: JFK is unconditionally licensed effective May 1, 2008. JFK was granted CN approval to provide primary angioplasty on September 8, 2005 (CN# 050704-12-01) and was granted licensure approval on September 21, 2006 and performed its first case on October 9, 2006.*

b. Outcomes:

JFK's Diagnostic Cardiac Catheterization Outcomes

Year	*2005*		*2006*	
	# of Cases	*% of Total*	*# of Cases*	*% of Total*
Total Cases	*716*	*n/a*	*662*	*n/a*
Death in Hospital	*1*	*.14%*	*4*	*0.60%*
Death in Lab	*1*	*.14%*	*0*	*0%*
All in Lab Complications	*3*	*.42%*	*2*	*0.30%*

Source: NJDHSS Cardiac Data Registry (unaudited data)

The Department recorded two complications in 2006, while JFK reported three complications. In 2005, the Department found one death in hospital and three complications while JFK reported zero deaths in hospital and four complications.

ii. The applicant's ability to provide patient selection from among a community that is representative of the State's diverse regions and urban, suburban, and/or rural populations;

JFK is located in Middlesex, in the Central region of the state. The 2000 U.S. Census Bureau table titled "Urban and Rural Population: New Jersey, Counties and Municipalities" reports all of JFK's service area as urban.

JFK states that it is well positioned geographically to implement an elective PCI demonstration project. The applicant's location in the northern region of Middlesex County, is only 3 miles from the western border of Union County and the City of Plainfield, and is 15 miles from the only cardiac surgery center (Robert Wood Johnson University Hospital in New Brunswick) in either of the two counties. The population in JFK's service area is over 40 percent minority and growing, with one of the largest Asian Indian American populations in the country. In addition, the Plainfield area, which has a 52 percent minority population, is a significant part of JFK's service area. Despite the fact that these population groups have a higher prevalence of heart disease and a higher mortality rate from heart disease, they have a lower use rate of cardiac interventions such as PCI.

iii. The potential to increase access to care for minorities and the medically underserved by selection of the applicant; and

As presented below, JFK's total service area population is comprised of 37.68% non-white and the over age 45 population is comprised of 27.7% non-white based on 2000 Census data. *JFK's percentage of diagnostic cardiac catheterization caseload performed on non-white patients was 24.0% in 2005; and 25.1% in 2006. JFK's minority use rate of diagnostic cardiac catheterization is below the % of non-white residents in the service area population in 2005 and 2006.*

JFK's Service Area Population by Race

Age Category	White	Non-White	Total	% of Non-White to Total Population
Under 45	101,403	86,903	188,306	46.15%
45-64	66,228	32,453	98,681	32.89%
65-74	22,634	6,088	28,722	21.20%
75-84	17,812	2,758	20,570	13.41%
85 +	5,173	728	5,901	12.34%
Total	213,250	128,930	342,180	37.68%

Source: JFK Completeness Questions

JFK's Diagnostic Cardiac Catheterization by Race

	White Non-Hispanic	*Black Non-Hispanic*	*Hispanic*	*Asian & Pacific Islander*	*Other*	*% of Non-White Cases*
2005	*76.0%*	*8.4%*	*6.6%*	*8.7%*	*0.4%*	*24.0%*
2006	*74.9*	*7.9%*	*7.1%*	*9.4%*	*0.6%*	*25.1%*

Source: NJDHSS Cardiac Catheterization Data Registry

iv. Projected demonstration project elective angioplasty case volume.

Based on the average 689 cardiac catheterizations performed between 2005 and 2007, a 30% conversion rate would be 207 patients, of which a maximum of 75%, or 155, would be randomized to be eligible to participate in the research project at JFK, assuming they all met the patient eligibility criteria of the research study and gave informed consent. In addition to the 155 elective PCIs anticipated, JFK performed 58 primary PCIs in 2007. Total annual volume of PCIs projected based on past performance would be 213, which is above the 200 annual minimum C-PORT-E demonstration project requirement. JFK also predicts further increases in volume based on population growth, historic primary PCI volume that exceeds minimum requirements and anticipated referral changes largely due to the imminent closure of SHS' Muhlenberg Regional Medical Center.

JFK Medical Center states it anticipates a significant impact resulting from the closure of Muhlenberg Regional Medical Center (Muhlenberg), since there is considerable service area overlap. JFK Medical Center is the closest provider to Muhlenberg. JFK Medical Center's service area encompasses all of the zip codes in Muhlenberg's primary service area and all but one zip code in Muhlenberg's secondary service area. JFK Medical Center estimates that between 25% - 30% of current Muhlenberg patients will be admitted to JFK Medical Center after the closure of Muhlenberg.

II. FINANCIAL

Department staff reviewed and found that the applicant has documented adequate financial resources to implement and maintain the project.

STATE HEALTH PLANNING BOARD
CERTIFICATE OF NEED PROJECT SUMMARY
ELECTIVE ANGIOPLASTY WITHOUT ON-SITE SURGERY BACK-UP
DEMONSTRATION PROJECT

Applicant:	Raritan Bay Medical Center-Perth Amboy (Raritan Bay)
CN Number:	FR 071207-12-01
Location:	Perth Amboy, New Jersey
Project Cost:	$0

PROJECT DESCRIPTION:
Applicant is proposing to provide elective PCI without back-up surgery on-site and further proposes to participate in the Atlantic C-PORT-E, Elective Angioplasty Study, a multi-state demonstration trial to assess safety, quality and cost of elective PCI offered at community hospitals that do not offer cardiac surgery services on site. Raritan Bay is a current participant in the Atlantic C-PORT-E trial, having been CN approved in 2005 and licensed by the Department in 2006. There are no construction or project costs associated with this project. The applicant proposes to contract with Robert Wood Johnson University Hospital as the participating cardiac surgery center.

I. SUMMARY OF THE APPLICANT'S REPRESENTATIONS

A. APPLICANT JUSTIFICATION

Raritan Bay states it is highly qualified for participation in the Atlantic C-Port Trial because it has shown through its application and prior performance in providing diagnostic services and emergency angioplasty that it has a proven ability to provide high quality patient care service and be a conscientious partner in this research protocol. Raritan Bay states that it also serves a community that is representative of the State's diverse regions – urban/suburban/rural and thereby provides a diverse patient base for research. The applicant states that it has an extensive past history of participating in multi-institutional, national and international studies. The applicant further states that participation in this research project would provide the potential to increase access to care for minorities and the medically underserved and that it has the necessary angioplasty case volume to support participation in this demonstration project.

B. STATUTORY CRITERIA

a. The availability of facilities or services that may serve as alternatives or substitutes.

The applicant states that the nearest elective angioplasty facility is Robert Wood Johnson University Hospital (13 miles away and the only other provider in Middlesex County), which has agreed to participate in the C-PORT-E as Raritan Bay's cardiac surgery center.

b. The need for special equipment and services in the area.

The applicant indicates that no additional expenditures are necessary.

c. The adequacy of financial resources and sources of present and future revenues.

The applicant states it has the financial resources to implement this project.

d. The availability of sufficient staff in the several professional disciplines involved.

No additional staff is necessary as the applicant is presently a participant in the study.

e. The project is necessary to provide required health care in the region.

The applicant states that elective angioplasty services in Middlesex County are only provided by Raritan Bay under the C-PORT research protocol and Robert Wood Johnson University Hospital, which is located 13 miles from Perth Amboy, and that limiting elective angioplasty to one program underserves Middlesex County.

f. The project will not have an adverse impact on access to health care services in the region or Statewide.

As stated by the applicant, it made 362 cardiac surgery and PCI referrals in 2006 with the following impact: 188 or 51.93% were referred to Robert Wood Johnson University Hospital and 162 or 45% were referred to University Hospital. *Robert Wood Johnson's PCI volume was 3,370 in 2006 and the impact of 75% of Raritan Bay's referrals being lost would account for only 4.2% of Robert Wood Johnson's volume. University's PCI volume was 730 in 2006 and the impact of 75% of Raritan Bay's referrals being lost would account for 16.6% of University's PCI volume assuming all referrals were for PCI.*

Department analysis of 2006 UB discharge data indicates the percentage of each cardiac surgery center's PCI cases which came from each applicant's service area. Service area is defined as those zip codes that comprise 75% of an applicant's discharges, using 2006 UB discharge data, reported by the applicants in completeness responses. The impact is as follows: 1.3% of Newark Beth Israel's, 4.6% of RWJUH's and 2% of University's PCI cases came from Raritan Bay's service area in 2006.

C. DEMONSTRATION PROJECT CRITERIA AT N.J.A.C. 8:33-3.11(e)

The applicant has sufficiently documented the ability to satisfy demonstration project eligibility criteria at N.J.A.C. 8:33-3.11(e)4 and the Atlantic C-PORT-E trial site inclusion criteria, including: (a) how the applicant will satisfy the patient selection criteria specified in the Atlantic C-PORT-E protocol, which is designed to assure informed consent and appropriate randomization, as provided in the Manual of Operations (N.J.A.C. 8:33-3.11(e)6iii); (b) approval of the study protocol by the applicant's Institutional Review Board, and if approval is pending, the status of that application (N.J.A.C. 8:33-3.11(e)6iv); (c) how the applicant will meet the target volume specified in

the Atlantic C-PORT-E protocol of primary and elective angioplasties performed at the applicant's site, after randomization (that is, 100 PCI cases in year one and 200 cases in year two and each year thereafter) (N.J.A.C. 8:33-3.11(e)6v); (d) the applicant's compliance with the criteria for performance of primary PCI at N.J.A.C. 8:33E-2.16, 2.16(b) and N.J.A.C. 8:43G-7 (N.J.A.C. 8:33-3.11(e)6vi); and (e) documentation of the applicant's willingness to report elective PCI data to the Department separate from data collected as part of the study protocol, to support the Department's ongoing monitoring of cardiac services pursuant to N.J.A.C. 8:33E-1.9 and 2.10 (N.J.A.C. 8:33-3.11(e)6vii).

a. C-PORT-E Study Site Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6i):

The applicant has documented how it would satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol, including: (1) capability of performing a minimum volume of diagnostic cardiac catheterizations per year (N.J.A.C. 8:33-3.11(e)6i(1)); (2) agreement to complete an elective PCI development program (N.J.A.C. 8:33-3.11(e)6i(2)); (3) agreement to abide by physician, patient and device selection criteria defined in the study's Manual of Operations (N.J.A.C. 8:33-3.11(e)6i(3)); (4) agreement to collect and transmit study data in a timely fashion (N.J.A.C. 8:33-3.11(e)6i(4)); (5) agreement to perform elective PCI only via the study protocol and only while cases are being enrolled in the study (N.J.A.C. 8:33-3.11(e)6i(5)); and (6) agreement to develop and maintain a quality and error management program, including a weekly interventional conference and monthly quality and error management review (N.J.A.C. 8:33-3.11(e)6i(6)).

b. Participating Interventional Cardiologist Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6ii):

The applicant has documented that its participating interventional cardiologists have agreed to: (1) be in compliance and continue to be in compliance with minimum annual statewide interventional volume standards as set forth at N.J.A.C. 8:33E-2.16(b)6 (N.J.A.C. 8:33-3.11(e)6ii(1)); (2) practice in accordance with Atlantic C-PORT-E trial defined device and patient selection criteria (N.J.A.C. 8:33-3.11(e)6ii(2)); (3) obtain necessary informed consent for patient participation in the demonstration including the identity and location of the participating cardiac surgery center(s) that are to receive randomized study patients (N.J.A.C. 8:33-3.11(e)6ii(3));

Participating Interventional Cardiologist Performance Criteria:

1. The applicant states that all interventionalists will comply with Atlantic C-PORT-E criteria, including its minimum physician volume standard (in accordance with N.J.A.C. 8:33E-2.16(b)6).

2. *Listed below are participating physicians and their respective 2006 angioplasty case volumes. Staff Note: Department staff found that seven of the eight interventionalists met the 75 case minimum in 2006. There may be mitigating factors regarding the volume of the eighth interventionalists.*

Physician Name	All facilities where physicians perform angioplasties
Alam, Mahmood	RBMC, RWJUH, NIBMC *(98)*
Haik, Bruce	RBMC, SMMC, SBMC (*256)*
Noveck, Howard	RBMC, RWJUH, SMMC *(73)*
Passi, Rakesh	RBMC, RWJUH *(434)*
Patel, Ravindra	RBMC, RWJUH, UMDNJ *(199)*
Sahgal, Puneet	RBMC, RWJUH *(158)*
Sahni, Rakesh	RBMC, SMMC, UMDNJ *(168)*
Snyder, Craig	RBMC, RWJUH *(169)*

NIBMC - Newark Beth Medical Center
RBMC - Raritan Bay Medical Center
RWJUH - Robert Wood Johnson University Hospital
SBMC - Saint Barnabas Medical Center
SMMC - Saint Michael's Medical Center
UMDNJ - University of Medicine and Dentistry of New Jersey
Source: Raritan's completeness response – Table 4 and NJDOH Cardiac Registry

c. Additional Demonstration Project Evaluative Criteria (N.J.A.C. 8:33-3.11(e)7i.-iv.):

i. Ability to offer a high quality program.

a. Licensure:

Raritan Bay's full service diagnostic cardiac catheterization program is currently licensed unconditionally through September 30, 2008. Raritan Bay received licensure to perform primary PCI on April 6, 2004 and is unconditionally licensed through September 30, 2008.

b. Outcomes:

Raritan Bay's Diagnostic Cardiac Catheterization Outcomes

	2005		*2006*	
	# of Cases	*% of Total*	*# of Cases*	*% of Total*
Total Cases	*834*	*n/a*	*1048*	*n/a*
Death in Hospital	*2*	*.24%*	*3*	*.37%*
Death in Lab	*0*	*0*	*1*	*.12%*
All In lab Complications	*10*	*.12%*	*8*	*.76%*

Source: NJDHSS Cardiac Data Registry (unaudited data)

In 2005, the Department recorded 834 cases, and ten complications, while Raritan Bay reported 874 cases and zero complications. In 2006, the Department reported three deaths in hospital and eight complications, while Raritan Bay reported one death in hospital and zero complications. Raritan Bay failed to provide information regarding deaths in lab.

ii. Representation of State's diverse regions and urban/suburban/rural population.

Raritan Bay is located in the Perth Amboy, Middlesex County, in the Central region of the state. The 2000 U.S. Census Bureau table titled "Urban and Rural Population: New Jersey, Counties and Municipalities" reports a small population residing in rural areas in East Brunswick and Old Bridge, while the remainder of Raritan Bay's service area is considered to be urban.

iii. Potential to increase access to care for minorities and medically underserved.

As presented below, Raritan Bay's total service area population is comprised of 36.9% non-white and the 45 and over population is comprised of 35.5% non-white. *Raritan Bay's diagnostic cardiac catheterization patient population percentage of non-white patients was 41.4% in 2005 and 40.1% in 2006. Raritan Bay's minority use of diagnostic catheterization is above the % of non-white residents in the service area population in 2005 and 2006.*

Raritan Bay's Service Area Population by Race

Age	Total	White	Non-white	% of Non-White to Total Population
< 45	215,756	134,463	81,293	37.67%
45 - 64	74,136	48,045	26,091	35.19%
65-74	21,428	13,845	7,583	35.39%
75-84	14,457	9,161	5,296	36.63%
85+	3,850	2,402	1,448	37.61%
Total	329,627	207,916	121,711	36.92%

Source: 2000 US Census

Raritan Bay's Diagnostic Cardiac Catheterization by Race

	White Non-Hispanic	*Black Non-Hispanic*	*Hispanic*	*Asian & Pacific Islander*	*Other*	*% of Non-White Cases*
2005	*58.6%*	*9.5%*	*26.3%*	*5.3%*	*.4%*	*41.4%*
2006	*59.92%*	*10.8%*	*21.8%*	*5.7%*	*.1%*	*40.1%*

Source: NJDHSS Cardiac Catheterization Data Registry

iv. Projected demonstration project elective angioplasty case volume

Based on the average of 951 cardiac catheterizations performed between 2005 and 2007, a 30% conversion rate would result in 285 patients, of which a maximum of 75%, or 214, would be randomized to be eligible to participate in the research project at Raritan Bay, assuming they all met the patient eligibility criteria of the research study and gave informed consent. In addition to the 214 elective angioplasties anticipated, Raritan Bay performed 55 primary angioplasties in 2007. Total annual volume of angioplasties projected based on past performance would be 269, which is above the annual 200 case minimum volume C-PORT-E demonstration project requirement.

In its completeness response, Raritan Bay states that the closure of Muhlenberg Regional Medical Center would result in an increase of patients in its cath lab as one of Raritan Bay's interventional cardiologists also has privileges at Muhlenberg. Raritan Bay anticipates seeing patients from this cardiologist in its cath lab. Raritan Bay reports that its cardiac catheterization laboratory and staff are more than adequately equipped to handle additional patients.

II. FINANCIAL

Department staff reviewed and found that the applicant has documented adequate financial resources to implement and maintain the project.

STATE HEALTH PLANNING BOARD
CERTIFICATE OF NEED PROJECT SUMMARY
ELECTIVE ANGIOPLASTY WITHOUT ON-SITE SURGERY BACK-UP
DEMONSTRATION PROJECT

Applicant:	St. Peter's Medical Center (St. Peter's)
CN Number:	FR 071218-12-01
Location:	New Brunswick, Middlesex County
Project Cost:	$0

PROJECT DESCRIPTION:
St. Peter's is proposing to provide elective PCI without back-up surgery on-site and further proposes to participate in the Atlantic C-PORT, Elective Angioplasty Study, a multi-state demonstration trial to assess safety, quality and cost of elective PCI offered at community hospitals that do not offer cardiac surgery services on site. There are no project costs associated with this project. The applicant proposes to contract with Robert Wood Johnson University Hospital as participating cardiac surgery centers.

I. SUMMARY OF THE APPLICANT'S REPRESENTATIONS

A. APPLICANT JUSTIFICATION

St. Peter's states that "Approval of this application would expand St. Peter's existing primary PCI program and provide over 2.3 million residents of Central New Jersey with increased access to leading-edge treatment within the framework of a nationally recognized clinical trial."

St. Peter's states that its "existing cardiac cath volume ... is representative of a demonstrated and growing need within the community."

The applicant states that the most effective path for it to respond to need in its service area and to continue to build its cardiology services is "through participation in a nationally recognized clinical trial" that will improve "the overall level of cardiac care for all patients, not just those in Saint Peter's community."

The applicant states that approval of the application "will improve the hospital's ability to care for its patients, will provide a diverse community with improved access to healthcare services, will provide medical researchers with critical data needed to improve cardiac treatment, will have a balanced economic effect on Saint Peter's and its competitors, and ultimately will serve to increase the quality of care provided at all of New Jersey's hospitals.

B. STATUTORY CRITERIA

a. The availability of facilities or services that may serve as alternatives or substitutes.

The applicant states that elective PCI is available at the following facilities within or bordering its primary service area:

- Robert Wood Johnson University Hospital (Cardiac Surgery Center)
- Raritan Bay Medical Center (Previously approved Elective PCI)
- Somerset Medical Center (Previously approved Elective PCI)
- Muhlenberg Medical Center (Previously approved Elective PCI)

St. Peter's expects that approval would have "minimal (if any) impact upon competitor services as all projected volume is based upon the number of transfers for PCI that St. Peter's is currently experiencing."

b. The need for special equipment and services in the area.

There are no construction or equipment costs associated with this demonstration project.

c. The adequacy of financial resources and sources of present and future revenues.

St. Peter's indicates that it has adequate resources to initiate and maintain the program.

d. The availability of sufficient staff in the several professional disciplines involved.

St. Peter's states that it is adequately staffed to provide safe and efficient elective PCI. St. Peter's would recruit one research nurse and an economic study coordinator for the project.

e. The project is necessary to provide required health care in the region.

St. Peter's states that the "need for the proposed project is based upon the Department's call for Certificates of Need from hospitals throughout the State with an interest in participating in the proposed multi-state elective angioplasty trial."

f. The project will not have an adverse impact on access to health care services in the region or Statewide.

As stated by the applicant in completeness response tables 2 and 3, Robert Wood Johnson University Hospital is St. Peter's only referral center (414, or 100% of St. Peter's PCI referrals in 2006). *Robert Wood Johnson's PCI volume was 3,370 in 2006 and the impact of 75% of St. Peter's referrals being lost would account for 9.2% of Robert Wood Johnson's volume assuming all referrals were for PCI.*

Department analysis of 2006 UB discharge data indicates the percentage of each cardiac surgery center's PCI cases which came from each applicant's service area. Service area is defined as those zip codes that comprise 75% of an applicant's discharges, using 2006 UB discharge data, reported by the applicants in completeness responses. The impact is as follows: 53.6% of Robert Wood Johnson's, 3.1% of

Newark Beth Israel's, 3.2% of Jersey Shore Medical Center's, and 4.4% of UMDNJ-University Hospital's PCI cases came from St. Peter's service area in 2006.

C. DEMONSTRATION PROJECT CRITERIA AT N.J.A.C. 8:33-3.11(e)

*For the most part, the applicant has sufficiently documented the ability to satisfy demonstration project eligibility criteria at N.J.A.C. 8:33-3.11(e)4 and the Atlantic C-PORT-E trial site inclusion criteria, including: (a) how the applicant will satisfy the patient selection criteria specified in the Atlantic C-PORT-E protocol, which is designed to assure informed consent and appropriate randomization, as provided in the Manual of Operations (N.J.A.C. 8:33-3.11(e)6iii); (b) approval of the study protocol by the applicant's Institutional Review Board, and if approval is pending, the status of that application (N.J.A.C. 8:33-3.11(e)6iv); (c) how the applicant will meet the target volume specified in the Atlantic C-PORT-E protocol of primary and elective angioplasties performed at the applicant's site, after randomization (that is, 100 PCI cases in year one and 200 cases in year two and each year thereafter) (N.J.A.C. 8:33-3.11(e)6v)**; (d) the applicant's compliance with the criteria for performance of primary PCI at N.J.A.C. 8:33E-2.16, 2.16(b) and N.J.A.C. 8:43G-7 (N.J.A.C. 8:33-3.11(e)6vi); and (e) documentation of the applicant's willingness to report elective PCI data to the Department separate from data collected as part of the study protocol, to support the Department's ongoing monitoring of cardiac services pursuant to N.J.A.C. 8:33E-1.9 and 2.10 (N.J.A.C. 8:33-3.11(e)6vii).*

**Staff Note: The applicant has <u>not</u> sufficiently documented the ability to satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol of performing at least 200 angioplasties per year.*

a. C-PORT-E Study Site Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6i):

The applicant has documented how it would satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol, including: (1) capability of performing a minimum volume of diagnostic cardiac catheterizations per year (N.J.A.C. 8:33-3.11(e)6i(1)); (2) agreement to complete an elective PCI development program (N.J.A.C. 8:33-3.11(e)6i(2)); (3) agreement to abide by physician, patient and device selection criteria defined in the study's Manual of Operations (N.J.A.C. 8:33-3.11(e)6i(3)); (4) agreement to collect and transmit study data in a timely fashion (N.J.A.C. 8:33-3.11(e)6i(4)); (5) agreement to perform elective PCI only via the study protocol and only while cases are being enrolled in the study (N.J.A.C. 8:33-3.11(e)6i(5)); and (6) agreement to develop and maintain a quality and error management program, including a weekly interventional conference and monthly quality and error management review (N.J.A.C. 8:33-3.11(e)6i(6)).

b. Participating Interventional Cardiologist Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6ii):

The applicant has documented that its participating interventional cardiologists have agreed to: (1) be in compliance and continue to be in compliance with minimum annual statewide interventional volume standards as set forth at N.J.A.C. 8:33E-2.16(b)6 (N.J.A.C. 8:33-3.11(e)6ii(1)); (2) practice in accordance with Atlantic C-PORT-E trial

defined device and patient selection criteria (N.J.A.C. 8:33-3.11(e)6ii(2)); (3) obtain necessary informed consent for patient participation in the demonstration including the identity and location of the participating cardiac surgery center(s) that are to receive randomized study patients (N.J.A.C. 8:33-3.11(e)6ii(3));

Participating Interventional Cardiologist Performance Criteria:

1. The applicant states that all interventionalists will comply with Atlantic C-PORT-E criteria, including its minimum physician volume standard (in accordance with N.J.A.C. 8:33E-2.16(b)6).

2. *Listed below are participating physicians and their respective 2006 angioplasty PCI case volumes. Staff Note: Department staff found that eight of nine interventionalists met the 75 case minimum. There may be mitigating factors regarding physician volume that have not been brought to the Department's attention.*

Physician Name	All facilities where physician performs angioplasties
Agarwala, Ajay	Robert Wood Johnson UH *(189)*
Altmann, Dory	Robert Wood Johnson UH *(81)*
Burns, John	Robert Wood Johnson UH (*94)*
Mermelstein, Erwin	Robert Wood Johnson UH *(71)*
Patel, Pratik	Robert Wood Johnson UH *(138)*
Schaer, David	Robert Wood Johnson UH *(75)*
Singal, Dinesh	Robert Wood Johnson UH *(98)*
Snyder, Craig	Robert Wood Johnson UH, JFK Medical Center *(169)*
Stroh, Jack	Robert Wood Johnson UH *(94)*

Source: Applicant's completeness response and NJDOH Cardiac Registry

c. Additional Demonstration Project Evaluative Criteria (N.J.A.C. 8:33-3.11(e)7i.-iv.):

i. Ability to offer a high quality program.

a. Licensure:

St. Peter's is unconditionally licensed for full service cardiac diagnostic catheterization through March 31, 2009 St. Peter's was licensed for primary PCI December 5, 2006 and will be evaluated during the April 1, 2009 licensure renewal.

b. Outcomes:

St. Peter's Diagnostic Cardiac Catheterization Outcomes

	2005		*2006*	
	# of Cases	*% of Total*	*# of Cases*	*% of Total*
Total Cases	*590*	*n/a*	*988*	*n/a*
Death in Hospital	*0*	*0%*	*0*	*0%*
Death in Lab	*0*	*0*	*0*	*0%*
All In lab Complications	*3*	*.51%*	*3*	*.30%*

Source: NJDHSS Cardiac Data Registry (unaudited data)

While the Department has three complications recorded for both 2005 and 2006, St. Peter's in its application reported four complications in 2005 and six in 2006.

ii. Representation of State's diverse regions and urban/suburban/rural population.

St. Peter's is located in the Middlesex County, in the Central region of the state. The 2000 U.S. Census Bureau table titled "Urban and Rural Population: New Jersey, Counties and Municipalities" reports a small population residing in rural areas in Edison, while the remainder of St. Peter's service area is considered to be urban.

St. Peter's states that it's primary service area is Middlesex and Somerset counties, while it's secondary service area includes portions of Monmouth, Union and Hunterdon counties. St. Peter's further states that its patient base is ethnically and racially diverse, and that its service area includes urban and suburban communities.

iii. Potential to increase access to care for minorities and medically underserved.

As presented below, St. Peter's total service area population is comprised of 32.22% non-white and the 45 and over population is 21.81% non-white based on 2000 Census data. *St. Peter's percentage of diagnostic cardiac catheterization caseload performed on non-whites was 29.5% in 2005 and 40.9% in 2006. St.Peter's minority use rate of diagnostic cardiac catheterization was comparable to the % of non-white residents in the service area population in 2005 and 2006.*

St. Peter's Service Area Population by Race

Age	Total	White	Non-White	% of Non-White to Total Population
<45	503,335	314,768	188,567	37.46%
45-64	164,997	121,699	43,298	26.24%
65-74	46,367	38,682	7,685	16.57%
75-84	32,327	28,889	3,438	10.64%
85+	9,997	9,094	903	9.03%
Total	757,023	513,132	243,891	32.22%

Source: 2000 US Census

St. Peter's Diagnostic Cardiac Catheterization by Race

	White Non-Hispanic	*Black Non-Hispanic*	*Hispanic*	*Asian & Pacific Islander*	*Other*	*% of Non-White Cases*
2005	*70.5%*	*19.0%*	*3.7%*	*1.5%*	*5.1%*	*29.5%*
2006	*59.0%*	*15.8%*	*15.6%*	*2.0%*	*7.6%*	*40.9%*

Source: NJDHSS Cardiac Catheterization Data Registry

iv. Projected demonstration project elective angioplasty case volume

Based on the average 853 cardiac catheterizations performed between 2005 and 2007, a 30% conversion rate would result in 256 patients, of which a maximum of 75%, or 192, would be randomized to be eligible to participate in the research project at St. Peter's, assuming they all met the patient eligibility criteria of the research study and gave informed consent. In addition to the 192 elective angioplasties anticipated, St. Peters performed 27 primary PCIs in 2007. Total annual volume of angioplasties projected based on past performance would be 219. St. Peter's would meet the 200 annual minimum C-PORT-E demonstration project requirement.

In its completeness response, St. Peter's states that the closure of Muhlenberg Regional Medical Center is expected to increase volume in its cardiac cath lab 21% but will have no impact on its ability to provide high quality care

II. FINANCIAL

Department staff reviewed and found that the applicant has documented adequate financial resources to implement and maintain the project.

STATE HEALTH PLANNING BOARD
CERTIFICATE OF NEED PROJECT SUMMARY
ELECTIVE ANGIOPLASTY WITHOUT ON-SITE SURGERY BACK-UP
DEMONSTRATION PROJECT

Applicant:	Somerset Medical Center (Somerset)
CN Number:	FR 071222-18-01
Location:	Somerville, Somerset County
Project Cost:	$0

PROJECT DESCRIPTION:
Applicant is proposing to provide elective PCI without back-up surgery on-site and further proposes to participate in the Atlantic C-PORT, Elective Angioplasty Study (C-PORT-E), a multi-state demonstration trial to assess safety, quality and cost of elective PCI offered at community hospitals that do not offer cardiac surgery services on site. There are no construction or project costs associated with this project. Somerset is a current participant in the Atlantic C-PORT-E trial, having been CN approved in 2005 and licensed by the Department in 2006. The applicant proposes to contract with Robert Wood Johnson University Hospital as the participating cardiac surgery center.

I. SUMMARY OF THE APPLICANT'S REPRESENTATIONS

A. APPLICANT JUSTIFICATION

Somerset states that it demonstrates strong performance and qualifications with respect to the Department's competitive review criteria. The applicant is able to offer a high quality program as predicted from the cardiology services currently provided. There are six interventional cardiologists on staff with a total of 122 angioplasty procedures in 2006, including 45 elective C-PORT-E cases. The applicant states that its technical staff, facilities and equipment are superior. Somerset's service area contains many small cities, towns, suburbs and some semi-rural areas and it is highly representative of New Jersey with an increasingly diverse population. The applicant states that it has worked aggressively to attract residents from areas of low income/minority populations to Somerset's Family Health Center for routine care and early case finding. The applicant states that it has extremely high volumes and will easily meet the 200-procedure C-PORT-E minimum volume requirement.

B. STATUTORY CRITERIA

a. The availability of facilities or services that may serve as alternatives or substitutes.

The applicant states that there is no elective angioplasty program located in Somerset County.

b. The need for special equipment and services in the area.

The applicant indicates that there is no additional equipment or services needed for the project. The applicant states that a third cath room will be added if procedure volume makes it necessary.

c. The adequacy of financial resources and sources of present and future revenues.

The applicant states it has the financial resources to implement this project.

d. The availability of sufficient staff in the several professional disciplines involved.

The applicant states that the additional staff required are already working on the project: one RN Research Coordinator, three RNs, and .5 secretary who are already working on the project. This is in addition to the 11.2 FTE nurses, technicians and clericals already on staff in invasive and interventional cardiology. Six interventionalists already support the program.

e. The project is necessary to provide required health care in the region.

The applicant states that the November 5, 2007 CN call for elective angioplasty without on-site surgery back-up defines the need for the health care service in the state. The applicant is the only cardiac catheterization and primary angioplasty provider in Somerset County, and there are no providers of elective angioplasty in the county.

f. The project will not have an adverse impact on access to health care services in the region or Statewide.

As stated by the applicant in completeness response tables 2 and 3, Robert Wood Johnson University Hospital is Somerset's primary referral center (339, or 83% of Somerset's angioplasty referrals in 2006). *Robert Wood Johnson's angioplasty volume was 3,370 in 2006 and the impact of 75% of Somerset's referrals being lost would account for 7.5% of Robert Wood Johnson's volume.*

Department analysis of 2006 UB discharge data indicates the percentage of each cardiac surgery center's PCI cases which came from each applicant's service area. Service area is defined as those zip codes that comprise 75% of an applicant's discharges, using 2006 UB discharge data, reported by the applicants in completeness responses. The impact is as follows: 5.3% of Robert Wood Johnson University Hospital's and 1.7% of Morristown Memorial Hospital's PCI cases came from Somerset's service area in 2006.

C. DEMONSTRATION PROJECT CRITERIA AT N.J.A.C. 8:33-3.11(e)

The applicant has sufficiently documented the ability to satisfy demonstration project eligibility criteria at N.J.A.C. 8:33-3.11(e)4 and the Atlantic C-PORT-E trial site inclusion criteria, including: (a) how the applicant will satisfy the patient selection criteria specified in the Atlantic C-PORT-E protocol, which is designed to assure informed

consent and appropriate randomization, as provided in the Manual of Operations (N.J.A.C. 8:33-3.11(e)6iii); (b) approval of the study protocol by the applicant's Institutional Review Board, and if approval is pending, the status of that application (N.J.A.C. 8:33-3.11(e)6iv); (c) how the applicant will meet the target volume specified in the Atlantic C-PORT-E protocol of primary and elective angioplasties performed at the applicant's site, after randomization (that is, 100 PCI cases in year one and 200 cases in year two and each year thereafter) (N.J.A.C. 8:33-3.11(e)6v); (d) the applicant's compliance with the criteria for performance of primary PCI at N.J.A.C. 8:33E-2.16, 2.16(b) and N.J.A.C. 8:43G-7 (N.J.A.C. 8:33-3.11(e)6vi); and (e) documentation of the applicant's willingness to report elective PCI data to the Department separate from data collected as part of the study protocol, to support the Department's ongoing monitoring of cardiac services pursuant to N.J.A.C. 8:33E-1.9 and 2.10 (N.J.A.C. 8:33-3.11(e)6vii).

a. C-PORT-E Study Site Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6i):

The applicant has documented how it would satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol, including: (1) capability of performing a minimum volume of diagnostic cardiac catheterizations per year (N.J.A.C. 8:33-3.11(e)6i(1)); (2) agreement to complete an elective PCI development program (N.J.A.C. 8:33-3.11(e)6i(2)); (3) agreement to abide by physician, patient and device selection criteria defined in the study's Manual of Operations (N.J.A.C. 8:33-3.11(e)6i(3)); (4) agreement to collect and transmit study data in a timely fashion (N.J.A.C. 8:33-3.11(e)6i(4)); (5) agreement to perform elective PCI only via the study protocol and only while cases are being enrolled in the study (N.J.A.C. 8:33-3.11(e)6i(5)); and (6) agreement to develop and maintain a quality and error management program, including a weekly interventional conference and monthly quality and error management review (N.J.A.C. 8:33-3.11(e)6i(6)).

b. Participating Interventional Cardiologist Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6ii):

The applicant has documented that its participating interventional cardiologists have agreed to: (1) be in compliance and continue to be in compliance with minimum annual statewide interventional volume standards as set forth at N.J.A.C. 8:33E-2.16(b)6 (N.J.A.C. 8:33-3.11(e)6ii(1)); (2) practice in accordance with Atlantic C-PORT-E trial defined device and patient selection criteria (N.J.A.C. 8:33-3.11(e)6ii(2)); (3) obtain necessary informed consent for patient participation in the demonstration including the identity and location of the participating cardiac surgery center(s) that are to receive randomized study patients (N.J.A.C. 8:33-3.11(e)6ii(3));

Participating Interventional Cardiologist Performance Criteria:

1. The applicant states that all interventionalists will comply with Atlantic C-PORT-E criteria, including its minimum physician volume standard (in accordance with N.J.A.C. 8:33E-2.16(b)6).

2. *Listed below are participating physicians and their respective 2006 angioplasty PCI case volumes. Staff Note: Department staff found that five of six interventional cardiologists met the 75 case annual interventional volume standard. There may be*

mitigating factors regarding physician volume that have not been brought to the Department's attention.

Physician	All cardiac centers where physician performs angioplasties
Hall, Jason	Robert Wood Johnson, Somerset *(72)*
Mahal, Sharan	Robert Wood Johnson, Somerset *(107)*
Patel, Parag	Robert Wood Johnson, Somerset *(98)*
Randazzo, Domenick	Morristown Memorial Hospital , Somerset *(196)*
Sternberg, Kenneth	Robert Wood Johnson, Somerset *(101)*
Taylor, Jeff	Robert Wood Johnson, Somerset *(210)*

Source: Somerset completeness response Table 4 and NJDHSS Cardiac Data Registry

c. Additional Demonstration Project Evaluative Criteria (N.J.A.C. 8:33-3.11(e)7i.-iv.):

i. Ability to offer a high quality program.

a. Licensure:

Somerset's full service diagnostic cardiac catheterization and primary PCI programs are currently licensed unconditionally through December 31, 2008.

b. Outcomes:

Somerset's Diagnostic Cardiac Catheterization Outcomes

	2005		*2006*	
	# of Cases	*% of Total*	*# of Cases*	*% of Total*
Total Cases	*980*	*n/a*	*967*	*n/a*
Death in Hospital	*6*	*.61%*	*6*	*.62%*
Death in Lab	*0*	*0*	*0*	*0%*
All In lab Complications	*4*	*.41%*	*5*	*.53%*

Source: NJDHSS Cardiac Data Registry (unaudited data)

In 2006, the Department reported 967 cases, six deaths in hospital and five complications, while Somerset reported 953 cases, seven deaths in hospital and one complication in its application. In 2005, the Department reported six deaths in hospital and four complications, while Somerset reported eight deaths in hospital and seven complications.

ii. Representation of State's diverse regions and urban/suburban/rural population.

Somerset is located in the Somerset County, in the Central region of the state. The 2000 U.S. Census Bureau table titled "Urban and Rural Population: New Jersey, Counties and Municipalities" reports a small population residing in rural areas in Bridgewater and Hillsborough, while the remainder of Somerset's service area is considered to be urban.

iii. Potential to increase access to care for minorities and medically underserved.

As presented below, Somerset's total service area population is comprised of 32.27% non-white and the over age 45 population is comprised of 23.3% non-white*. As calculated by the Department, Somerset's diagnostic cardiac catheterization patient population percentage of non-white patients was 15.1% in 2005 and 17% in 2006. Somerset's minority use rate of diagnostic cardiac catheterization was below the % of non-white residents in the service area population in 2005 and 2006.*

Somerset's Service Area Population by Race

Age Category	White **	Non-White	% of Non-White to Total Population
Under 45	126,387	73,570	36.79%
45-64	48,640	18,457	27.51%
65-74	14,806	3,209	17.81%
75-84	10,156	1,434	12.37%
85 +	3,694	393	9.62%
Total	203,683	97,063	32.27%

*Source: Somerset Completeness response Q6a-c US 2000 Census ** Includes Hispanic White*
*Plainfield is included in the top 75% of admissions to SMC. The inclusion of Plainfield is a zip code anomaly which may skew the ethnic mix of SMC's service area and suggest a higher minority population than is actually the case. *Note: 08844 data unavailable on zip code level*

Somerset's Diagnostic Cardiac Catheterization by Race

	White Non-Hispanic	*Black Non-Hispanic*	*Hispanic*	*Asian & Pacific Islander*	*Other*	*% of Non-White Cases*
2005	*84.9%*	*5.2%*	*4.6%*	*3.1%*	*2.2%*	*15.1%*
2006	*83.0%*	*5.9%*	*5.5%*	*4.4%*	*.9%*	*17.0%*

Source: NJDHSS Cardiac Catheterization Data Registry

Somerset states that the service area methodology required by the Department creates an anomaly in that the Plainfield zip code is included, which may skew the ethnic mix of Somerset's service area and suggest a higher minority population than is actually the case. Plainfield residents accounted for 2.7% of Somerset's discharges in 2006. *The Department was unable to verify Somerset's statement on the Plainfield zip code anomaly.*

iv. Projected demonstration project elective angioplasty case volume

Based on the average of 925 cardiac catheterizations performed between 2005 and 2007, a 30% conversion rate would result in 278 patients, of which a maximum of 75%, or 208, would be randomized to be eligible to participate in the research project at Somerset, assuming they all met the patient eligibility criteria of the research study and gave informed consent. In addition to the 208 elective angioplasties anticipated, Somerset performed 78 primary angioplasties in 2007.

Total annual volume of angioplasties projected based on past performance would be 286, which is above the annual 200 case minimum volume C-PORT-E demonstration project requirement.

The applicant states that it has a potential pool of over 1,000 PCI patients in its service area. In its completeness question response, Somerset states that the closure of Muhlenberg Regional Medical Center would result in an additional 6 to 8 PCI cases based on 2006 volume.

II. FINANCIAL

Department staff reviewed and found that the applicant has documented adequate financial resources to implement and maintain the project.

STATE HEALTH PLANNING BOARD
CERTIFICATE OF NEED PROJECT SUMMARY
ELECTIVE ANGIOPLASTY WITHOUT ON-SITE SURGERY BACK-UP
DEMONSTRATION PROJECT

Applicant:	University Medical Center at Princeton (Princeton)
CN Number:	FR 071208-11-01
Location:	Princeton, Mercer County
Project Cost:	$0

PROJECT DESCRIPTION:
Applicant is proposing to provide elective PCI without back-up surgery on-site and further proposes to participate in the Atlantic C-PORT, Elective Angioplasty Study, a multi-state demonstration trial to assess safety, quality and cost of elective PCI offered at community hospitals that do not offer cardiac surgery services on site. There are no project costs associated with this project. The applicant proposes to contract with Robert Wood Johnson University Hospital (RWJUH) in New Brunswick as its participating cardiac surgery center. Princeton's new replacement facility is anticipated to open by mid 2011 with a cardiac catheterization laboratory with expansion room to accommodate a second laboratory.

I. SUMMARY OF THE APPLICANT'S REPRESENTATIONS

A. APPLICANT JUSTIFICATION

Princeton states it has a long record of commitment to providing local residents with comprehensive, high quality health care services. Providing elective PCI will enhance Princeton's ability to serve its patients and contribute to the scientific evaluation of this service. Princeton has the proven ability to offer a high quality program as evidenced by excellent outcomes for diagnostic catheterizations and for emergency PCI; the patient population is representative of the diverse regions in the state; Princeton has the potential to increase access to care for minorities and the medically underserved in the region and the projected case volume is sufficient to meet the requirements of the demonstration project.

B. STATUTORY CRITERIA

a. The availability of facilities or services that may serve as alternatives or substitutes.

There are three regional cardiac centers and one approved elective angioplasty facility that draw cardiac patients from Princeton's service area (Robert Wood Johnson University Hospital, RWJ-Hamilton, Deborah Heart and Lung Center, and St. Francis Medical Center.)

b. The need for special equipment and services in the area.

The applicant indicates that there is no additional equipment or services needed for the project.

c. The adequacy of financial resources and sources of present and future revenues.

The applicant states it has the financial resources to implement this project.

d. The availability of sufficient staff in the several professional disciplines involved.

The applicant states that the specific staff to be recruited to support the project includes: one data analyst. Four interventionalists, who already practice at Princeton, would support the program.

e. The project is necessary to provide required health care in the region.

The applicant states that the November 5, 2007 CN call for elective angioplasty without on-site surgery back-up defines the need for the health care service in the state.
The applicant states that approval of Princeton would help reverse the out-migration of patients from the area to out of state hospitals.

f. The project will not have an adverse impact on access to health care services in the region or Statewide.

As stated by the applicant, it made 156 cardiac surgery and PCI referrals in 2006 with the following impact: 32 or 20.9% were referred to Columbia Presbyterian in New York, 25 or 16.3% to Graduate Hospital in Philadelphia, 32 or 20.9% to Temple Hospital in Philadelphia, and 34 or 22.2% to RWJUH in New Brunswick. *RWJUH's angioplasty volume was 3,370 in 2006 and the impact of 75% of Princeton's referrals being lost would account for only 0.8% of RWJUH's PCI volume assuming all referrals were for PCI. Graduate Hospital in Philadelphia recently closed; therefore, the noted referral relationship is no longer relevant.*

Department analysis of 2006 UB discharge data indicates the percentage of each cardiac surgery center's PCI cases which came from each applicant's service area. Service area is defined as those zip codes that comprise 75% of an applicant's discharges, using 2006 UB discharge data, reported by the applicants in completeness responses. The impact is as follows: 0.1% of Deborah Heart and Lung Center's, 2.5% of Robert Wood Johnson University Hospital's, and 5.5% of St. Francis Medical Center's PCI cases came from Princeton's service area in 2006.

The applicant states that expanding its services to include elective PCI would have minimal impact upon other New Jersey providers and is likely to retain some patients who seek care at hospitals in Pennsylvania and New York.

C. DEMONSTRATION PROJECT CRITERIA AT N.J.A.C. 8:33-3.11(e)

For the most part, the applicant has sufficiently documented the ability to satisfy demonstration project eligibility criteria at N.J.A.C. 8:33-3.11(e)4 and the Atlantic C-PORT-E trial site inclusion criteria, including: (a) how the applicant will satisfy the patient selection criteria specified in the Atlantic C-PORT-E protocol, which is designed to assure informed consent and appropriate randomization, as provided in the Manual of Operations (N.J.A.C. 8:33-3.11(e)6iii); (b) approval of the study protocol by the applicant's Institutional Review Board, and if approval is pending, the status of that application (N.J.A.C. 8:33-3.11(e)6iv); (c) how the applicant will meet the target volume specified in the Atlantic C-PORT-E protocol of primary and elective angioplasties performed at the applicant's site, after randomization (that is, 100 PCI cases in year one and 200 cases in year two and each year thereafter) (N.J.A.C. 8:33-3.11(e)6v); (d) the applicant's compliance with the criteria for performance of primary PCI at N.J.A.C. 8:33E-2.16, 2.16(b) and N.J.A.C. 8:43G-7 (N.J.A.C. 8:33-3.11(e)6vi); and (e) documentation of the applicant's willingness to report elective PCI data to the Department separate from data collected as part of the study protocol, to support the Department's ongoing monitoring of cardiac services pursuant to N.J.A.C. 8:33E-1.9 and 2.10 (N.J.A.C. 8:33-3.11(e)6vii).

Staff Note: As noted below, the applicant has <u>not</u> sufficiently documented the ability to satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol of performing at least 200 angioplasties per year (N.J.A.C. 8:33-3.11(e)6v).

a. C-PORT-E Study Site Inclusion Criteria

The applicant has documented how it would satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol, including: (1) capability of performing a minimum volume of diagnostic cardiac catheterizations per year (N.J.A.C. 8:33-3.11(e)6i(1)); (2) agreement to complete an elective PCI development program (N.J.A.C. 8:33-3.11(e)6i(2)); (3) agreement to abide by physician, patient and device selection criteria defined in the study's Manual of Operations (N.J.A.C. 8:33-3.11(e)6i(3)); (4) agreement to collect and transmit study data in a timely fashion (N.J.A.C. 8:33-3.11(e)6i(4)); (5) agreement to perform elective PCI only via the study protocol and only while cases are being enrolled in the study (N.J.A.C. 8:33-3.11(e)6i(5)); and (6) agreement to develop and maintain a quality and error management program, including a weekly interventional conference and monthly quality and error management review (N.J.A.C. 8:33-3.11(e)6i(6)).

b. Participating Interventional Cardiologist Inclusion Criteria:

The applicant has documented that its participating interventional cardiologists have agreed to: (1) be in compliance and continue to be in compliance with minimum annual statewide interventional volume standards as set forth at N.J.A.C. 8:33E-2.16(b)6 (N.J.A.C. 8:33-3.11(e)6ii(1)); (2) practice in accordance with Atlantic C-PORT-E trial defined device and patient selection criteria (N.J.A.C. 8:33-3.11(e)6ii(2)); (3) obtain necessary informed consent for patient participation in the demonstration including the

identity and location of the participating cardiac surgery center(s) that are to receive randomized study patients (N.J.A.C. 8:33-3.11(e)6ii(3));

1. The applicant states that all interventionalists have met the annual statewide interventional volume standard of 75 cases in 2006 and that its participating physicians will continue to meet this standard in accordance with N.J.A.C. 8:33E-2.16(b)6.

2. *Listed below are participating physicians and their respective 2006 angioplasty case volumes. Staff Note: Department staff found that three of four interventionalists met the 75 case minimum. Case volume from Graduate Hospital, which has since closed, was unavailable for 2006 for the one physician that did not meet the 75 case volume.*

Physician Name	All facilities where physician performs Angioplasties
Mercuro, John T.	UMCP, Temple *(8 NJ, 18 Temple)*
Shanahan Andrew	UMCP, RWJ *(89 NJ)*
Vagaonescu, Tudor	UMCP, RWJ *(197 NJ)*
Agarwala, Ajay	UMCP, RWJ *(189 NJ)*

Source: Princeton's completeness response Table 4 and NJDOH Cardiac Registry

c. Additional demonstration project evaluative criteria (N.J.A.C. 8:33-3.11(e)7i.-iv.):

i. Ability to offer a high quality program.

a. Licensure: Princeton was conditionally licensed on August 31, 2007 for failure to achieve compliance with the annual adult diagnostic cardiac catheterization facility volume requirement, the primary PCI facility volume requirement and the primary PCI physician volume requirement for one physician. Princeton has satisfied all conditional licensure requirements and maintains a target date of compliance of September 1, 2008.

b. Outcomes:

Princeton's Diagnostic Cardiac Catheterization Outcomes

Year	*2005*		*2006*	
	# of Cases	*% of Total*	*# of Cases*	*% of Total*
Total Cases	*440*	*n/a*	*394*	*n/a*
Death in Hospital	*0*	*0%*	*4*	*1.02%*
Death in Lab	*0*	*0%*	*1*	*0.25%*
All in Lab Complications	*0*	*0%*	*13*	*3.30%*

Source: NJDHSS Cardiac Data Registry (unaudited data)

In 2005, the Department reported 440 cases while Princeton reported 446 cases. In 2006, the Department reported 1 death in lab and thirteen complications, while Princeton reported 0 deaths in lab and 3 complications.

ii. Representation of State's diverse regions and urban/suburban/rural population.

Princeton is located in Princeton, in Mercer County, in the Central region of the state. The 2000 U.S. Census Bureau table titled "Urban and Rural Population: New Jersey, Counties and Municipalities" reports that 95% of Princeton's service area is considered to be urban, 5% is considered rural.

iii. Potential to increase access to care for minorities and medically underserved.

As presented below, Princeton's total service area population is comprised of 27% non-white and the 45 and over population is comprised of 18.5% non-white based on 2000 Census data. Princeton*'s percentage of diagnostic cardiac catheterization caseload performed on non-white patients was 12.7% in 2005; and 18.3% in 2006. Princeton's minority use rate of diagnostic cardiac catheterization is below the % of non-white residents in the service area population in 2005 and 2006.*

Princeton's Service Area Population by Race and Age Distribution

Age	Total	White	Non-white	% of Non-White to Total Population
< 45	732,283	497,774	234,509	32%
45 - 64	247,810	194,622	53,188	21%
65 - 74	68,306	57,778	10,528	15%
75 - 84	47,523	42,579	4,944	10%
85+	15,245	13,874	1,371	9%
Total	1,111,167	806,627	304,540	27%

Source: 2000 U.S. Census data from Claritas Inc.

Princeton's Diagnostic Cardiac Catheterization by Race

	White Non-Hispanic	*Black Non-Hispanic*	*Hispanic*	*Asian & Pacific Islander*	*Other*	*% of Non-White Cases*
2005	*87.3%*	*4.3%*	*2.7%*	*2.1%*	*3.6%*	*12.7%*
2006	*81.7%*	*7.6%*	*4.1%*	*3.3%*	*3.3%*	*18.3%*

Source: NJDHSS Cardiac Catheterization Data Registry

iv. Projected demonstration project elective angioplasty case volume

Based on the average 410 cardiac catheterizations performed between 2005 and 2007, a 30% conversion rate would result in a maximum of 123 patients, of which 75%, or 92, would be randomized to be eligible to participate in the research project at Princeton, assuming they all met the patient eligibility criteria of the research study and gave informed consent. Princeton primary PCI program was licensed on 9/26/04, but did not report any cases in 2005. Princeton performed 28 primary PCIs in 2007. Total annual volume of PCI projected would be 120, which is below the annual 200 cases minimum C-PORT-E demonstration project requirement.
The applicant does not anticipate any impact resulting from the closure of Muhlenberg Regional Medical Center.

II. FINANCIAL

Department staff reviewed and found that the applicant has documented adequate financial resources to implement and maintain the project.

Toms River Hospital Market Area

1. Community Medical Center
2. Monmouth Medical Center
3. Ocean Medical Center
4. Riverview Medical Center

STATE HEALTH PLANNING BOARD
CERTIFICATE OF NEED PROJECT SUMMARY
ELECTIVE ANGIOPLASTY WITHOUT ON-SITE SURGERY BACK-UP
DEMONSTRATION PROJECT

Applicant:	Community Medical Center (Community)
CN Number:	FR 071220-15-01
Location:	Toms River, Ocean County
Project Cost:	$ 0

PROJECT DESCRIPTION
Applicant is proposing to provide elective PCI without back-up surgery on-site and further proposes to participate in the Atlantic C-PORT, Elective Angioplasty Study, a multi-state demonstration trial to assess safety, quality and cost of elective PCI offered at community hospitals that do not offer cardiac surgery services on site. There are no construction or project costs associated with this project. The applicant proposes to contract with Jersey Shore University Medical Center (Jersey Shore) as the participating cardiac surgery center.

I. SUMMARY OF THE APPLICANT'S REPRESENTATIONS

A. APPLICANT JUSTIFICATION

The applicant states that: (1) it has the ability to offer a high quality program, (2) its patient population is representative of the diverse regions in the State, (3) it has potential to increase access to care for minorities and medically underserved in the region, and (4) its projected case volume is sufficient to meet the requirements of the proposed trial. Community states that its cardiac catheterization laboratory has the highest volume among New Jersey's full service cardiac catheterization providers without cardiac surgery, 1,096 cases or 7% of 15,136 cases statewide. Primary PCI cases are 62% higher then the primary PCI provider with the next highest volume. Further, approval of Community's application would enhance access for the more than 2,200 Ocean County residents who require this intervention each year.

B. STATUTORY CRITERIA

a. The availability of facilities or services that may serve as alternatives or substitutes.

The applicant states that there is no elective angioplasty program located in Ocean County. The applicant states that Jersey Shore is the only cardiac surgery center in the area.

b. The need for special equipment and services in the area.

The applicant indicates that there is no additional equipment needed for the project including the software for participation in C-PORT-E.

c. The adequacy of financial resources and sources of present and future revenues.

The applicant states it has the financial resources to implement this project.

d. The availability of sufficient staff in the several professional disciplines involved.

The applicant states that the specific staff to be recruited includes: 1.36 FTE RN and 1.36 FTE RN-Research Data Collection and .68 FTE Cardiovascular Tech. Seven interventionalists on the staff of Community would support the program.

e. The project is necessary to provide required health care in the region.

The applicant states that there are no current providers of elective angioplasty in Ocean County.

f. The project will not have an adverse impact on access to health care services in the region or Statewide.

As stated by the applicant, Deborah Heart and Lung Center and Jersey Shore are Community's primary referral centers (135, or 33.8% and 105, or 26.3% respectively of Community's cardiac surgery and PCI referrals in 2006). *Deborah's angioplasty volume was 1,799 in 2006 and Jersey Shore's was 2,596. The impact of 75% of Community's referrals being lost would account for 101 cases or 5.6% of Deborah's volume and 79 cases or 3% of Jersey Shore's volume, assuming all the referrals were for PCI.*

Department analysis of 2006 UB discharge data indicates the percentage of each cardiac surgery center's PCI cases which came from each applicant's service area. Service area is defined as those zip codes that comprise 75% of an applicant's discharges using 2006 UB discharge data, which is reported by the applicants in completeness responses. The impact is as follows: 10.6% of Deborah Heart and Lung Center's, 1.4% of Hackensack University Medical Center's, 9.7% of Jersey Shore Medical Center's,.4% of Robert Wood Johnson University Hospital's, and 6.1% of St. Barnabas Medical Center's, PCI cases came from Community's service area in 2006.

Community states that since Atlantic C-PORT-E is a controlled clinical research study, it will have minimal impact on other New Jersey facilities that provide elective PCI. The applicant also states that interventional procedures will continue to increase in Ocean County because the growing population is aging, technological advances continue and high risk behaviors continue to exist.

C. DEMONSTRATION PROJECT CRITERIA AT N.J.A.C. 8:33-3.11(e)

The applicant has sufficiently documented the ability to satisfy demonstration project eligibility criteria at N.J.A.C. 8:33-3.11(e)4 and the Atlantic C-PORT-E trial site inclusion criteria, including: (a) how the applicant will satisfy the patient selection criteria specified in the Atlantic C-PORT-E protocol, which is designed to assure informed consent and appropriate randomization, as provided in the Manual of Operations (N.J.A.C. 8:33-3.11(e)6iii); (b) approval of the study protocol by the applicant's Institutional Review Board, and if approval is pending, the status of that application (N.J.A.C. 8:33-3.11(e)6iv); (c) how the applicant will meet the target volume specified in the Atlantic C-PORT-E protocol of primary and elective angioplasties performed at the applicant's site, after randomization (that is, 100 PCI cases in year one and 200 cases in year two and each year thereafter) (N.J.A.C. 8:33-3.11(e)6v); (d) the applicant's compliance with the criteria for performance of primary PCI at N.J.A.C. 8:33E-2.16, 2.16(b) and N.J.A.C. 8:43G-7 (N.J.A.C. 8:33-3.11(e)6vi); and (e) documentation of the applicant's willingness to report elective PCI data to the Department separate from data collected as part of the study protocol, to support the Department's ongoing monitoring of cardiac services pursuant to N.J.A.C. 8:33E-1.9 and 2.10 (N.J.A.C. 8:33-3.11(e)6vii).

a. C-PORT-E Study Site Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6i):

The applicant has documented how it would satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol, including: (1) capability of performing a minimum volume of diagnostic cardiac catheterizations per year (N.J.A.C. 8:33-3.11(e)6i(1)); (2) agreement to complete an elective PCI development program (N.J.A.C. 8:33-3.11(e)6i(2)); (3) agreement to abide by physician, patient and device selection criteria defined in the study's Manual of Operations (N.J.A.C. 8:33-3.11(e)6i(3)); (4) agreement to collect and transmit study data in a timely fashion (N.J.A.C. 8:33-3.11(e)6i(4)); (5) agreement to perform elective PCI only via the study protocol and only while cases are being enrolled in the study (N.J.A.C. 8:33-3.11(e)6i(5)); and (6) agreement to develop and maintain a quality and error management program, including a weekly interventional conference and monthly quality and error management review (N.J.A.C. 8:33-3.11(e)6i(6)).

b. Participating Interventional Cardiologist Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6ii):

The applicant has documented that its participating interventional cardiologists have agreed to: (1) be in compliance and continue to be in compliance with minimum annual statewide interventional volume standards as set forth at N.J.A.C. 8:33E-2.16(b)6 (N.J.A.C. 8:33-3.11(e)6ii(1)); (2) practice in accordance with Atlantic C-PORT-E trial defined device and patient selection criteria (N.J.A.C. 8:33-3.11(e)6ii(2)); (3) obtain necessary informed consent for patient participation in the demonstration including the identity and location of the participating cardiac surgery center(s) that are to receive randomized study patients (N.J.A.C. 8:33-3.11(e)6ii(3));

Participating Interventional Cardiologist Performance Criteria:

1. The applicant states that all interventionalists have met the annual statewide interventional volume standard of 75 cases in 2006 and that its participating physicians will continue to meet this standard in accordance with N.J.A.C. 8:33E-2.16(b)6.

2. Listed below are participating physicians and their respective 2006 angioplasty case volumes. *The Department finds that all physicians met the 75 case volume requirement in 2006*.

Physician Name	All cardiac centers where physician performs angioplasties
Tony Chu	Jersey Shore MC, Community MC *(131)*
Scott Eisenberg	Jersey Shore MC, Community MC *(110)*
Stephen Fedec	Deborah, Community MC *(120)*
James Orlando	Jersey Shore MC, Community MC *(171)*
Pareg Patel	Jersey Shore MC, Community MC *(83)*
Sanjiv Sobti	Deborah, Community MC *(82)*
Jay Stone	Jersey Shore MC, Community MC *(75)*

Source: Community completeness response Table 2.2 and NJDOH Cardiac Registry

c. Additional Demonstration Project Evaluative Criteria (N.J.A.C. 8:33-3.11(e)7i.-iv.):

i. Ability to offer a high quality program.

a. Licensure:
Community's primary PCI program is conditionally licensed effective April 1, 2008 for failure to achieve compliance with physician volume standards.

b. Outcomes:

Community's Diagnostic Cardiac Catheterization Outcomes

	2005		*2006*	
	# of Cases	*% of Total*	*# of Cases*	*% of Total*
Total Cases	1,275	n/a	1,096	n/a
Death in Hospital	7	.55%	4	.36%
Death in Lab	1	.08%	0	0
All In lab Complications	3	.24%	2	.18%

Source: NJDHSS Cardiac Data Registry (unaudited data)

In 2005, the Department reported 1,275 cases, seven deaths in hospital and one death in lab, while Community reported 1,277 cases and one death in hospital in 2005 in its application. In 2006, the Department reported four deaths in hospital and two complications in 2006 while Community reported two deaths in hospital and three complications.

ii. Representation of State's diverse regions and urban/suburban/rural population.

Community is located in Ocean County, in the Southern region of the state. The 2000 U.S. Census Bureau table titled "Urban and Rural Population: New Jersey, Counties and Municipalities reports their service area is primarily urban.

The applicant states that Ocean County is the 6th most populated county and one of the fastest growing counties. The applicant further states that the county has the highest proportion of seniors statewide and more seniors live in Ocean County than 19 other counties.

iii. Potential to increase access to care for minorities and medically underserved.

As presented in the tables below, Community's total service area population is comprised of 5.5% non-white and the over 45 population is comprised of 2.8% non-white. *Community's diagnostic cardiac catheterization patient population was 2.9% minority patients in 2005 and 4.5% in 2006. Community's minority use rate of diagnostic cardiac catheterization was comparable to the % of non-white residents in the service area population in 2005 and 2006.*

Community's Service Area Population by Race and Age

Age	Total	White	Non-white	% of Non-White to Total Population
< 45	86,447	78,928	7519	8.7%
45 - 64	40,998	39,069	1929	4.7%
65-74	26,945	26,391	554	2.1%
75-84	24,981	24,750	231	0.9%
85+	7,954	7853	101	1.3%
Total	187,325	176,991	10334	5.5%

Source: 2000 US Census

Community's Diagnostic Cardiac Catheterization by Race

	White Non-Hispanic	*Black Non-Hispanic*	*Hispanic*	*Asian & Pacific Islander*	*Other*	*% of Non-White Cases*
2005	*97.1%*	*1.2%*	*.9%*	*0%*	*.8%*	*2.9%*
2006	*95.5%*	*1.2%*	*1.8%*	*.2%*	*1.3%*	*4.5%*

Source: NJDHSS Cardiac Catheterization Data Registry

The applicant further states that 17% of its primary PCI patients were uninsured, charity care, indigent and self-pay patients. The applicant further states that Ocean Health Initiatives, an FQHC located in Lakewood and Toms River would refer cardiac cases to Community if its application is approved.

iv. Projected demonstration project elective angioplasty case volume.

Based on the average1,141 cardiac catheterizations performed between 2005 and 2007, a 30% conversion rate would result in 342 patients, of which a maximum of 75%, or 257, would be randomized and eligible to participate in the research project at Community, assuming that they all meet the patient eligibility criteria of the research study and give informed consent. Community performed 122 primary PCIs in 2007. Total annual volume of PCIs projected based on past performance would be 379, which is above the 200 minimum C-PORT-E demonstration project requirement.

Community also predicts further increases in volume based on population growth and changes. The applicant does not anticipate any impact resulting from the closure of Muhlenberg Regional Medical Center.

II. FINANCIAL

Department staff reviewed and found that the applicant has documented adequate financial resources to implement and maintain the project.

STATE HEALTH PLANNING BOARD
CERTIFICATE OF NEED PROJECT SUMMARY
ELECTIVE ANGIOPLASTY WITHOUT ON-SITE SURGERY BACK-UP
DEMONSTRATION PROJECT

Applicant:	Monmouth Medical Center (Monmouth)
CN Number:	FR 071216-13-01
Location:	Long Branch, Monmouth County
Project Cost:	$ 0

PROJECT DESCRIPTION
Applicant is proposing to provide elective PCI without back-up surgery on-site and further proposes to participate in the Atlantic C-PORT, Elective Angioplasty Study, a multi-state demonstration trial to assess safety, quality and cost of elective PCI offered at community hospitals that do not offer cardiac surgery services on site. Monmouth is a current participant in the Atlantic C-PORT-E trial, having been CN approved in 2005 and licensed by the Department in 2006. There are no construction or project costs associated with this project. The applicant proposes to continue to contract with Jersey Shore University Medical Center (Jersey Shore) as the participating cardiac surgery center site.

I. SUMMARY OF THE APPLICANT'S REPRESENTATIONS

A. APPLICANT JUSTIFICATION

Monmouth states that it is highly qualified to continue enrolling patients in the Atlantic C-PORT-E clinical trial since it is currently an authorized trial site which meets the study's guidelines; is a major academic teaching hospital committed to research; provides access to minority patients; and has the clinical expertise and quality measures to continue participating to participate in the trial. Monmouth's already trained and experienced professional team can ensure that the trial and the elective PCI service will not be interrupted after the CN process is complete. Monmouth states it has enrolled nearly 625 people into the trial.

B. STATUTORY CRITERIA

a. The availability of facilities or services that may serve as alternatives or substitutes.

The applicant states that Jersey Shore is the only other elective PCI provider located in Monmouth County, which also serves as Monmouth's cardiac surgery partner in the C-PORT-E trial. Monmouth's continued participation in the trail would have minimal impact on Jersey Shore and would enhance access to this service for residents of northern and central Monmouth County, since those patients would not be required to be transferred to facilities outside of the area.

b. The need for special equipment and services in the area.

The applicant indicates that there is no additional equipment needed for the project.

c. The adequacy of financial resources and sources of present and future revenues.

The applicant states it has the financial resources to implement this project.

d. The availability of sufficient staff in the several professional disciplines involved.

As a current participant in the C-PORT-E study, all necessary staff are already in place. Five interventional cardiologists on the staff of Monmouth and Jersey Shore support the program.

e. The project is necessary to provide required health care in the region.

The applicant states that the November 7, 2007 CN call for elective angioplasty without on-site surgery back-up defines the need for the health care service in the state. The applicant further establishes its eligibility to participate in the project in its service area.

f. The project will not have an adverse impact on access to health care services in the region or Statewide.

Jersey Shore Medical Center is Monmouth's primary referral center (135 or 84% of Monmouth's angioplasty and cardiac surgery referrals in 2006; and 176 or 84% referrals in 2005). *Jersey Shore's angioplasty volume was 2,596 in 2006 and the impact of 75% of Monmouth's referrals being lost would amount to 101 cases or 3.9% of Jersey Shore's volume, assuming all referrals were for angioplasty.* Jersey Shore is Monmouth's cardiac surgery partner for C-PORT-E trial.

Department analysis of 2006 UB discharge data indicates the percentage of cardiac surgery center's PCI cases which came from each applicant's service area. Service area is defined as those zip codes that comprise 75% of an applicant's discharges using 2006 UB discharge data, reported by the applicants in completeness responses. The impact is as follows: 1.3% of Deborah Heart and Lung Center's, 16.6% of Jersey Shore Medical Center's, 1.6% of Newark Beth Israel Medical Center's, and 3.1% of Robert Wood Johnson University Hospital's PCI cases came from Monmouth's service area in 2006.

C. DEMONSTRATION PROJECT CRITERIA AT N.J.A.C. 8:33-3.11(e)

For the most part, the applicant has sufficiently documented the ability to satisfy demonstration project eligibility criteria at N.J.A.C. 8:33-3.11(e)4 and the Atlantic C-PORT-E trial site inclusion criteria, including: (a) how the applicant will satisfy the patient selection criteria specified in the Atlantic C-PORT-E protocol, which is designed to assure informed consent and appropriate randomization, as provided in the Manual

of Operations (N.J.A.C. 8:33-3.11(e)6iii); (b) approval of the study protocol by the applicant's Institutional Review Board, and if approval is pending, the status of that application (N.J.A.C. 8:33-3.11(e)6iv); (c) how the applicant will meet the target volume specified in the Atlantic C-PORT-E protocol of primary and elective angioplasties performed at the applicant's site, after randomization (that is, 100 PCI cases in year one and 200 cases in year two and each year thereafter) (N.J.A.C. 8:33-3.11(e)6v); (d) the applicant's compliance with the criteria for performance of primary PCI at N.J.A.C. 8:33E-2.16, 2.16(b) and N.J.A.C. 8:43G-7 (N.J.A.C. 8:33-3.11(e)6vi); and (e) documentation of the applicant's willingness to report elective PCI data to the Department separate from data collected as part of the study protocol, to support the Department's ongoing monitoring of cardiac services pursuant to N.J.A.C. 8:33E-1.9 and 2.10 (N.J.A.C. 8:33-3.11(e)6vii).

Staff Note: As noted below, the applicant has <u>not</u> sufficiently documented the ability to satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol of performing at least 200 angioplasties per year (N.J.A.C. 8:33-3.11(e)6v).

a. C-PORT-E Study Site Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6i):

The applicant has documented how it would satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol, including: (1) capability of performing a minimum volume of diagnostic cardiac catheterizations per year (N.J.A.C. 8:33-3.11(e)6i(1)); (2) agreement to complete an elective PCI development program (N.J.A.C. 8:33-3.11(e)6i(2)); (3) agreement to abide by physician, patient and device selection criteria defined in the study's Manual of Operations (N.J.A.C. 8:33-3.11(e)6i(3)); (4) agreement to collect and transmit study data in a timely fashion (N.J.A.C. 8:33-3.11(e)6i(4)); (5) agreement to perform elective PCI only via the study protocol and only while cases are being enrolled in the study (N.J.A.C. 8:33-3.11(e)6i(5)); and (6) agreement to develop and maintain a quality and error management program, including a weekly interventional conference and monthly quality and error management review (N.J.A.C. 8:33-3.11(e)6i(6)).

b. Participating Interventional Cardiologist Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6ii):

The applicant has documented that its participating interventional cardiologists have agreed to: (1) be in compliance and continue to be in compliance with minimum annual statewide interventional volume standards as set forth at N.J.A.C. 8:33E-2.16(b)6 (N.J.A.C. 8:33-3.11(e)6ii(1)); (2) practice in accordance with Atlantic C-PORT-E trial defined device and patient selection criteria (N.J.A.C. 8:33-3.11(e)6ii(2)); (3) obtain necessary informed consent for patient participation in the demonstration including the identity and location of the participating cardiac surgery center(s) that are to receive randomized study patients (N.J.A.C. 8:33-3.11(e)6ii(3));

Participating Interventional Cardiologist Performance Criteria:

1. The applicant states that all interventionalists have met the annual statewide interventional volume standard of 75 cases in 2006 and that its participating physicians will continue to meet this standard in accordance with N.J.A.C. 8:33E-2.16(b)6.

2. *Listed below are participating physicians and their respective 2006 angioplasty case volumes*. *Staff Note: Department staff found four interventional cardiologists met the 75 case annual interventional volume standard and one completed his fellowship in 2006 and is on target to perform 75 cases in 2007.*

Physician Name	All facilities where physician performs angioplasties
Mathew Bach	Monmouth, Jersey Shore MC *(199)*
Edward Choi (1)	Monmouth, Jersey Shore MC *(28)*
Nelson LaMarche	Monmouth, Jersey Shore MC *(210)*
Michael Wappel	Monmouth, Jersey Shore MC *(178)*
R.M. Watson	Monmouth, Jersey Shore MC *(174)*

Source: Monmouth completeness response Table 2.2 and NJDOH Cardiac Registry
(1) Completed Fellowship in June 2006.

c. Additional Demonstration Project Evaluative Criteria (N.J.A.C. 8:33-3.11(e)7i.-iv.):

i. Ability to offer a high quality program.

a. Licensure: *Monmouth's cardiac services program was conditionally licensed June 1, 2007 for failure to achieve compliance with N.J.A.C. 8:33E-2.16(b)4, whereby facilities performing primary PCI must perform at least 36 primary PCI cases each year and N.J.A.C. 8:33E-1.4(b)2 whereby the director of the laboratory must perform 150 procedures a year, with 100 of those performed at the laboratory where the physician is director. Monmouth has satisfied all conditional licensure requirements and maintains a target date of compliance of July 31, 2008.*

b. Outcomes:

Monmouth's Diagnostic Cardiac Catheterization Outcomes

	2005		*2006*	
	# of Cases	*% of Total*	*# of Cases*	*% of Total*
Total Cases	*541*	*n/a*	*512*	*n/a*
Death in Hospital	*3*	*.55%*	*1*	*.20%*
Death in Lab	*0*	*0*	*0*	*0*
All In lab Complications	*4*	*.74%*	*2*	*.39%*

Source: NJDHSS Cardiac Data Registry (unaudited data)

In 2005, the Department recorded three deaths in hospital and four complications while Monmouth recorded two deaths in hospital and six complications in its application. In 2006, the Department recorded two complications in 2006, while Monmouth recorded three complications in 2006.

ii. Representation of State's diverse regions and urban/suburban/rural population.

Monmouth is located in Monmouth County, in the Central region of the state. The 2000 U.S. Census Bureau table titled "Urban and Rural Population: New Jersey, Counties and Municipalities" reports rural areas as follows, Howell-11.2%, Jackson-9.8%, Freehold-6.1%, Wall-5.2% and a very small level in Lakewood, while the remainder of Monmouth's service area is considered to be urban.

The applicant states that its service area consists of both urban and suburban municipalities in Monmouth County with most being in suburban areas. However, Long Branch City, where the applicant is located, is an ethnically diverse community which is a Health Professional Shortage Area (HPSA); is designated as a "Medically Underserved Population"; and is a state-designated economic development zone.

iii. Potential to increase access to care for minorities and medically underserved.

As presented in the tables below, Monmouth's total service area population is comprised of 16% non-white and the 45 and over population is comprised of 11% non-white. *Monmouth's diagnostic cardiac catheterization patient population of non-white patients was 14.23% in 2005 and 16.6% in 2006. Monmouth's minority use rate of diagnostic cardiac catheterization was comparable to the % of non-white residents in the service area population in 2005 and 2006.*

Monmouth's Service Area Population by Race and Age Distribution

Age	Total	White	Non-white	% of Non-White to Total Population
< 45	403,989	329,168	74,821	19%
45 - 64	141,597	123,264	18,333	13%
65-74	42,183	37,789	4,394	10%
75-84	29,532	27,289	2,243	8%
85+	11,437	10,766	671	6%
Total	628,738	528,276	100,462	16**%**

Source: Applicant's completeness response, 2000 US Census

Monmouth's Diagnostic Cardiac Catheterization by Race

	White Non-Hispanic	*Black Non-Hispanic*	*Hispanic*	*Asian & Pacific Islander*	*Other*	*% of Non-White Cases*
2005	*85.8%*	*8.7%*	*4.4%*	*.6%*	*.6%*	*14.2%*
2006	*83.4%*	*10.2%*	*4.7%*	*1.0%*	*.7%*	*16.6%*

Source: NJDHSS Cardiac Catheterization Data Registry

The applicant states that nearly 20% of the county's African-American population resides in its service area, including Long Branch City (12%). Long Branch City has the highest number of Hispanic/Latino residents in all of Monmouth County,

accounting for 17% of the county's total Hispanic/Latino population. The applicant presents that to better serve its community, it transitioned its clinics into a certified Federally Qualified Health Center Look Alike (FQHCLA), in Long Branch where 15% of households live below the poverty level compared to 5% statewide.

iv. Projected demonstration project elective angioplasty case volume

Based on the average 509 cardiac catheterizations performed between 2005 and 2007, a 30% conversion rate would result in 153 patients, of which a maximum of 75%, or 115, would be randomized and eligible to participate in the research project at Monmouth, assuming that they all meet the patient eligibility criteria of the research study and give informed consent. Monmouth performed 26 primary PCIs in 2007. Total annual volume of PCIs projected based on past performance would be 141, which is below the 200 minimum C-PORT-E demonstration project requirement. As a current C-PORT-E participant, Monmouth has performed 71 total PCIs in 2006 (40 elective, 31 primary) and 86 total PCIs in 2007 (60 elective, 26 primary).

Staff Note: The applicant has <u>not</u> sufficiently documented the ability to satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol of performing at least 200 angioplasties per year (N.J.A.C. 8:33-3.11(e)6v). The applicant was able to document its ability to timely implement the original CN approval of an elective PCI demonstration program in 2006. The applicant has performed 100 elective PCI cases from its initial Atlantic C-PORT-E patient enrollment through December 31, 2007.

The applicant states that it will meet the target volume in the C-PORT-E protocol and that the recruitment of an additional interventional cardiologist will increase volume at the facility. Monmouth also predicts further increases in volume based on population growth and anticipated referral changes. The applicant does not anticipate any impact resulting from the closure of Muhlenberg Regional Medical Center.

II. FINANCIAL

Department staff reviewed and found that the applicant has documented adequate financial resources to implement and maintain the project.

STATE HEALTH PLANNING BOARD
CERTIFICATE OF NEED PROJECT SUMMARY
ELECTIVE ANGIOPLASTY WITHOUT ON-SITE SURGERY BACK-UP
DEMONSTRATION PROJECT

Applicant:	Ocean Medical Center (Ocean)
CN Number:	FR 071231-15-01
Location:	Brick, Ocean County
Project Cost:	$ 0

PROJECT DESCRIPTION
Applicant is proposing to provide elective PCI without back-up surgery on-site and further proposes to participate in the Atlantic C-PORT, Elective Angioplasty Study, a multi-state demonstration trial to assess safety, quality and cost of elective PCI offered at community hospitals that do not offer cardiac surgery services on site. There are no construction or project costs associated with this project. The applicant proposes to contract with Jersey Shore Medical Center (Jersey Shore) as the participating cardiac surgery center.

I. SUMMARY OF THE APPLICANT'S REPRESENTATIONS

A. APPLICANT JUSTIFICATION

The applicant states that it is a current provider of primary angioplasty. Ocean currently has nursing and technical staff who are already trained in interventional procedures who routinely return to Jersey Shore for retraining and to maintain skills. The catheterization laboratory is staffed with interventional cardiologists who also practice at Jersey Shore, which would serve as the control site for the study. The applicant further states that the integrity of the trial will be maintained since control group patients will be treated by the same physicians as the study group patients. Ocean currently has all the major capital equipment needed to initiate an elective angioplasty program; only a small amount of minor moveable equipment will be needed.

B. STATUTORY CRITERIA

a. The availability of facilities or services that may serve as alternatives or substitutes.

Jersey Shore and Monmouth Medical Center are the only hospitals in the Monmouth-Ocean county area that are existing providers of elective PCI, with Monmouth being a current Atlantic C-PORT-E participant. The applicant states that should one of the non-cardiac surgery hospitals in Monmouth or Ocean counties be approved for elective PCI as a result of this CN batch, there will be a negative impact on Jersey Shore's volume of PCI cases. Given that Riverview and Ocean Medical Center are affiliated with Jersey

Shore through the Meridian Health System, the impact to Jersey Shore will be minimized if one of these two applicants were approved.

b. The need for special equipment and services in the area.

The applicant indicates that there is no additional equipment needed for the project, including the software for participation in C-PORT-E.

c. The adequacy of financial resources and sources of present and future revenues.

The applicant states it has the financial resources to implement this project.

d. The availability of sufficient staff in the several professional disciplines involved.

The applicant states that the specific staff to be recruited to support the project include: 1 RN, 1 cardio vascular tech/RT and 1 unit secretary for the cardiac cath lab. Six interventional cardiologists on the staff of Ocean and Jersey Shore support the program.

e. The project is necessary to provide required health care in the region.

The applicant states that there are no current providers of elective angiography in Ocean County and approval would eliminate the need to transfer patients to another facility.

f. The project will not have an adverse impact on access to health care services in the consortium region or Statewide.

As stated by the applicant, Jersey Shore is Ocean's primary referral center (271, or 95% of Ocean's 286 PCI and cardiac surgery referrals in 2006). *Jersey Shore's PCI volume was 2,596 in 2006 and the impact of 75% of Ocean's referrals (203 cases) being lost would account for only 7.8% of Jersey Shore's volume, assuming all the referrals were for angioplasty.*

Department analysis of 2006 UB discharge data indicates the percentage of each cardiac surgery center's PCI cases which came from each applicant's service area. Service area is defined as those zip codes that comprise 75% of an applicant's discharges using 2006 UB discharge data, reported by the applicants in completeness responses. The impact is as follows: 15.1% of Deborah Heart and Lung Center's, 3.8% of Hackensack University Medical Center's, 28.7% Jersey Shore Medical Center's, 3.2% of Newark Beth Israel Medical Center's, 1.1% of Robert Wood Johnson University Hospital's, and 6.5% of Saint Barnabas Medical Center's PCI cases came from Ocean's service area in 2006.

C. DEMONSTRATION PROJECT CRITERIA AT N.J.A.C. 8:33-3.11(e)

The applicant has sufficiently documented the ability to satisfy demonstration project eligibility criteria at N.J.A.C. 8:33-3.11(e)4 and the Atlantic C-PORT-E trial site inclusion criteria, including: (a) how the applicant will satisfy the patient selection criteria specified in the Atlantic C-PORT-E protocol, which is designed to assure informed consent and appropriate randomization, as provided in the Manual of Operations (N.J.A.C. 8:33-3.11(e)6iii); (b) approval of the study protocol by the applicant's Institutional Review Board, and if approval is pending, the status of that application (N.J.A.C. 8:33-3.11(e)6iv); (c) how the applicant will meet the target volume specified in the Atlantic C-PORT-E protocol of primary and elective angioplasties performed at the applicant's site, after randomization (that is, 100 PCI cases in year one and 200 cases in year two and each year thereafter) (N.J.A.C. 8:33-3.11(e)6v); (d) the applicant's compliance with the criteria for performance of primary PCI at N.J.A.C. 8:33E-2.16, 2.16(b) and N.J.A.C. 8:43G-7 (N.J.A.C. 8:33-3.11(e)6vi); and (e) documentation of the applicant's willingness to report elective PCI data to the Department separate from data collected as part of the study protocol, to support the Department's ongoing monitoring of cardiac services pursuant to N.J.A.C. 8:33E-1.9 and 2.10 (N.J.A.C. 8:33-3.11(e)6vii).

a. C-PORT-E Study Site Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6i):

The applicant has documented how it would satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol, including: (1) capability of performing a minimum volume of diagnostic cardiac catheterizations per year (N.J.A.C. 8:33-3.11(e)6i(1)); (2) agreement to complete an elective PCI development program (N.J.A.C. 8:33-3.11(e)6i(2)); (3) agreement to abide by physician, patient and device selection criteria defined in the study's Manual of Operations (N.J.A.C. 8:33-3.11(e)6i(3)); (4) agreement to collect and transmit study data in a timely fashion (N.J.A.C. 8:33-3.11(e)6i(4)); (5) agreement to perform elective PCI only via the study protocol and only while cases are being enrolled in the study (N.J.A.C. 8:33-3.11(e)6i(5)); and (6) agreement to develop and maintain a quality and error management program, including a weekly interventional conference and monthly quality and error management review (N.J.A.C. 8:33-3.11(e)6i(6)).

b. Participating Interventional Cardiologist Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6ii):

The applicant has documented that its participating interventional cardiologists have agreed to: (1) be in compliance and continue to be in compliance with minimum annual statewide interventional volume standards as set forth at N.J.A.C. 8:33E-2.16(b)6 (N.J.A.C. 8:33-3.11(e)6ii(1)); (2) practice in accordance with Atlantic C-PORT-E trial defined device and patient selection criteria (N.J.A.C. 8:33-3.11(e)6ii(2)); (3) obtain necessary informed consent for patient participation in the demonstration including the identity and location of the participating cardiac surgery center(s) that are to receive randomized study patients (N.J.A.C. 8:33-3.11(e)6ii(3));

Participating Interventional Cardiologist Inclusion Criteria:

1. The applicant states that all interventionalists have met the annual statewide interventional volume standard of 75 cases in 2006 and that its participating

physicians will continue to meet this standard in accordance with N.J.A.C. 8:33E-2.16(b)6.

2. Listed below are participating physicians and their respective 2006 angioplasty case volumes. Staff Note: Department staff found that all six interventional cardiologists met the 75 case annual interventional volume standard.

Physician Name	All facilities where physician performs angioplasties
Chu, Tony	Ocean, Jersey Shore, Riverview & Community *(131 cases)*
DeVita, Michael	Ocean, Jersey Shore *(155 cases)*
Moosvi, Ali	Ocean, Jersey Shore *(99 cases)*
Orlando, James	Ocean, Jersey Shore, Riverview, & Community *(171 cases)*
Pinnelas, David	Ocean, Jersey Shore, Riverview & Community *(93 cases)*
Weiss, Maurice	Ocean, Jersey Shore, Riverview & Community *(299 cases*)

Source: Ocean's completeness response Table 4 and NJDOH Cardiac Registry

c. Additional Demonstration Project Evaluative Criteria (N.J.A.C. 8:33-3.11(e)7i.-iv.):

i. Ability to offer a high quality program.

a. Licensure: *Ocean's full service cardiac catheterization and primary PCI programs were unconditionally licensed January 1, 2008.*

b. Outcomes:

Ocean's Diagnostic Cardiac Catheterization Outcomes

	2005		*2006*	
	# of Cases	*% of Total*	*# of Cases*	*% of Total*
Total Cases	*804*	*n/a*	*721*	*n/a*
Death in Hospital	*2*	*.25%*	*5*	*.69%*
Death in Lab	*0*	*0*	*2*	*.28%*
All In lab Complications	*2*	*.25%*	*0*	*0*

Source: NJDHSS Cardiac Data Registry (unaudited data)

In 2006, the Department reported two deaths in hospital and two complications, while Ocean reported one death in hospital and four complications in its application. In 2006, the Department reported five deaths in hospital, two deaths in lab and zero complications, while Ocean reported two deaths in hospital, zero deaths in lab and four complications .

ii. Representation of State's diverse regions and urban/suburban/rural population.

Ocean is located in Ocean County, in the Southern region of the state. The 2000 U.S. Census Bureau table titled "Urban and rural Population: New Jersey, Counties and Municipalities" reports a 12% rural population in Howell and a small rural population in Lakewood, while the remainder of Ocean's service area is considered to be urban.

iii. Potential to increase access to care for minorities and medically underserved.

As presented in the tables below, Ocean's total service area population is comprised of 8.6% non-white, and the 45 and over population is comprised of 4.8% non-white. Ocean's diagnostic cardiac catheterization patient population of non-white patients was 4.1% in 2005 and 4.9% in 2006. Ocean*'s minority use rate of diagnostic cardiac catheterization was comparable to the % of non-white residents in the service area population in 2005 and 2006.*

Ocean's Service Area Population by Race and Age Distribution

Age	Total	White	Non-white	% of Non-White to Total Population
< 45	144,362	127,867	16,495	11.4%
45 - 64	55,381	51,768	4,113	7.4%
65-74	25,683	24,802	836	3.3%
75-84	22,613	22,189	419	1.9%
85+	9,021	8,882	117	1.3%
Total	257,060	235,508	21,980	8.6%

Source: 2000 Census per Claritas, Inc.

Ocean's Diagnostic Cardiac Catheterization by Race

	White Non-Hispanic	*Black Non-Hispanic*	*Hispanic*	*Asian & Pacific Islander*	*Other*	*% of Non-White Cases*
2005	*95.9%*	*1.3%*	*1.9%*	*.2%*	*.7%*	*4.1%*
2006	*95.1%*	*2.6%*	*1.4%*	*.1%*	*.8%*	*4.9%*

Source: NJDHSS Cardiac Catheterization Data Registry

The applicant further states that Lakewood's population is 11.7% African-American and 18.2% Hispanic. These percentages are much higher than the 3.3% African-Americans and 6.6% Hispanics that comprise the total population of Ocean County. The applicant also notes the growing Orthodox Jewish population in Lakewood.

iv. Projected demonstration project elective angioplasty case volume.

Based on the average 746 cardiac catheterizations performed between 2005 and 2007, a 30% conversion rate would result in 224 patients, of which a maximum of 75%, or 168, would be randomized and be eligible to participate in the research project at Ocean, assuming they meet the patient eligibility criteria of the research study and give informed consent. In addition to the 168 elective PCIs anticipated, Ocean performed 77 primary PCIs in 2007. Total annual volume of PCIs projected based on past performance would be 245, which is above the required Atlantic C-PORT-E minimum volume of 200 cases per year.

The applicant does not anticipate any impact resulting from the closure of Muhlenberg Regional Medical Center.

II. FINANCIAL

Department staff reviewed and found that the applicant has documented adequate financial resources to implement and maintain the project.

STATE HEALTH PLANNING BOARD
CERTIFICATE OF NEED PROJECT SUMMARY
ELECTIVE ANGIOPLASTY WITHOUT ON-SITE SURGERY BACK-UP
DEMONSTRATION PROJECT

Applicant:	Riverview Medical Center (Riverview)
CN Number:	FR 071221-13-01
Location:	Red Bank, Monmouth County
Project Cost:	$ 0

PROJECT DESCRIPTION

Applicant is proposing to provide elective PCI without back-up surgery on-site and further proposes to participate in the Atlantic C-PORT, Elective Angioplasty Study, a multi-state demonstration trial to assess safety, quality and cost of elective PCI offered at community hospitals that do not offer cardiac surgery services on site. There are no construction or project costs associated with this project. The applicant proposes to contract with Jersey Shore Medical Center (Jersey Shore) as the participating cardiac surgery center.

I. SUMMARY OF THE APPLICANT'S REPRESENTATIONS

A. APPLICANT JUSTIFICATION

The applicant states that it is a current provider of primary angioplasty. Riverview currently has nursing and technical staff who are already trained in interventional procedures who routinely return to Jersey Shore for retraining and to maintain skills. The catheterization laboratory is staffed with interventional cardiologists who also practice at Jersey Shore, which would serve as the control site for the study. The applicant further states that the integrity of the trial will be maintained since control group patients will be treated by the same physicians as the study group patients. Riverview currently has all the major capital equipment needed to initiate an elective angioplasty program; only a small amount of minor moveable equipment will be needed.

B. STATUTORY CRITERIA

a. The availability of facilities or services that may serve as alternatives or substitutes.

Jersey Shore and Monmouth Medical Center are the only hospitals in the Monmouth-Ocean county area that are existing providers of elective PCI, with Monmouth being a current Atlantic C-PORT-E participant. The applicant states that should one of the non-cardiac surgery hospitals in Monmouth or Ocean counties be approved for elective PCI as a result of this CN batch, there will be a negative impact on Jersey Shore's volume of PCI cases. Given that Riverview and Ocean Medical Center are affiliated with Jersey Shore through the Meridian Health System, the impact to Jersey Shore will be minimized if one of these two applicants were approved.

b. The need for special equipment and services in the area.

The applicant indicates that there is no additional equipment needed for the project, including the software for participation in C-PORT-E.

c. The adequacy of financial resources and sources of present and future revenues.

The applicant states it has the financial resources to implement this project.

d. The availability of sufficient staff in the several professional disciplines involved.

The applicant states that the specific staff to be recruited to support the project include: 2 RNs and 1 RT for the Cardiac Cath Lab; and 3.6 RNs and 2.6 PCA for the Post Elective PCI unit. Eight interventional cardiologists on the staff of Riverview and Jersey Shore would support the program.

e. The project is necessary to provide required health care in the region.

The applicant states that approval would eliminate the need to transfer patients to another facility.

f. The project will not have an adverse impact on access to health care services in the region.

As stated by the applicant in completeness response tables 2 and 3, Jersey Shore Medical Center is Riverview's primary referral center (169 cases or 95% of Riverview's PCI and cardiac surgery referrals in 2006). *Jersey Shore's PCI volume was 2,596 in 2006 and the impact of 75% of Riverview's referrals being lost would account for only 127 cases or 4.8% of Jersey Shore's volume, assuming all the referrals were for PCI.*

Department analysis of 2006 UB discharge data indicates the percentage of each cardiac surgery center's PCI cases which came from the applicant's service area. Service area is defined as those zip codes that comprise 75% of an applicant's discharges using 2006 UB discharge data, reported by the applicants in completeness responses. The impact is as follows: 1.3% of Deborah Heart and Lung Center's, 25.4% Jersey Shore Medical Center's, .8% of Newark Beth Israel Medical Center's, 4.8% of Robert Wood Johnson University Hospital's, 11.1% of St. Michael's Medical Center's, and 1.1% of University Hospital's PCI cases came from Riverview's service area in 2006.

C. DEMONSTRATION PROJECT CRITERIA AT N.J.A.C. 8:33-3.11(e)

For the most part, the applicant has sufficiently documented the ability to satisfy demonstration project eligibility criteria at N.J.A.C. 8:33-3.11(e)4 and the Atlantic C-

PORT-E trial site inclusion criteria, including: (a) how the applicant will satisfy the patient selection criteria specified in the Atlantic C-PORT-E protocol, which is designed to assure informed consent and appropriate randomization, as provided in the Manual of Operations (N.J.A.C. 8:33-3.11(e)6iii); (b) approval of the study protocol by the applicant's Institutional Review Board, and if approval is pending, the status of that application (N.J.A.C. 8:33-3.11(e)6iv); (c) how the applicant will meet the target volume specified in the Atlantic C-PORT-E protocol of primary and elective angioplasties performed at the applicant's site, after randomization (that is, 100 PCI cases in year one and 200 cases in year two and each year thereafter) (N.J.A.C. 8:33-3.11(e)6v); (d) the applicant's compliance with the criteria for performance of primary PCI at N.J.A.C. 8:33E-2.16, 2.16(b) and N.J.A.C. 8:43G-7 (N.J.A.C. 8:33-3.11(e)6vi); and (e) documentation of the applicant's willingness to report elective PCI data to the Department separate from data collected as part of the study protocol, to support the Department's ongoing monitoring of cardiac services pursuant to N.J.A.C. 8:33E-1.9 and 2.10 (N.J.A.C. 8:33-3.11(e)6vii).

Staff Note: As noted below, the applicant has <u>not</u> sufficiently documented the ability to satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol of performing at least 200 angioplasties per year (N.J.A.C. 8:33-3.11(e)6v).

a. C-PORT-E Study Site Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6i):

The applicant has documented how it would satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol, including: (1) capability of performing a minimum volume of diagnostic cardiac catheterizations per year (N.J.A.C. 8:33-3.11(e)6i(1)); (2) agreement to complete an elective PCI development program (N.J.A.C. 8:33-3.11(e)6i(2)); (3) agreement to abide by physician, patient and device selection criteria defined in the study's Manual of Operations (N.J.A.C. 8:33-3.11(e)6i(3)); (4) agreement to collect and transmit study data in a timely fashion (N.J.A.C. 8:33-3.11(e)6i(4)); (5) agreement to perform elective PCI only via the study protocol and only while cases are being enrolled in the study (N.J.A.C. 8:33-3.11(e)6i(5)); and (6) agreement to develop and maintain a quality and error management program, including a weekly interventional conference and monthly quality and error management review (N.J.A.C. 8:33-3.11(e)6i(6)).

b. Participating Interventional Cardiologist Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6ii):

The applicant has documented that its participating interventional cardiologists have agreed to: (1) be in compliance and continue to be in compliance with minimum annual statewide interventional volume standards as set forth at N.J.A.C. 8:33E-2.16(b)6 (N.J.A.C. 8:33-3.11(e)6ii(1)); (2) practice in accordance with Atlantic C-PORT-E trial defined device and patient selection criteria (N.J.A.C. 8:33-3.11(e)6ii(2)); (3) obtain necessary informed consent for patient participation in the demonstration including the identity and location of the participating cardiac surgery center(s) that are to receive randomized study patients (N.J.A.C. 8:33-3.11(e)6ii(3));

Participating Interventional Cardiologist Performance Criteria:

1. The applicant states that all interventionalists have met the annual statewide interventional volume standard of 75 cases in 2006 and that its participating physicians will continue to meet this standard in accordance with N.J.A.C. 8:33E-2.16(b)6.

2. *Listed below are participating physicians and their respective 2006 angioplasty case volumes. Staff Note: Department staff found that seven interventional cardiologists met the 75 case annual interventional volume standard, one did not. The Department notes that this physician did not perform cases at Riverview during 2006.*

Physician Name	All cardiac centers where physician performs angioplasties
Vlahos, Aristotelis	Riverview MC & Jersey Shore MC *(171 cases)*
Younan, Shaddy	Riverview MC, Jersey Shore MC & St. Michael's MC *(62 cases)*
Abbud, Ziad	Riverview MC & Jersey Shore MC *(208 cases)*
Chu, Tony	Riverview MC, Ocean MC & Jersey Shore MC *(131 cases)*
Demchuk, Beverly	Riverview MC & Jersey Shore MC *(115 cases)*
Pinnelas, David	Riverview MC, Ocean MC & Jersey Shore MC *(93 cases)*
Uppal, Parveen	Riverview MC & St. Michael's MC *(91 cases*)
Weiss, Maurice	Riverview MC, Ocean MC & Jersey Shore MC *(299 cases)*

Source: Riverview's completeness response Table 4 and NJDOH Cardiac Registry

c. Additional Demonstration Project Evaluative Criteria (N.J.A.C. 8:33-3.11(e)7i.-iv.):

i. Ability to offer a high quality program.

a. Licensure: *Riverview's full service cardiac catheterization and primary PCI programs were unconditionally licensed January 1, 2008.*

b. Outcomes:

Riverview's Diagnostic Cardiac Catheterization Outcomes

	2005		*2006*	
	# of Cases	*% of Total*	*# of Cases*	*% of Total*
Total Cases	*584*	*n/a*	*496*	*n/a*
Death in Hospital	*5*	*.86%*	*8*	*1.61%*
Death in Lab	*1*	*.17%*	*2*	*.40%*
All In lab Complications	*6*	*1.03%*	*4*	*.81%*

Source: NJDHSS Cardiac Data Registry (unaudited data)

In 2005, the Department reported five deaths in hospital and six complications in while Riverview reported three deaths in hospital and four complications in its application. In 2006, the Department reported eight deaths in hospital and two deaths in lab, while Riverview reported four deaths in hospital and one death in lab.

ii. Representation of State's diverse regions and urban/suburban/rural population.

Riverview is located in Monmouth County, in the Central region of the state. The 2000 U.S. Census Bureau table titled "Urban and Rural Population: New Jersey, Counties and Municipalities" reports a small population residing in rural areas in Holmdel and Middletown, while the remainder of Riverview's service area is considered to be urban.

The applicant states that its service area is a socio-economically and ethnically diverse suburban area, which reflects many of the demographic trends of the state. While minorities do not represent an overwhelming number of the service area as a whole, there are communities with higher proportions of minorities represented.

iii. Potential to increase access to care for minorities and medically underserved.

As presented in the tables below, Riverview's total service area population is comprised of 18.9% non-white and the 45 and over population is comprised of 13.9% non-white. *Riverview's diagnostic cardiac catheterization patient population of non-white patients was 8.1% in 2005 and 8.7% in 2006. Riverview's minority use rate of diagnostic cardiac catheterization was below the % of non-white residents in the service area population in 2005 and 2006.*

Riverview's Service Area Population by Race and Age Distribution

Age	Total	White	Non-white	% of Non-White to Total Population
< 45	201,781	157,888	43,893	21.8%
45 - 64	76,800	65,328	11,472	14.9%
65-74	20,969	18,056	2,913	13.9%
75-84	14,011	12,521	1,490	10.6%
85+	5,139	4,690	449	8.7%
Total	318,700	258,483	60,217	18.9%

Source: 2000 US Census

Riverview's Diagnostic Cardiac Catheterization by Race

	White Non-Hispanic	*Black Non-Hispanic*	*Hispanic*	*Asian & Pacific Islander*	*Other*	*% of Non-White Cases*
2005	*91.1%*	*6.0%*	*2.4%*	*0%*	*.5%*	*8.1%*
2006	*91.3%*	*6.3%*	*1.2%*	*.2%*	*1.0%*	*8.7%*

Source: NJDHSS Cardiac Catheterization Data Registry

The applicant further states that Red Bank is comprised of 8.7% African-American and 14.9% Hispanic.

iv. Projected demonstration project elective angioplasty case volume

Based on the average 522 cardiac catheterizations performed between 2005 and 2007, a 30% conversion rate would result in 157 patients, of which a maximum of 75%, or 117, would be randomized and be eligible to participate in the research

project at Riverview, assuming they meet the patient eligibility criteria of the research study and give informed consent. In addition to the 117 elective angioplasties anticipated, Riverview performed 35 primary PCIs in 2007. Total annual volume of PCIs projected based on past performance would be 152, which is below the 200 minimum C-PORT-E demonstration project requirement.

Riverview also predicts further increases in volume based on population growth and anticipated referral changes. The applicant does not anticipate any impact resulting from the closure of Muhlenberg Regional Medical Center.

Staff Note: The applicant has not sufficiently documented the ability to satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol of performing at least 200 angioplasties per year.

II. FINANCIAL

Department staff reviewed and found that the applicant has documented adequate financial resources to implement and maintain the project.

Trenton Hospital Market Area

1. Capital Health System at Mercer
2. Robert Wood Johnson University Hospital at Hamilton

STATE HEALTH PLANNING BOARD
CERTIFICATE OF NEED PROJECT SUMMARY
ELECTIVE ANGIOPLASTY WITHOUT ON-SITE SURGERY BACK-UP
DEMONSTRATION PROJECT

Applicant:	Capital Health System – Mercer (Capital)
CN Number:	FR 071211-11-01
Location:	Trenton, Mercer County
Project Cost:	$0

PROJECT DESCRIPTION
Applicant is proposing to provide elective PCI without back-up surgery on-site and further proposes to participate in the Atlantic C-PORT, Elective Angioplasty Study, a multi-state demonstration trial to assess safety, quality and cost of elective PCI offered at community hospitals that do not offer cardiac surgery services on site. There are no construction or project costs associated with this project. The applicant proposes to contract with Deborah Heart and Lung Center (Deborah) as the participating cardiac surgery center.

I. SUMMARY OF THE APPLICANT'S REPRESENTATIONS

A. APPLICANT JUSTIFICATION

Capital states that it is uniquely qualified to reach people in need and collect useful study data. Three of every 4 patients hospitalized in Trenton are at Capital's two campuses, including 3 of every 4 charity care patients. Capital's 2007 charity care allocation and hospital relief subsidy of $27 million tripled combined total of the 3 other Mercer County hospitals. The applicant further states that participation should also help reverse the significant out-migration of patients from the greater Trenton area to Pennsylvania hospitals and other out-of-county New Jersey.

B. STATUTORY CRITERIA

a. The availability of facilities or services that may serve as alternatives or substitutes.

The applicant states that there are three regional cardiac centers and one approved elective angioplasty facility that draw cardiac patients from Capital's service area (Robert Wood Johnson University Hospital, RWJ-Hamilton, Deborah Heart and Lung Center, and St. Francis Medical Center.)

b. The need for special equipment and services in the area.

The applicant indicates that there is no additional equipment or services needed for the project.

c. The adequacy of financial resources and sources of present and future revenues.

The applicant states it has the financial resources to implement this project.

d. The availability of sufficient staff in the several professional disciplines involved.

The applicant states that the specific staff to be recruited and/or designated to support the project include: six RNs and two technicians. Seven interventionalists, who already practice at Capital, would support the program.

e. The project is necessary to provide required health care in the region.

The applicant states that the November 5, 2007 CN call for elective angioplasty without on-site surgery back-up defines the need for the health care service in the state. The applicant states that approval of Capital would help reverse the significant out-migration of patients from the greater Trenton area to Pennsylvania hospitals and other out-of-county New Jersey hospitals.

f. The project will not have an adverse impact on access to health care services in the region or Statewide.

As stated by the applicant, St. Mary's, Langhorne, PA is Capital's primary referral center (86, or 62%, of Capital's angioplasty and cardiac surgery referrals in 2006). Capital referred 44, or 32%, of its angioplasty and cardiac surgery patients to St. Francis Medical Center in 2006 and 3 or 2% to Deborah Heart and Lung Center. *St. Francis Medical Center's angioplasty volume was 707 in 2006 and the impact of 75% of Capital's referrals being lost would account for only 4.7% of St. Francis' volume. The Department notes that the increased collaboration between Capital-Mercer and Deborah as suggested in this application may result in fewer referrals by Capital to St. Francis.*

Department analysis of 2006 UB discharge data indicates the percentage of each cardiac surgery center's PCI cases which came from each applicant's service area. Service area is defined as those zip codes that comprise 75% of an applicant's discharges, using 2006 UB discharge data, reported by the applicants in completeness responses. The impact is as follows: 1.2% of Deborah Heart and Lung Center's, .3% of Robert Wood Johnson University Hospital's, and 54.9% of St. Francis Medical Center's PCI cases came from Capital's service area in 2006. The Department notes that Capital and St. Francis share overlapping service areas and St. Francis' cases as reported may not have originated at Capital.

The applicant states that there are three regional cardiac centers and one approved elective angioplasty facility that draw cardiac patients from Capital's service area (RWJUH, RWJ-Hamilton, Deborah, and St. Francis.) The applicant states that all sites have experienced a substantial increase in volume and that a program of Capital's size would not impact any of these providers. Capital anticipates that most of their potential volume would come from New Jersey residents out-migrating to Pennsylvania.

C. DEMONSTRATION PROJECT CRITERIA AT N.J.A.C. 8:33-3.11(e)

For the most part, the applicant has sufficiently documented the ability to satisfy demonstration project eligibility criteria at N.J.A.C. 8:33-3.11(e)4 and the Atlantic C-PORT-E trial site inclusion criteria, including: (a) how the applicant will satisfy the patient selection criteria specified in the Atlantic C-PORT-E protocol, which is designed to assure informed consent and appropriate randomization, as provided in the Manual of Operations (N.J.A.C. 8:33-3.11(e)6iii); (b) approval of the study protocol by the applicant's Institutional Review Board, and if approval is pending, the status of that application (N.J.A.C. 8:33-3.11(e)6iv); (c) how the applicant will meet the target volume specified in the Atlantic C-PORT-E protocol of primary and elective angioplasties performed at the applicant's site, after randomization (that is, 100 PCI cases in year one and 200 cases in year two and each year thereafter) (N.J.A.C. 8:33-3.11(e)6v); (d) the applicant's compliance with the criteria for performance of primary PCI at N.J.A.C. 8:33E-2.16, 2.16(b) and N.J.A.C. 8:43G-7 (N.J.A.C. 8:33-3.11(e)6vi); and (e) documentation of the applicant's willingness to report elective PCI data to the Department separate from data collected as part of the study protocol, to support the Department's ongoing monitoring of cardiac services pursuant to N.J.A.C. 8:33E-1.9 and 2.10 (N.J.A.C. 8:33-3.11(e)6vii).

Staff Note: As noted below, the applicant has <u>not</u> sufficiently documented the ability to satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol of performing at least 200 angioplasties per year (N.J.A.C. 8:33-3.11(e)6v).

a. C-PORT-E Study Site Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6i):

The applicant has documented how it would satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol, including: (1) capability of performing a minimum volume of diagnostic cardiac catheterizations per year (N.J.A.C. 8:33-3.11(e)6i(1)); (2) agreement to complete an elective PCI development program (N.J.A.C. 8:33-3.11(e)6i(2)); (3) agreement to abide by physician, patient and device selection criteria defined in the study's Manual of Operations (N.J.A.C. 8:33-3.11(e)6i(3)); (4) agreement to collect and transmit study data in a timely fashion (N.J.A.C. 8:33-3.11(e)6i(4)); (5) agreement to perform elective PCI only via the study protocol and only while cases are being enrolled in the study (N.J.A.C. 8:33-3.11(e)6i(5)); and (6) agreement to develop and maintain a quality and error management program, including a weekly interventional conference and monthly quality and error management review (N.J.A.C. 8:33-3.11(e)6i(6)).

b. Participating Interventional Cardiologist Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6ii):

The applicant has documented that its participating interventional cardiologists have agreed to: (1) be in compliance and continue to be in compliance with minimum annual statewide interventional volume standards as set forth at N.J.A.C. 8:33E-2.16(b)6 (N.J.A.C. 8:33-3.11(e)6ii(1)); (2) practice in accordance with Atlantic C-PORT-E trial defined device and patient selection criteria (N.J.A.C. 8:33-3.11(e)6ii(2)); (3) obtain necessary informed consent for patient participation in the demonstration including the

identity and location of the participating cardiac surgery center(s) that are to receive randomized study patients (N.J.A.C. 8:33-3.11(e)6ii(3));

Participating Interventional Cardiologist Inclusion Criteria:

1. The applicant states that all interventionalists have met the annual statewide interventional volume standard of 75 cases in 2006 and that its participating physicians will continue to meet this standard in accordance with N.J.A.C. 8:33E-2.16(b)6.

2. *Listed below are participating physicians and their respective 2006 angioplasty case volumes including out-state volume. Staff Note: Department staff found that six interventional cardiologists met the 75 case annual interventional volume standard. One cardiologist did not do 75 cases in 2006.*

Physician Name	All facilities where physician performs angioplasties
Drucker, David	CHS; St. Francis MC; RWJ at Hamilton; St. Mary's MC *(26 in NJ, 221 in PA , 247 total)*
Venkatesulu, Sunder	CHS; RWJ at Hamilton; St. Mary's MC *(25 in NJ, 76 in Pa, 101 total)*
Heyrich, George	CHS; RWJ at Hamilton, St. Mary's MC *(17 in NJ, 223 in PA, 240 total)*
Mustafa, Muhammad	CHS; St. Francis Med Ctr, *(29 in NJ)*
Patel, Jay	CHS; St. Francis MC, NJ; RWJ at Hamilton, NJ *(245 in NJ)*
Soffer, Mark[1]	CHS; St. Francis Med Ctr *(78 in NJ)*
Goldstein, Stephen[2]	CHS; Deborah Heart & Lung *(220 in NJ)*

All of these physicians are currently credentialed members of the CHS medical staff.
[1] - Indicates this physician was previously credentialed at CHS for angioplasty and is in the process of becoming recredentialed for this privilege.
[2] - Indicates this physician is in the process of obtaining privileging for angioplasty at CHS.
Source: Mercer's completeness response Tables 4 & 4a and NJDOH Cardiac Registry

c. Additional demonstration project evaluative criteria (N.J.A.C. 8:33-3.11(e)7i.-iv.):

i. Ability to offer a high quality program.

a. Licensure: *Capital's full service diagnostic cardiac catheterization program was unconditionally licensed on August 1, 2007. Capital's primary PCI program was initially licensed on September 30, 2005 and will be evaluated during the August 1, 2008 licensure renewal.*

b. Outcomes:

Capital's Diagnostic Cardiac Catheterization Outcomes

	2005		*2006*	
	# of Cases	*% of Total*	*# of Cases*	*% of Total*
Total Cases	*410*	*n/a*	*486*	*n/a*
Death in Hospital	*3*	*.73%*	*4*	*.82%*
Death in Lab	*0*	*.73%*	*1*	*.21%*
All In lab Complications	*0*	*0%*	*7*	*1.44%*

Source: NJDHSS Cardiac Data Registry (unaudited data)

In 2005, the Department found 410 cases and 3 deaths in hospital, while Capital reported 404 cases and 2 deaths. In 2006, the Department found 486 cases, 4 deaths in hospital, one death in lab and 7 complications, while Capital reported 445 cases, 1 death in hospital, 0 deaths in lab and 0 complications.

ii. Representation of State's diverse regions and urban/suburban/rural population.

Capital is located in the city of Trenton, in Mercer County, in the Central region of the state. The 2000 U.S. Census Bureau table titled "Urban and Rural Population: New Jersey, Counties and Municipalities" reports that all of Capital's service area is considered to be urban.

iii. Potential to increase access to care for minorities and medically underserved.

As presented below, Capital's total service area population is comprised of 34.66% non-white and the 45 and over population is comprised of 24.64% non-white based on 2000 Census data. *Capital's percentage of diagnostic cardiac catheterization caseload performed on non-white patients was 56.8% in 2005; and 61.3% in 2006. Capital's minority use rate of diagnostic cardiac catheterization exceeded the % of non-white residents in the service area population in 2005 and 2006.*

Capital's Service Area Population by Race and Age Distribution

Age	Total	White	Non-white	% of Non-White to Total Population
< 45	157,498	94,167	63,331	40.21%
45 - 64	54,195	39,085	15,110	27.88%
65-74	16,678	12,789	3,889	23.32%
75-84	12,475	10,544	1,931	15.48%
85+	3,881	3,321	560	14.43%
Total	244,727	159,906	84,821	34.66%

Source: Capital's completeness response Table 5c (2000 US Census)

Capital's Diagnostic Cardiac Catheterization by Race

	White Non-Hispanic	*Black Non-Hispanic*	*Hispanic*	*Asian & Pacific Islander*	*Other*	*% of Non-White Cases*
2005	*43.2%*	*52.0%*	*4.1%*	*.2%*	*.5%*	*56.8%*
2006	*38.7%*	*55.8%*	*4.5%*	*.8%*	*.2%*	*61.3%*

Source: NJDHSS Cardiac Catheterization Data Registry

iv. Projected demonstration project elective angioplasty case volume.

Based on the average 443 cardiac catheterizations performed between 2005 and 2007, a 30% conversion rate would result in a maximum of 133 patients, of which 75%, or 100, would be randomized to be eligible to participate in the research project at Capital, assuming they all met the patient eligibility criteria of the research study and gave informed consent. Capital performed 39 cases in 2007. Total annual volume of angioplasties projected would be 139, below the annual 200 cases minimum C-PORT-E demonstration project requirement.

Capital predicts increases in volume based on anticipated referral changes, specifically related to out of state migration. The applicant does not anticipate any impact resulting from the closure of Muhlenberg Regional Medical Center.

Staff Note: The applicant has not sufficiently documented the ability to satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol of performing at least 200 angioplasties per year.

D. OTHER

Capital is building a replacement hospital for its Mercer campus in Hopewell, which will include a two lab cardiac catheterization suite. In its completeness response #9, Capital states that it is seeking to expand its interventional suite to two rooms at its Fuld campus in Trenton. *The Department clarifies that the two Capital campuses are separately licensed. The current diagnostic cardiac catheterization and primary PCI services provided at the Mercer campus will move to the replacement hospital. Cardiac catheterization services are not currently offered at the Fuld campus. Capital would need to submit a certificate of need application to provide low risk diagnostic cardiac catheterization at Fuld.*

II. FINANCIAL

Department staff reviewed and found that the applicant has documented adequate financial resources to implement and maintain the project.

STATE HEALTH PLANNING BOARD
CERTIFICATE OF NEED PROJECT SUMMARY
ELECTIVE ANGIOPLASTY WITHOUT ON-SITE SURGERY BACK-UP
DEMONSTRATION PROJECT

Applicant:	Robert Wood Johnson University Hospital – Hamilton (Hamilton)
CN Number:	FR 071227-11-01
Location:	Hamilton, Mercer County
Project Cost:	$0

PROJECT DESCRIPTION
Applicant is proposing to provide elective PCI without back-up surgery on-site and further proposes to participate in the Atlantic C-PORT, Elective Angioplasty Study, a multi-state demonstration trial to assess safety, quality and cost of elective PCI offered at community hospitals that do not offer cardiac surgery services on site. Hamilton is a current participant in the Atlantic C-PORT-E trial, having been CN approved in 2005 and licensed by the Department in 2006. There are no construction or project costs associated with this project. The applicant proposes to contract with Robert Wood Johnson University Hospital (RWJUH) and St. Francis Medical Center (St. Francis) as the participating cardiac surgery centers.

I. SUMMARY OF THE APPLICANT'S REPRESENTATIONS

A. APPLICANT JUSTIFICATION

Hamilton states that it has the proven ability to offer a high quality program; its patient population is representative of the diverse regions in the State; it has the potential to increase access to care for minorities and the medically underserved in the region; and its projected case volume is sufficient to meet the requirements of the demonstration project. Further, approval of Hamilton's application would enhance access for the more than 300 primary service area residents who travel to Pennsylvania for this care.

B. STATUTORY CRITERIA

a. The availability of facilities or services that may serve as alternatives or substitutes.

Through its current participation in the C-PORT-E trial, the applicant is the only provider of elective angioplasty without cardiac surgery on site in its service area. The applicant states that there is one hospital, St. Francis Medical Center, in Hamilton's service area which provides elective angioplasty.

b. The need for special equipment and services in the area.

The applicant indicates that there is no need for additional equipment or services for this project.

c. The adequacy of financial resources and sources of present and future revenues.

The applicant states it has the financial resources to implement this project.

d. The availability of sufficient staff in the several professional disciplines involved.

The applicant states that it has sufficient current staffing to implement an elective angioplasty program. Eight interventionalists already practice at Hamilton who would support the program.

e. The project is necessary to provide required health care in the region.

The applicant states that the November 7, 2007 CN call for elective angioplasty without on-site surgery back-up defines the need for the health care service in the state. The applicant further establishes its eligibility to participate in the project in its service area.

f. The project will not have an adverse impact on access to health care services in the consortium region or Statewide.

As stated by the applicant in completeness response tables 2.9, St. Francis Medical Center is Hamilton's primary referral center (74, or 73% of Hamilton's angioplasty and cardiac surgery referrals in 2005 and 112 or 89% in 2006). *St. Francis' angioplasty volume was 707 in 2006 and the impact of 75% (84 cases) of Hamilton's referrals being lost would account for 12% of St. Francis' volume assuming all the referrals were for angioplasty.*

Department analysis of 2006 UB discharge data indicates the percentage of each cardiac surgery center's PCI cases which came from each applicant's service area. Service area is defined as those zip codes that comprise 75% of an applicant's discharges, using 2006 UB discharge data, reported by the applicants in completeness responses. The impact is as follows: 0.3% of Deborah Heart and Lung Center's, .1% of Robert Wood Johnson University Hospital's, and 22.9% of St. Francis' PCI cases came from Hamilton's service area in 2006. The Department notes that Hamilton and St. Francis share overlapping service areas and St. Francis' cases as reported may not have necessarily originated at Hamilton.

The applicant anticipates not impact resulting from the closure of Muhlenberg Regional Medical Center, since there is no service area overlap.

C. DEMONSTRATION PROJECT CRITERIA AT N.J.A.C. 8:33-3.11(e)

The applicant has sufficiently documented the ability to satisfy demonstration project eligibility criteria at N.J.A.C. 8:33-3.11(e)4 and the Atlantic C-PORT-E trial site inclusion criteria, including: (a) how the applicant will satisfy the patient selection criteria specified in the Atlantic C-PORT-E protocol, which is designed to assure informed consent and appropriate randomization, as provided in the Manual of Operations (N.J.A.C. 8:33-3.11(e)6iii); (b) approval of the study protocol by the applicant's Institutional Review Board, and if approval is pending, the status of that application (N.J.A.C. 8:33-3.11(e)6iv); (c) how the applicant will meet the target volume specified in the Atlantic C-PORT-E protocol of primary and elective angioplasties performed at the

applicant's site, after randomization (that is, 100 PCI cases in year one and 200 cases in year two and each year thereafter) (N.J.A.C. 8:33-3.11(e)6v); (d) the applicant's compliance with the criteria for performance of primary PCI at N.J.A.C. 8:33E-2.16, 2.16(b) and N.J.A.C. 8:43G-7 (N.J.A.C. 8:33-3.11(e)6vi); and (e) documentation of the applicant's willingness to report elective PCI data to the Department separate from data collected as part of the study protocol, to support the Department's ongoing monitoring of cardiac services pursuant to N.J.A.C. 8:33E-1.9 and 2.10 (N.J.A.C. 8:33-3.11(e)6vii).

a. C-PORT-E Study Site Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6i):

The applicant has documented how it would satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol, including: (1) capability of performing a minimum volume of diagnostic cardiac catheterizations per year (N.J.A.C. 8:33-3.11(e)6i(1)); (2) agreement to complete an elective PCI development program (N.J.A.C. 8:33-3.11(e)6i(2)); (3) agreement to abide by physician, patient and device selection criteria defined in the study's Manual of Operations (N.J.A.C. 8:33-3.11(e)6i(3)); (4) agreement to collect and transmit study data in a timely fashion (N.J.A.C. 8:33-3.11(e)6i(4)); (5) agreement to perform elective PCI only via the study protocol and only while cases are being enrolled in the study (N.J.A.C. 8:33-3.11(e)6i(5)); and (6) agreement to develop and maintain a quality and error management program, including a weekly interventional conference and monthly quality and error management review (N.J.A.C. 8:33-3.11(e)6i(6)).

b. Participating Interventional Cardiologist Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6ii):

The applicant has documented that its participating interventional cardiologists have agreed to: (1) be in compliance and continue to be in compliance with minimum annual statewide interventional volume standards as set forth at N.J.A.C. 8:33E-2.16(b)6 (N.J.A.C. 8:33-3.11(e)6ii(1)); (2) practice in accordance with Atlantic C-PORT-E trial defined device and patient selection criteria (N.J.A.C. 8:33-3.11(e)6ii(2)); (3) obtain necessary informed consent for patient participation in the demonstration including the identity and location of the participating cardiac surgery center(s) that are to receive randomized study patients (N.J.A.C. 8:33-3.11(e)6ii(3));

Participating Interventional Cardiologist Performance Criteria:

1. The applicant states that all interventionalists have met the annual statewide interventional volume standard of 75 cases in 2006 and that its participating physicians will continue to meet this standard in accordance with N.J.A.C. 8:33E-2.16(b)6.

2. *Listed below are participating physicians and their respective 2006 angioplasty case volumes. Staff Note: Department staff found that the nine interventional cardiologists met the 75 case annual interventional volume standard in 2006.*

Physician Name	All facilities where physician performs angioplasties
Patel, Jay K	St Francis, Hamilton *(245 in NJ)*
Drucker, David	St Mary's Langhorne PA, Hamilton, Capital Mercer *(26 in NJ, 221 in PA, 247 total)*
Madiera, Samuel	St Francis, Hamilton *(90)*
Soffer, Mark	St Francis, Hamilton (1), Capital Mercer *(78)*
Garg, Sangeeta	St. Francis, Hamilton *(76 in NJ)*
Wolf, Andreas	St Francis, Hamilton *(132 in NJ)*
Heyrich, George	St Mary's Langhorne, Capital Mercer *(17 in NJ, 223 in PA, 240 total)*
Venkatesulu, Sunder	St Mary's MC, Hamilton, Capital *Mercer (25 in NJ, 76 in PA, 101 total)*
Bhavsar, Janak	St. Francis, Hamilton *(105 in NJ)*

Source: Hamilton completeness response Table 2.7a and NJDOH Cardiac Registry

c. Additional Demonstration Project Evaluative Criteria (N.J.A.C. 8:33-3.11(e)7i.-iv.):

i. Ability to offer a high quality program.

a. Licensure: *Hamilton's full service cardiac catheterization program is conditionally licensed effective June 1, 2008 for failure to achieve compliance with director volume standards.*

b. Outcomes:

Hamilton's Diagnostic Cardiac Catheterization Outcomes

	2005		*2006*	
	# of Cases	*% of Total*	*# of Cases*	*% of Total*
Total Cases	*795*	*n/a*	*826*	*n/a*
Death in Hospital	*2*	*.25%*	*6*	*.73%*
Death in Lab	*0*	*0*	*0*	*0%*
All In lab Complications	*1*	*.13%*	*13*	*1.57%*

Source: NJDHSS Cardiac Data Registry (unaudited data)

In 2005, the Department recorded two deaths in hospital, which Hamilton did not record in its completeness response. In 2006, the Department found 6 deaths in hospital and thirteen complications, while Hamilton reported 1 death in hospital and 2 complications.

The applicant states that in its first full year of participation in the Atlantic C-PORT trial, it exceeded the required target volume of 100 PCIs and demonstrated excellent patient outcomes.

ii. Representation of State's diverse regions and urban/suburban/rural population.

Hamilton is located in the Mercer County, in the Central region of the state. The 2000 U.S. Census Bureau table titled "Urban and Rural Population: New Jersey, Counties and Municipalities" reports a small population residing in rural areas in Bordentown, Hamilton and Lawrence, while the remainder of Hamilton's service area is considered to be urban.

iii. Potential to increase access to care for minorities and medically underserved.

As presented in the tables below, Hamilton's total service area population is comprised of 33.85% non-white and the over age 45 population is comprised of 23.91% non-white based on 2000 Census data. *Hamilton's percentage of diagnostic cardiac catheterization caseload performed on non-white patients was 23.8% in 2005; and 26.4% in 2006. Hamilton's minority use rate of diagnostic cardiac catheterization was comparable to the % of non-white residents in the service area population in 2005 and 2006.*

Hamilton's Service Area Population by Race and Age Distribution

Age	Total	White	Non-White	% of Non-White to Total Population
< 45	179,431	109,190	70,241	39.15%
45 - 64	60,380	44,258	16,122	26.70%
65-74	17,743	13,657	4,086	23.03%
75-84	13,149	11,080	2,069	15.74%
85+	4,363	3,770	593	13.59%
Total	275,066	181,955	93,111	33.85%

Source: 2000 US Census

Hamilton's Diagnostic Cardiac Catheterization by Race

	White Non-Hispanic	*Black Non-Hispanic*	*Hispanic*	*Asian & Pacific Islander*	*Other*	*% of Non-White Cases*
2005	*76.2%*	*13.5%*	*4.7%*	*1.6%*	*4.0%*	*23.8%*
2006	*73.6%*	*15.5%*	*4.4%*	*3.9%*	*2.6%*	*26.4%*

Source: NJDHSS Cardiac Catheterization Data Registry

iv. Projected demonstration project elective angioplasty case volume.

Based on the average 789 cardiac catheterizations performed between 2005 and 2007, a 30% conversion rate would result in 237 patients, of which a maximum of 75%, or 178 would be randomized to be eligible to participate in the research project at Hamilton, assuming they all met the patient eligibility criteria of the research study and gave informed consent. In addition to the 178 elective angioplasties anticipated, Hamilton performed 53 primary PCIs in 2007. Total annual volume of angioplasties projected based on past performance would be 231, which is above the annual 200 case minimum volume C-PORT-E demonstration project requirement. As a current C-PORT-E participant, Hamilton has performed 100 total PCIs in 2006 (36 elective, 64 primary) and133 total PCIs in 2007 (80 elective, 53 primary).

The applicant does not anticipate any impact resulting from the closure of Muhlenberg Regional Medical Center.

II. FINANCIAL

Department staff reviewed and found that the applicant has documented adequate financial resources to implement and maintain the project.

Camden Hospital Market Area

1. Virtua-West Jersey Hospital Marlton

STATE HEALTH PLANNING BOARD
CERTIFICATE OF NEED PROJECT SUMMARY
ELECTIVE ANGIOPLASTY WITHOUT ON-SITE SURGERY BACK-UP
DEMONSTRATION PROJECT

Applicant:	Virtua West Jersey Hospital Marlton (Marlton)
CN Number:	FR 071230-03-01
Location:	Marlton, Burlington County
Project Cost:	$ 0

PROJECT DESCRIPTION

Applicant is proposing to provide elective PCI without back-up surgery on-site and further proposes to participate in the Atlantic C-PORT, Elective Angioplasty Study, a multi-state demonstration trial to assess safety, quality and cost of elective PCI offered at community hospitals that do not offer cardiac surgery services on site. Marlton is a current participant in the Atlantic C-PORT-E trial, having been CN approved in 2005 and licensed by the Department in 2006. There are no construction or project costs associated with this project. The applicant proposes to continue to contract with AtlantiCare Regional Medical Center (AtlantiCare) as the participating cardiac surgery center.

I. SUMMARY OF THE APPLICANT'S REPRESENTATIONS

A. APPLICANT JUSTIFICATION

Marlton asserts throughout the application, strong evidence of its ability to provide high quality cardiac services to medically underserved populations throughout a region of New Jersey that presently has limited access to elective angiography. Marlton is in the top 15% of New Jersey hospitals in an evaluation of the treatment of heart attacks. Marlton states that it is highly qualified to continue enrolling patients in the Atlantic C-PORT-E clinical trial since it is currently an authorized trial site which meets the study's guidelines; has a rapidly increasing cardiac program that provides a high case volume for use in the project's evaluation process; and has the clinical expertise and quality measures to continue participating to participate in the trial. Marlton's already trained and experienced professional team can ensure that the trial and the elective PCI service will not be interrupted after the CN process is complete.

B. STATUTORY CRITERIA

a. The availability of facilities and services that may serve as alternatives or substitutes.

Through its current participation in the C-PORT-E trial, the applicant is the only provider of elective angioplasty without cardiac surgery on site in its service area. There are four cardiac surgery centers in the region that provide elective PCI: AtlantiCare, Cooper

University Medical Center, Deborah Heart and Lung Center and Our Lady of Lourdes Medical Center.

b. The need for special equipment and services in the area.

The applicant indicates that there is no need for additional equipment or services for this project.

c. The adequacy of financial resources and sources of present and future revenues.

The applicant states it has the financial resources to implement this project.

d. The availability of sufficient staff in the several professional disciplines involved.

The applicant states that the existing staff which support the project include: 5.8 RNs, 2.0 Management, 1.9 RT, 1.0 Staffing Analyst. The applicant states that this staffing compliment satisfies staffing requirements.

e. The project is necessary to provide required health care in the region.

The applicant states that currently there are no providers of elective angioplasty without cardiac surgical back-up on site in its service area.

f. The project will not have an adverse impact on access to health care services in the region or Statewide.

Our Lady of Lourdes Medical Center is Marlton's primary referral center (258, or 94.5% of Marlton's angioplasty and cardiac surgery referrals in 2006). *Our Lady of Lourdes angioplasty volume was 2,343 in 2006 and the impact of 75% of Marlton's referrals being lost would account for 194 cases or 8.3% of Our Lady of Lourdes' volume, assuming all the referrals were for angioplasty.*

Department analysis of 2006 UB discharge data indicates the percentage of each cardiac surgery center's PCI cases which came from each applicant's service area. Service area is defined as those zip codes that comprise 75% of an applicant's discharges using 2006 UB discharge data, reported by the applicants in completeness responses. The impact is as follows: 4.7% of AtlantiCare, 31% of Cooper Hospital's, 2.2% of Deborah Heart and Lung Center's, and 37.6% of Our Lady of Lourdes MC's PCI cases came from Virtua-Marlton's service area in 2006.

C. DEMONSTRATION PROJECT CRITERIA AT N.J.A.C. 8:33-3.11(e)

The applicant has sufficiently documented the ability to satisfy demonstration project eligibility criteria at N.J.A.C. 8:33-3.11(e)4 and the Atlantic C-PORT-E trial site inclusion criteria, including: (a) how the applicant will satisfy the patient selection criteria specified in the Atlantic C-PORT-E protocol, which is designed to assure informed consent and appropriate randomization, as provided in the Manual of Operations (N.J.A.C. 8:33-3.11(e)6iii); (b) approval of the study protocol by the applicant's

Institutional Review Board, and if approval is pending, the status of that application (N.J.A.C. 8:33-3.11(e)6iv); (c) how the applicant will meet the target volume specified in the Atlantic C-PORT-E protocol of primary and elective angioplasties performed at the applicant's site, after randomization (that is, 100 PCI cases in year one and 200 cases in year two and each year thereafter) (N.J.A.C. 8:33-3.11(e)6v); (d) the applicant's compliance with the criteria for performance of primary PCI at N.J.A.C. 8:33E-2.16, 2.16(b) and N.J.A.C. 8:43G-7 (N.J.A.C. 8:33-3.11(e)6vi); and (e) documentation of the applicant's willingness to report elective PCI data to the Department separate from data collected as part of the study protocol, to support the Department's ongoing monitoring of cardiac services pursuant to N.J.A.C. 8:33E-1.9 and 2.10 (N.J.A.C. 8:33-3.11(e)6vii).

a. C-PORT-E Study Site Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6i):

The applicant has documented how it would satisfy the study site inclusion criteria specified in the Atlantic C-PORT-E protocol, including: (1) capability of performing a minimum volume of diagnostic cardiac catheterizations per year (N.J.A.C. 8:33-3.11(e)6i(1)); (2) agreement to complete an elective PCI development program (N.J.A.C. 8:33-3.11(e)6i(2)); (3) agreement to abide by physician, patient and device selection criteria defined in the study's Manual of Operations (N.J.A.C. 8:33-3.11(e)6i(3)); (4) agreement to collect and transmit study data in a timely fashion (N.J.A.C. 8:33-3.11(e)6i(4)); (5) agreement to perform elective PCI only via the study protocol and only while cases are being enrolled in the study (N.J.A.C. 8:33-3.11(e)6i(5)); and (6) agreement to develop and maintain a quality and error management program, including a weekly interventional conference and monthly quality and error management review (N.J.A.C. 8:33-3.11(e)6i(6)).

b. Participating Interventional Cardiologist Inclusion Criteria (N.J.A.C. 8:33-3.11(e)6ii):

The applicant has documented that its participating interventional cardiologists have agreed to: (1) be in compliance and continue to be in compliance with minimum annual statewide interventional volume standards as set forth at N.J.A.C. 8:33E-2.16(b)6 (N.J.A.C. 8:33-3.11(e)6ii(1)); (2) practice in accordance with Atlantic C-PORT-E trial defined device and patient selection criteria (N.J.A.C. 8:33-3.11(e)6ii(2)); (3) obtain necessary informed consent for patient participation in the demonstration including the identity and location of the participating cardiac surgery center(s) that are to receive randomized study patients (N.J.A.C. 8:33-3.11(e)6ii(3));

Participating Interventional Cardiologist Performance Criteria:

1. The applicant states that all interventionalists have met the annual statewide interventional volume standard of 75 cases in 2006 and that its participating physicians will continue to meet this standard in accordance with N.J.A.C. 8:33E-2.16(b)6.

2. *Listed below are participating physicians and their respective 2006 angioplasty case volumes*. *Staff Note: Department staff found that both interventional cardiologists met the 75 case annual interventional volume standard.*

Physician Name	All facilities where physicians perform angioplasties.
Mintz, Randy T.	Our Lady of Lourdes, AtlantiCare MC, Virtua Marlton *(267 cases)*
Kovach, Richard C.	Our Lady of Lourdes, AtlantiCare MC, Virtua Marlton *(305 cases)*

Source: Marlton completeness response Table 4 and NJDOH Cardiac Registry

c. Additional Demonstration Project Evaluative Criteria (N.J.A.C. 8:33-3.11(e)7i.-iv.):

i. Ability to offer a high quality program.

a. Licensure: *Marlton's PCI program is conditionally licensed effective May 1, 2008 for failure to achieve compliance with facility volume standards.*

b. Outcomes:

Marlton's Diagnostic Cardiac Catheterization Outcomes

	2005		*2006*	
	# of Cases	*% of Total*	*# of Cases*	*% of Total*
Total Cases	*749*	*n/a*	*972*	*n/a*
Death in Hospital	*0*	*0%*	*3*	*.31%*
Death in Lab	*0*	*0%*	*1*	*.10%*
All In lab Complications	*3*	*.40%*	*0*	*0*

Source: NJDHSS Cardiac Data Registry (unaudited data)

In 2005, the Department reports 749 cases and three complications, while Virtua reports 767 cases and two complications. In 2006, the Department reports 972 cases three deaths in lab and zero complications while Virtua reports 956 cases, two deaths in hospital and one complication.

ii. Representation of State's diverse regions and urban/suburban/rural population.

Marlton is located in Burlington County, in the Southern region of the state. The 2000 U.S. Census Bureau table titled "Urban and Rural Population: New Jersey, Counties and Municipalities" reports that Medford and Pemberton are 12% rural, while the remainder of Marlton's service area is considered to be urban.

iii. Potential to increase access to care for minorities and medically underserved.

As presented in the tables below, Marlton's total service area population is comprised of 11.54% non-white and the 45 and over population is comprised of 10.45% non-white. *Marlton's diagnostic cardiac catheterization patient population of non-white patients was 13.8% in 2005 and 12.4% in 2006. Marlton's minority use rate of diagnostic cardiac catheterization was above the % of non-white residents in the service area population in 2005 and 2006.*

Virtua Marlton's Service Area Population by Race and Age Distribution

Age	Total	White	Non-white	% of Non-White to Total Population
< 45	51,059	40,495	10,564	20.69%
45 - 64	223,601	191,910	31,691	14.17%
65-74	99,477	90,673	8,804	8.85%
75-84	96,836	93,314	3,522	3.64%

85+	7,923	7,222	701	8.85%
Total	478,895	423,614	55,281	11.54%

Source: Marlton completeness response table 5b and c (2000 US Census)

Virtua Marlton's Diagnostic Cardiac Catheterization by Race

	White Non-Hispanic	*Black Non-Hispanic*	*Hispanic*	*Asian & Pacific Islander*	*Other*	*% of Non-White Cases*
2005	*86.2%*	*7.2%*	*1.7%*	*.4%*	*4.5%*	*13.8%*
2006	*87.6%*	*7.2%*	*1.2%*	*.5%*	*3.5%*	*12.4%*

Source: NJDHSS Cardiac Catheterization Data Registry

The applicant states that the non-white population (including Hispanics) in the year 2000 was 23.3% in Burlington County, 31.5% in Camden County and 14.9% for Gloucester County.

iv. Projected demonstration project elective angioplasty case volume

Based on the average 840 cardiac catheterizations performed between 2005 and 2007, a 30% conversion rate would be 252 patients, of which a maximum of 75%, or 189, would be randomized and eligible to participate in the research project at Marlton, assuming they all meet the patient eligibility criteria of the research study and gave informed consent. In addition to the 189 elective angioplasties anticipated, Marlton performed 35 primary PCIs in 2007. Total annual volume of PCIs projected based on past performance would be 224, which is above the 200 minimum C-PORT-E demonstration project requirement. As a current C-PORT-E participant, Marlton has performed 105 total PCIs in 2006 (53 elective, 52 primary) and113 total PCIs in 2007 (78 elective, 35 primary).

The applicant does not anticipate any impact resulting from the closure of Muhlenberg Regional Medical Center.

II. FINANCIAL

Department staff reviewed and found that the applicant has documented adequate financial resources to implement and maintain the project.