

THE STATE OF SOUTH CAROLINA
IN THE COURT OF APPEALS

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

SC Court of Appeals

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

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

v.

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

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

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

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January 15, 2020
Columbia, South Carolina

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1 this either, correct?

2 A: They did not.

3 Q: Okay.

4 A: Well they may have but not to remove St.
5 Francis.

6 Q: And whatever history there is regarding this
7 word existing, this is about the closest thing
8 that we get to it in all of the documents that
9 we've seen, correct? It deals with Standard 3,
10 which has the word existing but at that time it
11 was an aggregate standard, correct?

12 A: It was an aggregate standard. It was applied
13 a little bit differently, yes.

14 Q: Okay. So after the email -- I'm just going to
15 ask you -- the Petitioner's 5 email, ---

16 A: Okay.

17 Q: --- that does it appear to you that the
18 Department is going to take enforcement action
19 against the hospital for operating the service
20 that doesn't exist?

21 A: Are you -- you're referring to Mr. Eubank's
22 letter?

23 Q: Uh-huh.

24 A: It appears to me that they are putting St.
25 Francis on notice that they are going to take



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1 enforcement action to formally close the lab
2 if St. Francis does not provide an adequate
3 proposal to address the situation within ten
4 days.

5 Q: Okay. Would you agree with me that DHEC was
6 not going to approve East Cooper's CON
7 application without some sort of action on the
8 part of Roper with respect to closing the St.
9 Francis lab at some time?

10 MS. BIGGERS: Objection. That calls for speculation
11 on the part of -- for her -- for the witness to
12 speculate regarding the Department.

13 THE COURT: I agree. I sustain that objection. Mr.
14 Thomas she's -- she doesn't have any mind
15 reading ability to know what Mr. Eubank or the
16 Department would have done.

17 MR. THOMAS: Fair enough. I'll move on.

18 Q: Okay. Let's go to Petitioner's 5, page three
19 and four. Mr. Long asked you some questions
20 about that as well.

21 A: Okay.

22 Q: Do you take issue with anything that your
23 client said in this letter or stated in this
24 letter?

25 A: Not that I can think of.



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1 Q: Nothing, right?

2 A: Not that I can think of.

3 Q: Okay. And nowhere in the letter does Roper
4 state that it will close it's lab if it is not
5 approved, correct?

6 A: I don't believe that language is in this
7 letter.

8 Q: Okay. And would you at least agree with me
9 that for purposes of Standard 3, St. Francis
10 certainly believed that its cath lab existing
11 during the most recent year?

12 A: Could you ask that question again?

13 Q: Yeah. Would you agree with me that for
14 purposes of Standard 3, St. Francis certainly
15 believed its cath lab existed during the most
16 recent year? At this time the effected person
17 letter was written?

18 A: I don't think that's dealt with in this letter.
19 This letter is speaking to the East Cooper
20 challenge that St. Francis has lost its
21 authorization to provide services based on
22 utilization back in '08, '09, so I don't know
23 that that was dealt with in this letter.

24 Q: Okay. So, explain it on the record, do you
25 think St. Francis believed that it was an



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1 existing cath lab for purposes of Standard 3 at
2 the time that applied for a CON application of
3 Roper Berkeley?

4 A: St. Francis had not lost its authorization as
5 a cardiac cath lab. But its intent was to
6 close its lab formally so that it would no
7 longer exist. It would not continue to exist
8 at any time simultaneously with the proposed
9 application. So, for the purposes of Standard
10 3, it did not exist.

11 Q: Do you believe -- all right. So that
12 contradicts page 30 and the table where you say
13 utilization of existing labs. That was
14 incorrect information that you put in the CON
15 application, correct?

16 A: It was a table that presented all of the
17 reporting providers and perhaps it inartfully
18 used the word existing in the title. But it
19 was meant to show all reporting providers and
20 their data in full transparency for the three
21 years prior to filing the application.

22 Q: But you don't believe that Roper Berkeley's
23 diagnostic cath lab is in existence today for
24 purposes of Standard 3, do you?

25 A: It does not exist today.



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1 Q: Okay.

2 **MR. THOMAS:** Bear with me, Your Honor. I'm going
3 through a couple things in my outline. We've
4 covered a lot of ground.

5 Q: Just some questions about this whole FOIA
6 thing. What is your understanding of what
7 Trident would have done differently had they
8 had FOIA'd all of this information? That the
9 other side wants us to FOIA or said that we
10 should have FOIA'd? How does that -- do you
11 think that changes what Trident would have done
12 as a health planner?

13 A: I think they might have presented their
14 opposition letter a little differently. I
15 don't know that they would have even bothered
16 addressing the transfer criteria because at no
17 point was there ever any mention of a plan to
18 transfer a lab. So they may have presented
19 their opposition letter differently.

20 Q: They certainly wouldn't have conceded, right?
21 I mean, and said, oh, well, we're good with
22 this?

23 A: I think they probably would have opposed no
24 matter what.

25 Q: Okay. Now I think you were asked a question



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1 about whether or not you were -- that you don't
2 believe there was any kind of agreement between
3 DHEC and Roper, correct? In terms of, hey, you
4 apply and we'll approve it, right?

5 A: I don't believe there was an agreement. There
6 was a proposal by Roper St. Francis that they
7 hoped would meet DHEC's concerns about the lab.

8 Q: And then that email that I'm not going to drag
9 back up in terms of the Exhibit, but the email
10 where it says everything will work out for
11 everybody, you weren't aware of that email were
12 you?

13 A: Is that the one with Mr. Levitt? Or, which is
14 it?

15 Q: Between Mr. Levitt and Mr. Eubank.

16 A: I was not aware of that. That was not -- that
17 was part of the East Cooper file. That was not
18 this project.

19 Q: That email never made it to the DHEC record did
20 it? The East Cooper?

21 A: I don't believe it did.

22 Q: Okay. It didn't make in the DHEC record for
23 the St. -- or for the Roper Berkeley
24 application either, correct?

25 A: I don't think it was relevant to this. The St.



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1 Francis application was Mr. Levitt who was the
2 consultant for East Cooper.

3 Q: Okay. Now you agree with me there's no project
4 review for Trident in this situation, correct?

5 A: There was no project review meeting.

6 Q: Okay. And you stated I believe in terms of not
7 having enough time to respond to Trident's
8 opposition letter, is that what you stated?
9 That ---

10 A: I believe that the opposition letter was filed
11 on a Thursday and the decision was issued
12 Monday. So there wouldn't have been time for
13 us to respond.

14 Q: Did you know when the decision was going to be
15 issued?

16 A: No.

17 Q: Okay. Did you realize at the time that it was
18 going to be issued by the deadline for East
19 Cooper's application to be approved?

20 A: Not necessarily. I mean, I understand Mr.
21 Eubank's explanation for why. It made sense,
22 but I don't know that we necessarily knew that.

23 Q: Right. Because that was pretty quick, right?
24 From the time of application, to double
25 publication, to approval, correct?

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1 A: It was faster than some reviews but it wasn't
2 -- I mean, it was in the normal process.

3 Q: Okay. But you would agree with me that's a
4 pretty -- that's a pretty quick time line for
5 DHEC on a CON application like this, right? In
6 your experience as a health planner in this
7 situation?

8 A: As I said, it's faster than some, yes. But
9 it's -- I mean, it's within the -- their
10 guidelines and their time frames for review.

11 Q: Okay. Now the serious email -- remember -- do
12 you remember Mr. Long asked you is this a
13 serious email about Mr. Eubank's email?

14 A: Yes.

15 Q: Okay. It was never -- it was never shown to or
16 shared with you, correct?

17 A: I don't recall receiving it until we were into
18 this case.

19 Q: Okay. And you -- Mr. Long asked you a few
20 questions about OR, like different, you know,
21 situations where something might shut down and
22 something might open up, do you recall that?

23 A: Yes.

24 Q: But -- and you -- one of the examples you gave
25 was OR's, correct?



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1 A: Yes.

2 Q: There are no standards in the Health Plan for
3 OR's, right?

4 A: There are no standards in the Health Plan for
5 hospital OR's.

6 Q: All right.

7 A: There are for ambulatory surgery centers but
8 when you're looking at the need for ambulatory
9 surgery centers, one of the criteria requires
10 you to show where those patients are coming
11 from which would affect the utilization of
12 hospital OR's.

13 Q: Okay. But there are no standards in the Health
14 Plan for hospital OR's, correct?

15 A: That is correct. In and of themselves. But,
16 again, they're related to ambulatory surgery
17 which is a part of the State Health Plan.

18 Q: Okay. And in fact there's no inventory of
19 hospital OR's in the State Health Plan either,
20 is there?

21 A: There is not.

22 Q: But there is for ASC's, right?

23 A: Yes.

24 Q: Okay. And I believe Mr. Long asked you
25 questions about project review criteria and



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1 where those are listed, and I think you said in
2 the CON regulation, correct?

3 A: Yes.

4 Q: But they're also listed out in each of the
5 health planning standards for the various
6 health services, correct?

7 A: Uh-huh.

8 Q: Okay.

9 A: Some of them are. The ones that are deemed to
10 be most relevant or most important to those
11 services are also listed in the State Health
12 Plan.

13 Q: Okay. And the most important one in this case
14 that was listed is compliance with the State
15 Health Plan, correct?

16 A: I believe that was listed as first.

17 Q: Okay. And when you're reviewing a CON
18 application that's kind of the first thing you
19 look at as a health planner? You make sure
20 that it's in compliance with those standards in
21 the Health Plan, correct?

22 A: I mean, that certainly something I look at. I
23 think I probably focus on that and need
24 together as the most important.

25 Q: Okay. Mr. Long asked you a couple questions



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1 about quality of the existing labs and you
2 mentioned that Mr. Eubank referenced that and
3 that you agreed with what he said about the
4 quality aspects of Standard 3, correct?

5 A: I think there is an underlying quality
6 component that was considered in drafting
7 those. I also agree with his assessment that,
8 you know, quality in and of itself was not
9 necessarily an issue with St. Francis because
10 it's part of a system. The system obviously a
11 high volume system and those cardiologists are
12 providing, you know, a larger number of cases.
13 Just not at St. Francis.

14 Q: All right. And you never go on the quality in
15 B-11? You never talk about the aspects of
16 quality of St. Francis, correct?

17 A: Not in that part of the application. I don't
18 that we've necessarily touched on quality
19 there.

20 Q: Okay. Are you aware of any type of formal
21 flexibility exception in the standards for
22 diagnostic cath?

23 A: I don't know that it sets out -- the standards
24 set out the word exception explicitly. But,
25 again, they're standards that need to be

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1 interpreted.

2 Q: Okay. And in terms of cath labs near you go --
3 you gave with the two years, that's like a
4 worse case scenario isn't it, Ms. Platt? If
5 it's unopposed?

6 A: That would be worse case if some -- if the
7 closure happened after a plan was adopted. If
8 it had happened, you know, mid-way between
9 plans, then certainly that time frame would be
10 adopted. But if DHEC was not able to still
11 respond to it, waiting for another health plan
12 would cause additional delay for the services
13 to resume in the market.

14 Q: But you're not aware of this situation coming
15 up at any time in your history of doing state
16 health planning in South Carolina for caths,
17 correct?

18 A: That exact scenario, I can't think of that
19 occurring. But I think it's a relevant example
20 because it would be, you know, similar to, you
21 know, any other service might close and you
22 want to be able to make sure those services are
23 available to the population.

24 Q: It hasn't happened in caths since you've been
25 doing health planning in South Carolina, has



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1 it?

2 A: I can't think of that exact scenario occurring
3 but it certainly could.

4 Q: So it's so rare it's never happened in your
5 health planning lifetime in South Carolina,
6 correct?

7 A: Again, I don't know that I can think of a
8 situation where it's occurred.

9 Q: Fair enough. I'll go with that.
10 And you were also given another scenario about
11 there are two hospital in the community, one
12 has cath and one doesn't and the one with the
13 cath closes, right? That could pose some kind
14 of problem?

15 A: It could cause absence of a service in a
16 community.

17 Q: And maybe if that community is say, Lee County
18 and with a very low population where they can't
19 get cardiologists to go there, and they can't
20 get patients that want to get a cath in a
21 diagnostic cath lab -- a low volume cath --
22 maybe it's -- could be a good idea that they
23 don't have cath labs in that county, right?

24 A: It would depend on the situation. You'd have
25 to look at it in each market independently.



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1 Q: Okay. Because, as you said, and I believe this
2 -- Ms. Biggers' reference with Mr. Eubank and
3 the State Health Plan, quality is an issue,
4 correct?

5 A: Quality is definitely a consideration. But I
6 think the most important thing is that
7 regardless of the exact scenario, the agency
8 has the flexibility to be able to respond and
9 look at the specifics of the market in that
10 situation in the context of these standards.

11 Q: Now I think you've stated in response to
12 question Mr. Long asked you about Mr. Sullivan
13 and the positions they took in his opposition
14 letter. That it's not right or it's
15 contradictory that he considers an existing lab
16 for Standard 3 but not existing for the
17 transfer provision, correct? Is that your
18 testimony?

19 A: I mean existing is existing. If it exists,
20 then it would exist for transfer and you can't
21 have it existing for one and not the other.

22 Q: You can't have it both ways, right?

23 A: You can't have it both ways. You can either --
24 it either exists or it doesn't. So if it
25 doesn't exist for the purposes of Standard 3,



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1 it doesn't exist for transfer.

2 Q: Okay. But in your CON application that you
3 drafted B-11, you've got it existing for
4 purposes of determining the need for the
5 service area and the table you list for it says
6 existing cath labs, but for purposes of
7 approving the cath lab it can be non-existent,
8 right?

9 A: As I said, the table is showing all reported
10 providers in the -- in an effort to be
11 completely forthcoming and transparent we
12 provided all data for all reported providers,
13 and then we described how the plan was for the
14 lab to formally close and it would never be in
15 existence, one, at the same time as the
16 proposed lab and would not be available to meet
17 the need identified in the application.

18 Q: Okay. So it's not contradictory in that CON --
19 in the CON application but it is Mr. Sullivan's
20 letter? That's your position, right?

21 A: I don't believe what we put in the application
22 was contradictory. I believe Mr. Sullivan's
23 letter was contradictory.

24 Q: Okay. But you would agree with me this wasn't
25 a transfer situation now, right?



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1 A: It is not a transfer.

2 MR. THOMAS: Okay. I don't have any further
3 questions, Your Honor.

4 THE COURT: All right. Any redirect?

5 MR. LONG: Can I have a moment? No, we don't have
6 any redirect, Your Honor. Thank you.

7 THE COURT: All right.

8 MR. LONG: Your Honor, this is our only witness, so
9 ...

10 THE COURT: Ms. Platt, you may return to your seat.

11 MR. THOMAS: Your Honor, if I could have maybe 10
12 minutes with my expert so we can just kind of
13 go through, and I don't think my rebuttal case
14 is going to take any time whatsoever. We'll be
15 out of here before 4:30 if that.

16 THE COURT: Okay. Well, what a problem. We'll just
17 take about 10 minutes. Let me, before we do
18 that, we have the availability, if you chose
19 to accept it, to have a closing argument. You
20 may or may not want to use that time.
21 Alternatively, or in addition to, depending on
22 your point of view, the Court would entertain
23 proposed orders from both sides. Ms. Biggers
24 if you want to add your own you're welcome to
25 it. What would be a time frame for that is



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1 something you might think about in the few
2 minutes if you want to. If you want to say it
3 now that's fine, but if you want to take a few
4 minutes while we're thinking about ---

5 **MS. BIGGERS:** We'll respond when we come back from
6 the restroom.

7 **THE COURT:** All right. That'd be great. We'll take
8 ten.

9 (Off the record from 3:34 p.m. until 3:46 p.m.)

10 **THE COURT:** Mr. Thomas, you're gonna put Mr.
11 Sullivan back on the chair?

12 **MR. THOMAS:** Yes, sir. Just for a few minutes.

13 **MR. SULLIVAN - DIRECT EXAMINATION BY MR. THOMAS:**

14 Q: Good afternoon, Mr. Sullivan.

15 A: Good afternoon.

16 **THE COURT:** Just to remind you, sir, that for the
17 purpose of this proceeding you're still under
18 oath.

19 **MR. SULLIVAN:** Yes, Your Honor.

20 Q: Mr. Sullivan, we heard from the DHEC witness
21 and the Roper witness about this idea of
22 quality and, you know, the addition of another
23 service and taking one away, and so on and so
24 forth. But do you have an opinion as to
25 quality as it relates to Standard 3 and what

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1 the Department is looking for based on your
2 experience?

3 A: I do. And, I mean, I think Mr. Eubank went
4 over the first part of the section on cardiac
5 catheterization services and talked about
6 setting specific standards in terms of volume.
7 And there's -- so there's definitely literature
8 that talks about the correlation between the
9 volume of procedures performed and the quality
10 of the outcomes for the patients. You know,
11 within the broader context of the certificate
12 of need law, you want to avoid unnecessary
13 duplication of healthcare services and in part
14 because you want to ensure the quality of the
15 services that are being provided. Approving an
16 unnecessary cath lab could result in diluting
17 the volumes of existing providers. Which could
18 have an affect on the overall quality of the
19 services that are being provided.

20 Q: And in terms of closing the program at St.
21 Francis, how many patients are really affected
22 by that?

23 A: Well somewhere between three and seven
24 depending on which year you're in. So, I mean,
25 I don't think that there's really a quality



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1 issue as it relates to the closure of that
2 particular lab.

3 Q: And are they -- is there a dearth of providers
4 in the cath lab area in Charleston?

5 A: There are not. I mean, as we heard there are
6 11 other cath labs at three other programs.
7 And, specifically as it relates to the Berkeley
8 County area, Trident has a comprehensive
9 cardiac cath program located only about seven
10 miles away from Roper Berkeley is being
11 constructed.

12 Q: Okay. We heard a little bit about the purpose
13 of the CON Act with respect to Standard 3. Do
14 you have any opinions about that?

15 A: I do. You know, I think that, as I mentioned
16 earlier, I think that Standard 3, one of the
17 focuses of Standard 3 is to avoid unnecessary
18 duplication of healthcare resources. And, you
19 know, by having a floor if you will in terms of
20 what the minimum historical utilization is for
21 existing providers, that's to try to avoid
22 unnecessary duplication as both to quality
23 implications that I talked about before and it
24 also has economic implications. If you have
25 too many cath labs and the volume is

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1 insufficient then it becomes harder for
2 existing programs to maintain economic
3 viability.

4 Q: Okay. Thank you. Ms. Platt was specifically
5 asked about your kind of estimation of this as
6 a bizarre situation.

7 A: Okay.

8 Q: Why -- first of all, let me ask you this, I
9 think you testified earlier that you've been
10 doing CON work in South Carolina for the better
11 part of 37 years, is that right?

12 A: Right.

13 Q: Have you ever seen a situation even similar to
14 this in terms of the closure of a lab upon the
15 approval when there's a standard out there that
16 may be indicates that that should not have
17 happened?

18 **MS. HOLLINGSWORTH:** Your Honor, if I could object.
19 I think the question was improper because he's
20 making an assumption about the standard and
21 that's really not fair in terms of the question
22 he's asking. He's putting a conclusion saying
23 that the standard doesn't allow that and I
24 think that's him making a conclusion on the
25 ultimate issue and not just simply getting his



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1 opinion about prior experiences.

2 **MR. THOMAS:** I can rephrase it, Your Honor.

3 **THE COURT:** My understanding of the question was
4 that he was asking if this scenario had
5 occurred, which I assume doesn't have anything
6 to do with the standard so much as the timing
7 of the application and approval. Did I
8 understand ---

9 **MR. THOMAS:** Right.

10 **THE COURT:** --- is that correct?

11 **MR. THOMAS:** And I should have said Trident's
12 contention ---

13 **MS. HOLLINGSWORTH:** Right.

14 **MR. THOMAS:** --- that it was not a proper closure in
15 terms of timing at the lab.

16 **MS. HOLLINGSWORTH:** My objection, Your Honor, was
17 for the ending of the question where he said
18 where there's a standard that doesn't allow
19 that to happen, so.

20 **THE COURT:** Okay.

21 **MS. BIGGERS:** That's ---

22 **THE COURT:** I understand that. Let's just -- let's
23 rephrase the question then. Maybe rephrase it
24 so it's more what I heard.

25 **MR. THOMAS:** How about I just make it real simple,



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1 Your Honor.

2 Q: Have you ever seen a situation like this before
3 in your 37 years, Mr. Sullivan.

4 A: I have not where an applicant proposes to close
5 a service in one location contingent on the
6 approval of an application to provide the
7 service at another location, except as I think
8 I testified on direct, in cases of transfers of
9 services. But I've never seen this particular
10 situation before. Which is why I classified it
11 as bizarre.

12 Q: Okay. When Ms. Platt stated that at the four
13 standards that are applicable on the Health
14 Plan to diagnostic cath, she found Standard 4
15 to be more important. Do you agree with that
16 opinion, Mr. Sullivan?

17 A: I do not.

18 Q: Why not.

19 A: Because I think Standard 3 is really the
20 threshold issue. And that is should there be
21 another provider in the market. Standard 3
22 establishes whether or not there's a community
23 need using objective measures. And then once
24 you cross that threshold, then you get into
25 Standard 4, which is will the applicant be able



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1 to provide a reasonable volume of service. So
2 I believe that Standard 3 really is the
3 critical determination. You don't get to
4 Standard 4 unless you pass Standard 3.

5 Q: Okay. And in terms of this idea of flexibility
6 that was espoused by Ms. Platt and Mr. Eubank
7 with respect to the State Health Plan as a
8 whole, do you have any opinions about that and
9 their testimony.

10 A: I do. I mean I don't disagree that there has
11 to be a certain amount of flexibility in health
12 planning and in applying the South Carolina
13 Health Plan. But that flexibility doesn't mean
14 that you have objective standards that change
15 from project review to project review. I think
16 there needs to be a common understanding of
17 what is the inventory of services. Those
18 inventories can change with approvals of new
19 projects, and obviously you have to factor that
20 in. If externally someone closes a cath lab,
21 you would obviously factor that in to the
22 analysis. But that's a whole different type of
23 flexibility than what they're proposing here
24 and that is let's figure out a way to get rid
25 of this meddlesome, under utilized lab. Here's

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1 a solution, we can let them close it after the
2 fact and say we don't have to consider it. But
3 the standard I think is pretty clear and I
4 think there are good health planning reasons
5 why the standard is what it is. So I think
6 flexibility is appropriate, but I don't think
7 it's appropriate in this particular instance.

8 Q: And you certainly don't believe -- or, do you
9 agree with Ms. Platt's conclusion that this
10 decision complies with Standard 3 of the Health
11 Plan?

12 A: I do not.

13 Q: Do you believe that this is -- this decision
14 and this proposal is consistent with the South
15 Carolina Health Plan?

16 A: I do not.

17 Q: Okay. The last question I have for you and
18 three sub-parts. You're from -- originally
19 from Charleston, South Carolina, correct?

20 A: I am.

21 Q: Okay. And you have -- you actually live
22 between two cities now, Charleston and Atlanta,
23 is that right?

24 A: That's right.

25 Q: Okay. You heard testimony from Ms. Platt that

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1 Roper and St. Francis are relatively close to
2 one another in terms of facilities?

3 A: Yes.

4 Q: Okay. Do you agree with that?

5 A: I do not.

6 Q: Why not?

7 A: Well, first of all, the whole logic between
8 relocating St. Francis from the peninsula out
9 to the West Ashley area was because patients
10 had access problems coming into the peninsula
11 for services and it would be more appropriate
12 to serve those patients there. Secondly, that
13 area around St. Francis has developed
14 dramatically over the last 10 years. And
15 anybody who's driving from the peninsula -- the
16 easiest way to get to St. Francis is on 526,
17 which is a loop road outside of Charleston.
18 But if you're downtown you're not getting on
19 526, you're going to go up 17 or 61 out of town
20 and those are very busy roads for good portions
21 of the day. And then you have -- the last
22 stretch is you've got to get on Ashley River
23 Road to get to St. Francis or go some other
24 back way. And, you know, I guess you could
25 drive up 17 to Savage Road and go across that



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1 way, but those are very busy roads and during
2 certain times of the day it's a very difficult
3 commute. And it's something people in
4 Charleston complain about all the time, but.

5 Q: That's all the questions I have. Please answer
6 anything from Ms.

7 MS. HOLLINGSWORTH: Can I have just a couple
8 minutes, Your Honor?

9 THE COURT: Yeah.

10 MR. SULLIVAN - CROSS-EXAMINATION BY MS.

11 HOLLINGSWORTH:

12 Q: Mr. Sullivan, just a couple of questions, I
13 promise. And they won't even have multiple
14 sub-parts, it's just a few questions.

15 A: Okay.

16 Q: I did want to ask you though, in your first
17 discussions with Mr. Thomas just now in
18 addressing that there are discussions of
19 quality in the cardiovascular care chapter of
20 the Health Plan, is that right?

21 A: That's right.

22 Q: And you agree there is in several places within
23 the cardiovascular care chapter discussions and
24 references to quality, is that right?

25 A: Sure, and in much more detail in relation to



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1 therapeutic catheterization.

2 Q: Okay. But you would agree with me that in
3 interpreting the State Health Plan the
4 Department is required to read each section as
5 a whole, right?

6 A: Sure.

7 Q: Okay. So would that include references in
8 discussion of quality throughout the
9 cardiovascular care chapter?

10 A: Sure.

11 Q: Okay. I think you testified just now when you
12 were talking about Roper and the proximity to
13 St. Francis. And I believe your testimony was
14 that you disagree that they're not relative
15 close, is that right?

16 A: Right. I mean, by Charleston standards. By
17 Atlanta standards they're pretty close, but ---

18 Q: Okay.

19 A: --- but by Charleston standards. I mean, my
20 experience in driving from downtown to St.
21 Francis, which I had to do about a week ago,
22 and it takes somewhere between 20 and 30
23 minutes depending on the time of day to get
24 from downtown to the St. Francis campus.

25 Q: But do you agree with me the difference -- the



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1 distance between Roper Downtown's campus and
2 the St. Francis campus, is that roughly six or
3 seven miles?

4 A: It may be seven miles.

5 Q: Seven miles?

6 A: Yeah.

7 Q: So is your testimony that seven miles isn't
8 relatively close?

9 A: Depending on the roads you have to cross to get
10 there, it's a difficult commute. I mean, I
11 guess my point was that I don't think that the
12 reason why the St. Francis cath lab was not
13 being utilized is because Roper is so close.
14 I think there's enough distance there that
15 patients, I think in many cases would like to
16 be served there if the services were available.

17 Q: Would you agree with me though that moving a
18 service 20 or 30 miles into a completely
19 different population center where it would be
20 more highly utilized, isn't that good health
21 planning in guiding the distribution of
22 services?

23 A: If there were a need for the service.

24 Q: Would you agree with me -- your testimony about
25 diluting the volume of existing providers --



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1 that's addressed in Standard 4, right? Of the
2 diagnostic cath standards?

3 A: I think it's addressed in Standard 3 because
4 you don't approve another lab unless all
5 existing providers are at some threshold level
6 of utilization.

7 Q: Isn't Standard 4 the one that addresses the
8 volume the existing providers and what it
9 shouldn't drop below in projecting the
10 utilization of the plan service?

11 A: It does it there as well.

12 Q: And you testified that there's a gap in
13 Standard 3 as it relates to approved labs, do
14 you recall that testimony?

15 A: I do.

16 Q: And you would agree with me that DHEC has the
17 flexibility to address that gap, right?

18 A: They do and I think I said that.

19 Q: And I believe it is your testimony that it is
20 the job of the Department to interpret the
21 State Health Plan and apply the standards,
22 right?

23 A: Sure. As long as that's done reasonably.

24 Q: Thank you. I have nothing further.

25 A: Okay. Thank you.

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1 MS. HOLLINGSWORTH: Thank you, Your Honor.

2 THE COURT: Ms. Biggers?

3 MS. BIGGERS: I don't have any questions.

4 MR. THOMAS: I have no questions.

5 THE COURT: Mr. Sullivan, you can return to your
6 seat and ---

7 MR. SULLIVAN: Thank you, Your Honor.

8 THE COURT: --- you can find your way back to
9 Charleston.

10 MR. THOMAS: Your Honor, we conferred regarding
11 proposed Orders. I think that would be our
12 preference rather than doing closing arguments.

13 THE COURT: Okay.

14 MR. THOMAS: And we -- if it's okay with the Court -
15 - we would ask that we propose -- get you
16 proposed Orders within 45 days of receipt of
17 the transcript. Would that be okay with the
18 Court?

19 THE COURT: I was hoping for next week.

20 MS. HOLLINGSWORTH: Your court reporter might spin
21 in his chair.

22 THE COURT: I wasn't thinking about getting you a
23 transcript. I confess I really hadn't -- I had
24 not calculated that part. I was hoping for 30
25 days but I'll be glad to give you 45.



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1 **MR. LONG:** Well, Your Honor, the point is while we
2 often do all these Orders is cite to the
3 transcript.

4 **THE COURT:** I understand.

5 **MR. LONG:** And if that's helpful for Your Honor,
6 then it -- it can be burdensome and helpful for
7 us, frankly. But if that's helpful for Your
8 Honor, then we would need to get the
9 transcript. But if you -- if that's not
10 helpful to Your Honor we can confer about our
11 schedules.

12 **THE COURT:** Well, frankly, Mr. Long, I need all the
13 help I can get. So, no, that's fine with the
14 Court. 45 days from the deliver of the
15 transcript.

16 **MS. BIGGERS:** And we'll notify the Court. As soon
17 as it comes we'll let Ms. Miller know so that
18 you're aware of what that deadline will be.

19 **ADJOURNMENT:**

20 **THE COURT:** Appreciate it. Ladies and gentlemen,
21 thank you very much for your efforts on behalf
22 of your clients and on behalf of the healthcare
23 need of South Carolina.

24 (There being nothing further, the administrative
25 hearing concluded at 4:04 p.m.)

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1 (All Exhibits were marked for identification purposes
2 after the conclusion of the hearing.)
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APPLICATION FOR CERTIFICATION OF NEED
FOR A HEALTH FACILITY OR SERVICE

Proposal Prepared By:

Ms. Shannon Cantwell
Regulatory Affairs Specialist
Roper St. Francis Healthcare
125 Doughty Street Ste. 760
Charleston, South Carolina 29403
843.789.1754 phone
~~843.720.0000~~ fax
shannon.cantwell@rsfh.com

SCDHEC
Received

MAY 09 2016

Certificate of Need Program

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

Signature: Shannon Cantwell

Date: May 6, 2016

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

Trial Exhibit
16-ALJ-07-0386-CC
Joint Exhibit

J01

**APPLICATION FOR CERTIFICATION OF NEED
FOR A HEALTH FACILITY OR SERVICE**

PART A – QUESTIONNAIRE		
1. Name of Facility Roper St. Francis Hospital – Berkeley		
2. Address, City, County, State, Zip Code TBD on Highway 176 Goose Creek, SC 29461 Berkeley County		
3. Type of Facility (Circle)		
A. <u>Hospital</u>	B. Nursing Home	C. Psychiatric Facility
D. Rehabilitation Facility	E. Substance Abuse Facility	
F. Ambulatory Surgery Center	G. Other	
4. Purpose of Review (Circle)		
A. New Facility	B. Change of Licensure	Provision of diagnostic cardiac catheterization service
C. Addition to Existing Facility	D. Renovation of Existing Facility	
E. Change of Services	F. Other (Specify)-	
5. Management		
A. Name of Administrator Scott Broome	B. Address, City, State, Zip Code c/o 316 Calhoun Street Charleston, SC 29401	
C. Telephone (843) 724-2052	D. Fax Number	E. Email scott.broome@rsfh.com
6. Licensee		
A. Name of Licensee Roper St. Francis Hospital – Berkeley, Inc.	B. Address, City, State, Zip Code c/o 316 Calhoun Street Charleston, SC 29401	
7. Ownership or Control of the Facility (Circle)		
A. Individual	B. Partnership	C. <u>Corporation</u>
D. Proprietary	E. <u>Non-Profit</u>	F. Government
F. Government	G. Other (Specify)	

PART A – QUESTIONNAIRE (Continued)**8. Proposed Site of the Property (Circle)**A. Owned

B. Leased

C. Length of Site Lease:

D. Option

E. Length of Option:

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

Land: Roper St. Francis Hospital – Berkeley, Inc.

Bldg: CareAlliance Health Services

Reference B-8 for addresses

9. Total Bed Capacity for Which Application is Made: N/A**Existing Facilities**

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

PART A – QUESTIONNAIRE (Continued)	
10. Construction and Site	
A. Type of Construction New	B. Number of Buildings Pertaining to Project 1
C. Number of Stories Pertaining to Project: 1 floor	D. Size of the Site in Acres: 16.5 acres
E. Size of the Project Site in Acres 16.5 acres	F. Square Footage of the Project 1,600 s.f.
G. Anticipated Date of Beginning Construction July 2017	H. Anticipated Date of Licensing or Project Completion June 2019
I. Anticipated Date for Submission of Final Completion Report December 2019	
11. Zoning of Construction Site Carnes Crossroads Town Center (CC-TC)	
12. Costs (Provide Estimated Cost Statement from Either the Architect or Engineer)	
A. Land Cost \$0	B. Construction Cost \$643,072
C. Professional Fees \$57,876	D. Equipment Costs \$1,869,366 consisting of: \$936,494 Lab \$786,424 Other FFE \$146,448 8.5% Sales Tax
E. Financing Cost During Construction \$210,000 (capitalized interest) \$ 24,000 (1% issuance fee)	F. Other Costs (Specify) \$64,550 construction contingency \$ 4,502 signage
G. Total Project Cost \$2,873,366	H. Construction and Equipment Cost 1. Per Square Foot \$ 1,570 2. Per Bed (50 beds) \$50,249

B1. Document that the applicant has published notification of this project in a local newspaper as required by Section 201 of these Regulations.

A copy of the affidavit of publication is included in Attachment 1.

B2. Describe the project setting forth the proposed change in services or facilities in as much detail as possible. State whether the project will change the existing licensed or survey bed capacity, will encompass the development of a new service, or result in the discontinuance of an existing service. If a new facility is proposed, list all services to be provided.

The Roper St. Francis Healthcare system, a 657-bed system, includes three licensed hospitals. Roper Hospital was founded in 1850 as the first community hospital in the Carolinas. Bon Secours St. Francis Xavier Hospital opened in 1882 as St. Francis Xavier Infirmary, the first Catholic hospital in South Carolina. The third hospital, Mount Pleasant Hospital, opened in 2010. A Certificate of Need was issued in January of 2016 to Roper St. Francis Hospital - Berkeley for the construction of a 50-bed hospital in Berkeley County via a bed transfer from Roper Hospital. This will be the system's fourth hospital.

The architect is currently working to finalize the Roper St. Francis Hospital - Berkeley design, and construction is anticipated to begin in July of 2017. If approved, this project will initiate diagnostic cardiac catheterization service in conjunction with the hospital's planned opening in 2019. The project will not change Roper St. Francis Hospital - Berkeley's licensed bed capacity, nor result in the discontinuation of any service. Upon DHEC approval of the application, the diagnostic catheterization laboratory at its sister hospital, Bon Secours St. Francis Xavier Hospital, will close and the room will continue to be used as a special procedures lab.

B3. Provide the total cost of the project, indicating design fees, land cost, interest cost, construction cost, equipment cost, and any other cost involved in the project. Provide an estimate of the construction cost from a licensed architect or engineer; in the case of equipment, valid/current estimate from a vendor is acceptable.

The total project cost is outlined in the Questionnaire A-12 response above, and supporting documentation included in Attachment 2.

B4. State the specific location of the facility or service and/or equipment, including, where applicable, specific areas of an existing facility to be affected by the project. Provide room numbers of all patient rooms affected. Sufficient detail should be provided to allow the Department to visually inspect the site. The number of private and semi-private patient rooms shall be identified.

The architect will work to determine the specific location and graft the lab design (Reference Attachment 3) into the larger hospital design as it becomes available.

B5. Provide details regarding any proposed construction and/or renovations. Discuss alternatives to new construction and why these alternatives were rejected. For a multi-floor project, construction and/or renovation must be described, by floor, to include any additions and/or deletions made to each floor. Provide evidence that the applicant has adequately planned for any temporary move or relocation of any department, facility, or services, which may be necessary during the construction period. Document that plans exist to assure adequate protection (from fire, noise, dust, etc.) and continuation of all services during the proposed construction period.

There were no alternatives to new construction given the hospital is not yet built or licensed. The architect, Bruce Moore, with HDR has provided a scope narrative as a part of his cost estimate included in Attachment 2. The contractor will be responsible for ensuring adequate protection from fire, noise, dust, etc. during the hospital's construction.

B6. If a replacement facility or ancillary service is being constructed, describe plans for disposition of the existing facility or ancillary service area upon completion of the project.

Not applicable

B7. Provide a timetable for development and completion of the project to include, at a minimum, the date of site acquisition, date of architectural contract, architectural design schedule, date of closing for financing, date of valid construction contract, date that all necessary permits will be obtained, and date of start of construction. The timetable shall be presented in one-month increments commencing with the month following receipt of the Certificate of Need and ending with the execution of a contract or purchase order for equipment only projects.

Task	Est. Duration	Est. Mo / Yr
CON Issued	7 months	12/16
Complete Construction Drawings (to be incorporated into the hospital's CDs)	13 months	5/17
Bidding/Permitting	1 month	6/17
Execute Construction Contract (final GMP amendment)	1 month	7/17
Construction	20 months	2/19
Equip Hospital and Initiate Service (concurrent with hospital's initial licensure)	4 months	6/19

B8. Provide the following ownership information:**a. Proposed name of the facility.**

Roper St. Francis Hospital - Berkeley

b. Name and mailing address of Licensee/prospective Licensee. (Note: The licensee is defined as the legal entity who has ultimate responsibility and authority for the conduct of the facility or service and must be the entity to whom the CON will be issued.)

Roper St. Francis Hospital - Berkeley, Inc.
 Attn: Roper St. Francis Legal Department
 125 Doughty Street Suite 720
 Charleston, SC 29403

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

Board of Directors

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

The Chairperson has yet to be named.

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

Roper St. Francis Hospital - Berkeley, Inc. has as its sole member:

CareAlliance Health Services (CAHS) (100% ownership)
 d/b/a Roper St. Francis Healthcare
 125 Doughty St. Ste. 760
 Charleston, SC 29403

3 Members of CAHS include:

Medical Society of South Carolina (63%)
 69-B Barre Street
 Charleston, SC 29401

Bon Secours Health System, Inc. (27%)
 1505 Marriottsville Road
 Marriottsville, MD 21104

The Charlotte-Mecklenburg Hospital Authority (10%)
 d/b/a Carolinas Healthcare System
 P.O. Box 32861
 Charlotte, NC 28232

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

N/A

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

Officers have yet to be named.

h. Is the building on/in which the proposed facility or service is to be conducted owned by the licensee? Yes; X No (Land, Yes). If no, provide information on the land and building similar to that required in (b) through (g) above.

Building:

CareAlliance Health Services (CAHS) 100% ownership
 125 Doughty Street Ste. 760
 Charleston, SC 29403

3 Members of CAHS are detailed in "e" above

CareAlliance Health Services Corporate Officers

Brian Cuddy, M.D.	Chairman
Alison Dillon, M.D.	Vice Chairman
David L. Dunlap	President and Chief Executive Officer
Bret D. Johnson	Chief Financial Officer
Gregory T. Edwards	Secretary
Mark C. Dickson	Vice President of Mission

i. Has the licensee engaged an entity other than an employee of the licensee to manage or operate the facility or service? Yes; X No. If yes, provide information similar to that required in (b) through (g) above.

j. Is there any agreement, contract, option, understanding, intent, or other arrangement that will effect a change in any of the information requested and/or provided in (b) through (g) above? Yes; X No. If yes, provide a description to include information required in (b) through (g) above.

k. Provide a complete listing of all existing licensed health care facilities and/or services and Certificates of Need in which the proposed licensee currently has an ownership interest, to include names and addresses of each facility or service. In the cases of Certificates of Need for undeveloped facilities and services, provide the name, address, and telephone number of a contact person representing the authority which issued the Certificate of Need.

Certificates of Need for Undeveloped Facilities/Services:

SC-16-01 for the construction of a 50-bed hospital in Goose Creek

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

A CareAlliance Health Services organizational chart is located in Attachment 4. The names/mailling addresses of the three legal entities with ownership interests were provided in the "e" response above.

B9. Provide documentation that the applicant has sought cooperative agreements such as transfer agreements with other facilities, as applicable.

Diagnostic catheterization providers are required to have a patient referral and transfer agreement with at least one hospital providing open heart surgery. The Legal Department has drafted a patient transfer agreement between Roper St. Francis Hospital – Berkeley and Roper Hospital, the open heart surgery provider within the healthcare system, and it is located in Attachment 5.

B10. Indicate the means by which a person will have access to the facility's services (i.e. physician referral, self admission, etc.). Identify the specific facilities or agencies the applicant expects to receive referrals from (i.e. hospitals, home health agencies, etc.). Describe any limitations placed on admissions.

Referrals are expected to primarily come from cardiologists and primary care physicians. Access to the diagnostic cardiac catheterization service will require a physician's order, which is the only limitation placed.

B11. Demonstrate that the proposed project is needed or projected as necessary to meet an identified need of the public. This shall address at a minimum: identification of the target population; the degree of unmet need; projected utilization of the proposed facility / service; utilization of existing facilities and services; past utilization of existing facilities and services; and justification that the proposed project will not unnecessarily duplicate existing entities. The applicant must show all assumptions, data sources, and methodologies used. The applicant must use population statistics consistent with those generated by the State Demographer, State Budget and Control Board.

Project Overview

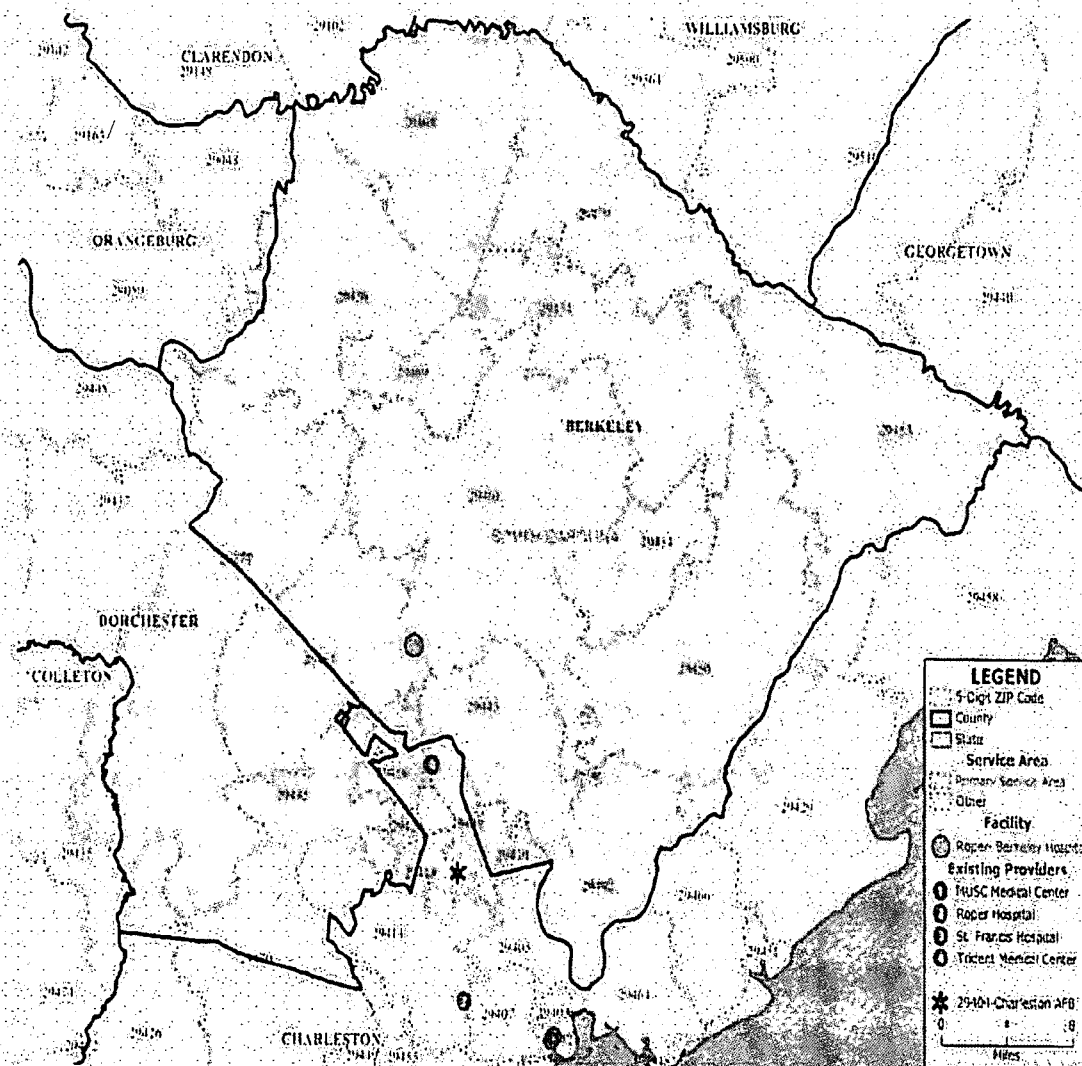
The Roper St. Francis Healthcare System received a Certificate of Need to establish Roper St. Francis Hospital - Berkeley, a community hospital located in Berkeley County in 2016. The hospital is expected to be under construction in 2017 and operational in 2019. Roper St. Francis Healthcare now proposes to establish a diagnostic cardiac catheterization laboratory within the hospital to better meet the needs of its patient base from Berkeley County and surrounding areas that are primarily traveling to Roper Hospital in downtown Charleston for diagnostic catheterization services.

Roper St. Francis Healthcare currently operates four cardiac catheterization laboratories. Three comprehensive cardiac catheterization labs are operated at Roper Hospital and one diagnostic cardiac catheterization laboratory is operated at Bon Secours St. Francis Xavier Hospital. In this application, Roper St. Francis Healthcare proposes to establish a new diagnostic cardiac catheterization laboratory to meet the needs of its Berkeley County patients and its other patients residing in the hospital's vicinity that must travel almost forty-five minutes to obtain diagnostic cath procedures from other providers in the system. Upon approval of this application, Bon Secours St. Francis Xavier Hospital will close its existing diagnostic catheterization lab. As a result, this project will not result in an increase in diagnostic cardiac catheterization capacity in the service area. In fact, it will result in a temporary decrease in service area capacity for the period of time between the closure of the Bon Secours St. Francis Xavier Hospital lab (estimated December 2016) and the opening of Roper St. Francis Hospital - Berkeley in 2019.

Target Population

As shown in the map below, the target population consists largely of those residing in Berkeley County. The primary service area will also include of a limited number of surrounding areas composed in part of North Charleston and Summerville area ZIP codes from Charleston and Dorchester Counties that border alongside or extend into Berkeley County.

Exhibit 1
Map of Primary Service Area



A secondary service area also includes the remainder of Charleston and Dorchester Counties as well as Colleton County. The primary and secondary service areas are outlined with specificity in **Exhibit 2** below.

Exhibit 2
Proposed Service Area

Primary Service Area
Berkeley County - All ZIP Codes
Dorchester County- 29420, 29472, 29483, 29485, 29456
Charleston County – 29406, 29410, 29418, 29420, 29456
Secondary Service Area
Remainder of Charleston County
Remainder of Dorchester County
Colleton County

It should be noted that based on historical utilization of the existing cardiac catheterization labs within the health system, Roper St. Francis Hospital - Berkeley only expects to shift diagnostic cardiac catheterizations from the existing labs within the Roper St. Francis Healthcare System when the proposed lab becomes operational. Roper St. Francis Hospital - Berkeley does not project to shift any patient volume from other existing providers to meet its volume projections and minimum utilization requirements.

These identified service areas are some of the most quickly growing in the state. As shown in **Exhibit 3** below, Berkeley County, the base of the primary service area for this project, is projected to grow 5.27%, faster than that of the state as a whole, from 2015-2020.

Exhibit 3
Projected Population Growth for Berkeley County 2015-2020

County	July 1, 2015	July 1, 2020	CAGR	% Growth 2015-2020
	Projection	Projection		
Berkeley	187,800	197,700	1.03%	5.27%
South Carolina	4,823,200	5,020,800	0.81%	4.10%

*Source: U.S. Census Bureau, S.C. Department of Health and Environmental Control,
and S.C. Budget and Control Board - Office of Research & Statistics.*

The additional ZIP codes which compose the remainder of the primary service area are identified below in **Exhibit 4** and account for a considerable share of the system's current diagnostic catheterization patient base and are also areas which are growing rapidly. As a result of the proposed project, some patients from these ZIP codes will also be shifted to Roper St. Francis Hospital - Berkeley, though not as densely as that of Berkeley County areas.

Exhibit 4
Primary Service Area Zip Codes that
Extend Outside of Berkeley County

Zip Code	2015 Population	2020 Population	% Change 2015-2020	CAGR
29483	75,662	82,769	9.39%	1.81%
29485	52,269	56,575	8.24%	1.60%
29456	30,968	34,194	10.42%	2.00%
29420	22,443	24,568	9.47%	1.83%
29410	18,926	20,003	5.69%	1.11%
29418	25,933	28,266	9.00%	1.74%
29472	9,981	10,260	2.80%	0.55%
29406	32,628	35,447	8.64%	1.67%
South Carolina	4,823,200	5,020,800	4.10%	0.80627%

Source: Claritas, U.S. Census Bureau, S.C. Department of Health and Environmental Control, and S.C. Budget and Control Board - Office of Research & Statistics.

As shown above, with the exception of 29472, these ZIP code areas are growing faster than that of the state as a whole. In addition, as shown in **Exhibit 5** below, the 65+ population for these areas is growing significantly faster than any other age cohort. In most cases, the 65+ population is growing 3-4 times more than the area as a whole. Because this population represents the most frequent users of cardiac diagnostic services, these figures are particularly relevant to the service area analysis and its potential future growth.

Exhibit 5
Percent Change in Zip Code Level Primary Service
Areas by Age for 2015-2020

Zip Code	0-17	18-44	45-64	65+	Total
29483	6.40%	6.02%	7.18%	31.08%	9.39%
29485	2.48%	5.42%	8.44%	27.97%	8.24%
29456	7.60%	6.27%	11.64%	33.85%	10.42%
29420	4.59%	6.69%	7.37%	45.41%	9.47%
29410	4.78%	1.05%	6.27%	19.86%	5.69%
29418	11.44%	4.91%	2.50%	34.69%	9.00%
29472	-0.27%	1.01%	-2.04%	23.01%	2.80%
29406	14.81%	2.48%	8.56%	22.78%	8.64%

Source: Claritas

The proposed project will also encompass a secondary service area that consists of the remainder of Dorchester and Charleston Counties, as well as Colleton County in its entirety. However, a far lesser percentage of patients from these areas are projected to shift to Roper St. Francis Hospital - Berkeley than that of the primary service area. Shown in **Exhibit 6** below, Dorchester County is projected to grow rapidly from 2015-2020 increasing in total population by more than ten percent, while a smaller level of growth is projected for Charleston and Colleton Counties.

Exhibit 6
Population Growth for Secondary Service Area Counties

County	July 1, 2015	July 1, 2020		% Growth
	Projection	Projection	CAGR	2015-2020
Charleston	360,600	370,900	0.5649%	2.86%
Colleton	39,000	39,200	0.1024%	0.51%
Dorchester	152,000	167,400	1.9489%	10.13%
South Carolina	4,823,200	5,020,800	0.80627%	4.10%

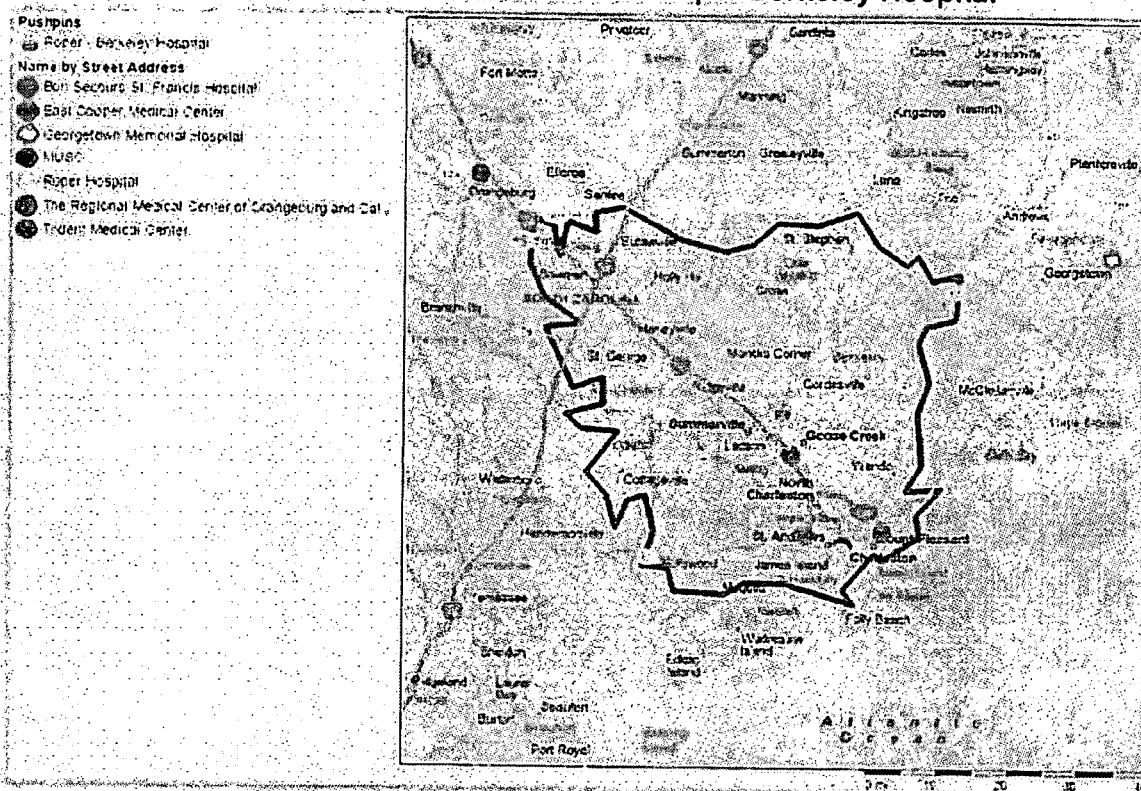
Source: U.S. Census Bureau, S.C. Department of Health and Environmental Control, and S.C. Budget and Control Board - Office of Research & Statistics.

As demonstrated above, the proposed project reaches a growing population, many of which must travel outside of his/her county of origin to receive diagnostic cardiac catheterization. This growing population includes a surge in the over 65 population that will be most likely to need cardiac diagnostic services in the future.

Utilization of Existing Facilities and Services

The current State Health Plan defines the service area for a new diagnostic cardiac catheterization laboratory to be all facilities within 45 minutes' one way automobile travel time. **Exhibit 7** below shows all facilities that currently offer diagnostic cath services within a 45 minute drive time of Roper St. Francis Hospital - Berkeley, the proposed site of this project. These facilities include MUSC Medical Center, Roper Hospital, Bon Secours St. Francis Xavier Hospital, and Trident Medical Center.

Exhibit 7
45 Minute Drive Time Radius for Roper Berkeley Hospital



Source: MapPoint

As indicated on the map, with the exception of Trident Medical Center, all existing providers within the service area are located near the very southern edge of the area, indicating close to a 45 minute drive for patients living in the center of the area close to Roper St. Francis Hospital - Berkeley or further for those living North, East or West of this location. The proposed project will bring diagnostic catheterization close to the homes of a significant base of patients that the Roper St. Francis Healthcare system already treats.

Shown in **Exhibit 8** below, with the exception of Bon Secours St. Francis Xavier Hospital, all existing providers in the service area are well utilized.

Exhibit 8
Detailed Historical Utilization for the Service Area

Facility	Cath Labs	2012			2013			2014		
		Diagnostic Caths	Therapeutic Caths	Pediatric Caths	Diagnostic Caths	Therapeutic Caths	Pediatric Caths	Diagnostic Caths	Therapeutic Caths	Pediatric Caths
MUSC Medical Center*	6	1,747	1,363	488	1,692	1,326	522	1,697	1,156	569
Roper Hospital	3	1,785	904		1,651	908		1,578	896	
Bon Secours St. Francis Hospital	1	9			3			4		
Trident Medical Center	2	1,332	390		995	479		1,007	445	
Service Area Total	12	4,873	2,657	488	4,341	2,713		4,287	2,497	569

Source: Joint Annual Reports 2012-2014

Except for Bon Secours St. Francis Xavier Hospital, all other providers in the defined service area operate comprehensive cardiac catheterization labs which offer both diagnostic and therapeutic catheterizations. As a result, to meaningfully show utilization, diagnostic equivalents are utilized to measure utilization within the service area in **Exhibit 9**.

Exhibit 9
Historic Utilization for the Service Area

Facility	Cath Labs	2012		2013		2014	
		Diagnostic Equivalents	Diagnostic Equivalents per Lab	Diagnostic Equivalents	Diagnostic Equivalents per Lab	Diagnostic Equivalents	Diagnostic Equivalents per Lab
MUSC Medical Center	6	5,688	948	5,648	941	5,431	905
Roper Hospital	3	3,593	1,198	3,467	1,156	3,370	1,123
St. Francis Hospital	1	9	9	3	3	4	4
Trident Medical Center	2	2,112	1,056	1,953	977	1,897	949
Total	12	11,402	950	11,071	923	10,702	892

Even considering the underutilization of the diagnostic catheterization laboratory at Bon Secours St. Francis Xavier Hospital, all existing cardiac catheterization laboratories in the service area aggregately operated at 892 diagnostic equivalents per lab in 2014.

This indicates that the service area labs are well-utilized as a whole. In addition, it should be noted that MUSC Medical Center is licensed to operate six total cardiac catheterization labs. Of these six, two are specifically designated as congenital cath labs and serve the entirety of the pediatric patient population and a limited number of designated adult cases. As a result of these specialized labs, the diagnostic equivalents per lab for MUSC are lower than they would be if all adult cases were considered to be performed (as they largely are) in the remaining four cath labs.

Past Utilization of Existing Similar Services within the Roper St. Francis Healthcare System

As discussed previously in the application, Roper St. Francis Healthcare currently operates four existing cardiac catheterization labs throughout the system. Three comprehensive labs are located at Roper Hospital in downtown Charleston and one diagnostic (only) lab is located at Bon Secours St. Francis Xavier Hospital 6.9 miles away in West Ashley. As a result of the close proximity between Roper Hospital and Bon Secours St. Francis Xavier Hospital and physician referral practices and tendencies, the Bon Secours St. Francis Xavier Hospital lab has been largely underutilized. Because of this, Bon Secours St. Francis Xavier Hospital will close this lab following the approval of the proposed Roper St. Francis Hospital - Berkeley lab.

In contrast, the labs at Roper Hospital are well utilized and were operating at almost 100 percent of capacity in 2012. Since that time, utilization has remained strong at Roper as demonstrated in **Exhibit 10** below. The three comprehensive labs at Roper Hospital operated at almost 93 percent of capacity in 2015. In fact, as shown previously, Roper Hospital's cath labs are the most highly utilized of all existing providers in the service area in terms of diagnostic equivalents per lab.

Exhibit 10
Roper Hospital Historic Utilization

	2012	2013	2014	2015
Diagnostic Catheterizations	1,785	1,651	1,578	1,568
Therapeutic Catheterizations	904	908	896	883
Diagnostic Equivalents	3,593	3,467	3,370	3,334
Capacity of 3 Labs	3,600	3,600	3,600	3,600
Percent Capacity	99.8%	96.3%	93.6%	92.6%

The proposed project will alleviate potential capacity constraints at Roper Hospital by shifting approximately one-third of the diagnostic catheterizations to Roper St. Francis Hospital - Berkeley by year three of operation. The benefit from this is two-fold. Roper Hospital will have additional capacity to better and more timely meet the needs of its patients and referring providers. Patients will be more efficiently and timely served at both Roper and Roper St. Francis Hospital - Berkeley and will have access to two locations in distinctly different areas to receive diagnostic care close to home, loved ones, and care takers.

The Degree of Unmet Need

Berkeley and Dorchester County patients do not have a local provider for cardiac catheterization services. The establishment of a diagnostic catheterization lab at Roper St. Francis Hospital - Berkeley will meet a currently unfilled need for Berkeley County and portions of Dorchester and Charleston County that are identified to be part of the primary service area. For these areas, the availability of diagnostic cardiac catheterization services will result in reduced drive time and greater proximity to their homes, loved ones, and caregivers.

As shown on the map in **Exhibit 7** above, with the exception of Trident Medical Center, all existing facilities that will remain operational after the approval of this project are on the periphery of the 45-minute drive-time radius. The patients that will be affected by this project are patients that would currently be referred to Roper St. Francis facilities for diagnostic catheterizations. As a result, the proposed project will allow patients to be closer to their families and their homes when receiving medical care and will result in a more time and cost-efficient experience.

Berkeley County patients are already seeking their cardiac care and more specifically, receiving diagnostic catheterizations, in the four existing Roper St. Francis Healthcare labs. As shown in detail below, more than one-third of the patients originating from Berkeley County who received a diagnostic catheterization in 2014 received it in a Roper St. Francis cath lab. As shown in detail in **Exhibit 11**, the percentage and total number of Berkeley County cath patients receiving care at Roper Hospital has increased over the past three years as overall diagnostic catheterization utilization has tapered slightly. This growth is expected to continue as Roper St. Francis has established and continues to grow a primary care presence in Berkeley and Dorchester Counties.

Exhibit 11**Roper St. Francis Market Share of Diagnostic Cardiac
Catheterization Patients Originating from Berkeley County**

	2012	2013	2014
Inpatient Diagnostic Catheterizations of Patients Originating from Berkeley County	519	506	429
Outpatient Diagnostic Catheterizations of Patients Originating from Berkeley County	430	443	468
Total Diagnostic Catheterizations of Patients Originating from Berkeley County	949	949	897
Number of Diagnostic Caths Performed at Roper St. Francis Facility on Patients Originating from Berkeley County	281	289	303
Percent of Total Berkeley County Diagnostic Cath Patients Which Received Cath from RSF Facility	29.6%	30.5%	33.8%

Sources: South Carolina Revenue and Fiscal Affairs Office, Roper St. Francis Internal Data

The trend in the figures above appears to correlate directly with the utilization of Roper St. Francis diagnostic catheterization services by Berkeley County residents. As shown in **Exhibit 12** below, from 2012 to 2015 the total percentage of total diagnostic caths performed on Berkeley County residents has grown and represented 18.6 percent of the total diagnostic catheterizations performed in Roper St. Francis cath labs in 2015.

Exhibit 12**Percentage of RSF Diagnostic Catheterizations Originating from
Berkeley County**

	2012	2013	2014	2015
Diagnostic Caths Performed of Patients Originating from Berkeley County	281	289	303	292
Total Diagnostic Catheterizations Performed at RSF Labs	1,796	1,756	1,582	1,571
% of RSF Diagnostic Cath Patients Originating from Berkeley County	15.6%	16.5%	19.2%	18.6%

Source: Roper St. Francis Health System Internal Data; Joint Annual Reports

Based on the data presented above, Roper St. Francis Healthcare is a leading provider for cardiac diagnostic services for Berkeley County residents. The addition of a diagnostic catheterization lab to Roper St. Francis Hospital - Berkeley is a natural

extension of the services that Roper St. Francis currently providing patients in this community which will reduce time, costs, and inconveniences related to traveling for medical care.

Projected Utilization

The projected utilization for the proposed diagnostic catheterization laboratory is presented below in **Exhibit 13**. The projection model divides the patient base into three categories: primary service area, secondary service area, and in-migration. As described previously in this section, the primary service area is broken down further into three categories: Berkeley County (in its entirety), select Dorchester County ZIP codes, and select Charleston County ZIP codes. The secondary service area is composed of the remainder of Dorchester and Charleston Counties and Colleton County in its entirety. In-migration is defined as all patients originating from outside the primary and secondary service areas.

The applicant utilized population projection data from the South Carolina Revenue and Fiscal Affairs Office and Claritas to determine the annual project growth rates for all defined primary and secondary service areas. This growth rate was applied to the Roper St. Francis Healthcare System's actual 2015 utilization for these areas to project utilization for years one through three of operation (2019-2021).

Of these total projected cases, a percentage was determined to be shifted from the existing labs to Roper St. Francis Hospital - Berkeley. In the primary service area, Berkeley County patients were most densely shifted to the proposed lab, with eighty percent of these patients expected to be served at Roper St. Francis Hospital - Berkeley in Year 3 of operation. Completing the primary service area, 65 percent of the select Dorchester County ZIP code patients and 50 percent of the select Charleston County ZIP code patients are shifted to Roper St. Francis Hospital - Berkeley in Year 3 of operation. As demonstrated in Exhibit 13, this shift is gradual and builds over the first three years of operation.

Similarly, the projected secondary service area utilization, composed of the remainder of Charleston and Dorchester Counties and Colleton County is projected based on 2015 utilization and relevant population growth and is gradually shifted based on appropriate percentages for the areas. In migration is calculated as an estimated six percent of total diagnostic cardiac catheterization cases which is conservatively based on the 2015 historical in migration of 7.89 percent of total diagnostic cardiac catheterization cases within the Roper St. Francis Healthcare System. The projections result in 510

diagnostic cardiac catheterizations in year three of operation at Roper St. Francis Hospital - Berkeley.

Exhibit 13
Projected Utilization

			Projected RSF Health System Diagnostic Caths			% Shifted to Roper Berkeley			Projected Diagnostic Caths for Roper Berkeley				
	2015 Diagnostic Caths at RSF Labs	CAGR for Population	2019	2020	2021	2019	2020	2021	2019	2020	2021		
Primary Service Area													
Berkeley County - All Zips			292	1.03%	304	307	311	45%	60%	80%	137	184	248
Dorchester County													
29420			27	1.83%	29	30	30	45%	55%	65%	13	16	20
29472			5	0.55%	5	5	5	45%	55%	65%	2	3	3
29483			62	1.81%	67	68	69	45%	55%	65%	30	37	45
29485			42	1.60%	45	45	46	45%	55%	65%	20	25	30
29456*			0	2.00%	0	0	0	45%	55%	65%	0	0	0
Charleston County													
29406			46	1.67%	49	50	51	30%	40%	50%	15	20	25
29410*			0	1.11%	0	0	0	30%	40%	50%	0	0	0
29418			60	1.74%	64	65	67	30%	40%	50%	19	26	33
29420*			0	1.83%	0	0	0	30%	40%	50%	0	0	0
29456*			0	2.00%	0	0	0	30%	40%	50%	0	0	0
Total Primary Service Area			534		563	571	578	42%	55%	70%	236	312	405
Secondary Service Area													
Remainder of Charleston County			782	0.56%	800	804	809	2.5%	5%	7.5%	20	40	61
Remainder of Dorchester County			13	1.95%	14	14	15	5%	8%	10%	1	1	1
Colleton County			118	0.10%	118	119	119	5%	8%	10%	6	9	12
Total Secondary Service Area			913		932	937	942	5%	8%	10%	27	51	74
In migration			124	7.89%				6.0%	6.0%	6.0%	17	23	31
Total Cath Patients			1,571		1496	1508	1521				280	386	510

Sources: Office of Revenue of Fiscal Affairs, Clartas, RSF Internal Data

*ZIP code overlaps Berkeley County and all patients from the ZIP code originated from Berkeley County and are included in Berkeley County utilization.

Unnecessarily Duplication of Existing Entities

The proposed project will not duplicate existing entities and will not affect existing providers of diagnostic cardiac catheterization services in the service area. As shown in the service area map in **Exhibit 1**, there are no existing providers of diagnostic cardiac catheterization in Berkeley County. Within the defined service area, the proposed Berkeley County location will bring these services away from the current consolidation of cath labs in Charleston County to a growing community that is seeking care close to home.

In addition, this project will not impact existing providers within the service area. This project is proposed to specifically address Roper St. Francis Healthcare System's existing patient base that resides in Berkeley County and surrounding areas that can be more conveniently served from a Berkeley County location. The utilization projections for the proposed project only assume a shift in Roper St. Francis' current patient base and do not assume Roper St. Francis Hospital - Berkeley will divert patients or change referral patterns from existing providers.

State Health Plan Standards for Diagnostic Catheterization

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

The definition of capacity outlined above is utilized throughout this application.

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

This definition for service area stated above is utilized throughout this application. All facilities within 45 minutes' one way drive time from Roper St. Francis Hospital - Berkeley are shown in **Exhibit 7**. These facilities include MUSC Medical Center, Roper Hospital, Bon Secours St. Francis Xavier Hospital, and Trident Medical Center.

Diagnostic and Mobile Catheterization Services

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

Cardiac catheterization utilization per lab has remained strong in the overall service area and the existing labs within the defined service area are performing on average almost 900 diagnostic equivalents per lab per year. Because Bon Secours St. Francis Xavier Hospital is the only existing cath lab in the service area that is restricted to diagnostic cardiac catheterizations, diagnostic equivalents must be used for all other labs in the service area which provide a mix of diagnostic and therapeutic catheterizations to provide a common measurement of utilization. This is shown below in **Exhibit 14**.

Exhibit 14
Historical Utilization of Existing Labs in the Service Area

		2012		2013		2014	
	Cath Labs	Diagnostic Equivalents	Diagnostic Equivalents per Lab	Diagnostic Equivalents	Diagnostic Equivalents per Lab	Diagnostic Equivalents	Diagnostic Equivalents per Lab
Facility							
Roper Hospital	3	3,593	1,198	3,467	1,156	3,370	1,123
MUSC Medical Center	6	5,688	948	5,648	941	5,431	905
Trident Medical Center	2	2,112	1,056	1,953	977	1,897	949
St. Francis Hospital	1	9	9	3	3	4	4
Total	12	11,402	950	11,071	923	10,702	892

Source: Joint Annual Reports

While Bon Secours St. Francis Xavier Hospital is operating below 500 diagnostic equivalents per year, the lab will be closed upon the approval of this project. As a result, all labs which will exist following the approval of this project are currently

operating well above 500 diagnostic equivalents per lab and meet the utilization requirements of this standard.

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

Projected utilization for the proposed project is outlined in detail above in **Exhibit 13**. In summary, Roper St. Francis Hospital - Berkeley projects to serve 510 patients in year 3 of operation as shown in **Exhibit 15** below.

Exhibit 15
Projected Utilization for Roper St. Francis Hospital - Berkeley

	Year 1	Year 2	Year 3
Projected Diagnostic Caths	280	386	510

Because this project proposes to serve the Berkeley County and surrounding residents that are currently seeking diagnostic catheterization services from the Roper St. Francis Healthcare System, it will simply shift patients from the labs within the Roper St. Francis Healthcare System to Roper St. Francis Hospital - Berkeley without any impact on the average diagnostic equivalents per laboratory throughout the service area for all other service area providers.

Because only three of the 1,571 diagnostic catheterizations that took place within the Health System in 2015 were provided by St. Francis Hospital and because the St. Francis lab will close following the approval of this proposed project, the only facility within the service to be quantitatively impacted by this project is Roper Hospital. Because of Roper's robust utilization, it will continue to be strongly utilized even following the patient shift to Roper St. Francis Hospital - Berkeley. As shown below in **Exhibit 16**, in year three of the proposed project, Roper Hospital is projected to provide 980 diagnostic equivalents in each of its three labs. In addition, each lab at Roper Hospital will operate at 82 percent of capacity in year three of the proposed project. It should be noted that the growth rate for Charleston County was applied to all 2015 cases to conservatively account for population growth since Charleston County has by far the lowest growth rate of the Tri-County area which makes up Roper Hospital's primary service area.

Exhibit 16
Impact on Roper Hospital

	2015	Charleston County CAGR	2019 Projection	2020 Projection	2021 Projection
Total Diagnostic Catheterizations at Roper Hospital	1,568	0.565%	1,604	1,613	1,622
Roper Berkeley Projected Diagnostic Catheterizations (Shifted from Roper Hospital)			-280	-386	-510
Diagnostic Catheterizations Remaining at Roper Hospital			1,324	1,227	1,112
Therapeutic Catheterizations at Roper Hospital	883	0.565%	903	908	913
Diagnostic Equivalent Factor	2		2	2	2
Therapeutic Catheterizations Converted to Diagnostic Equivalents	1,766		1,806	1,816	1,827
Total Diagnostic Equivalents	3,334		3,130	3,043	2,939
Total Labs	3		3	3	3
Diagnostic Equivalents per Lab at Roper Hospital	1,111		1,043	1,014	980
Capacity per Lab	1,200		1,200	1,200	1,200
Percent of Capacity for Each Lab	93%		87%	85%	82%

5. Expansion of an existing diagnostic catheterization service shall only be approved if the service has operated at a minimum use rate of 80% of capacity for each of the past two years and can project a minimum of 500 procedures per year within three years.

Not applicable. The proposed project is not an expansion of an existing service.

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

a. The applicant must document that the specific mobile unit utilized by the vendor will perform a combined minimum of 500 diagnostic equivalents per year;

b. The applicant must include vendor documentation of the complication rate of the mobile units operated by the vendor; and

c. If an application for a mobile lab is approved and the applicant subsequently desires to change vendors, the Department must approve such change in order to ensure that appropriate minimum utilization can be documented.

Not applicable. This application does not involve a mobile diagnostic cath lab.

Emergent and Elective PCI without On-Site Cardiac Backup

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

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

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

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

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

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

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

a) The physicians must be experienced interventionalists who regularly perform elective intervention at a surgical center (75 cases/year). The institution must perform a minimum of 36 primary PCI procedures per year.

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

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

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

e) The hospital administration must fully support the program and enable the fulfillment of the above institutional requirements.

f) There must be formalized written protocols in place for immediate (within one hour) and efficient transfer of patients to the nearest cardiac surgical facility that are reviewed/tested on a regular (quarterly) basis.

g) Primary (emergency) intervention must be performed routinely as the treatment of choice around the clock for a large proportion of patients with acute myocardial infarction (AMI) to ensure streamlined care paths and increased case volumes.

h) Case selection for the performance of primary (emergency) angioplasty must be rigorous. Criteria for the types of lesions appropriate for primary (emergency) angioplasty and for the selection for transfer for emergent aortocoronary bypass surgery are shown in Section E.2.

i) There must be an ongoing program of outcomes analysis and formalized periodic case review. Institutions should participate in a three-to-six month period of implementation during which time development of a formalized primary PCI program is instituted that includes establishing standards, training staff, detailed logistic development, and creation of a quality assessment and error management system.

2) Patient Selection Guidelines

a) Avoid intervention in hemodynamically stable patients with:

(1) Significant (60%) stenosis of an unprotected left main (LM) coronary artery upstream from an acute occlusion in the left coronary system that might be disrupted by the angioplasty catheter.

(2) Extremely long or angulated infarct-related lesions with TIMI grade 3 flow.

- (3) Infarct-related lesions with TIMI grade 3 flow in stable patients with 3-vessel disease.
- (4) Infarct-related lesions of small or secondary vessels.
- (5) Lesions in other than the infarct artery.
- b) Transfer emergent aortocoronary bypass surgery patients after PCI of occluded vessels if high-grade residual left main or multi-vessel coronary disease and clinical or hemodynamic instability are present, preferably with intra-aortic balloon pump support.

Not applicable. This project does not involve the provision of emergent and elective PCI without on-site cardiac backup.

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

- a. The applicant has performed a minimum of 250 diagnostic catheterization procedures in the most recent year and can reasonably demonstrate that it will perform a minimum of 500 diagnostic catheterizations annually within three years of the initiation of services.
- b. All existing comprehensive cardiac catheterization facilities in the service area performed a minimum of 300 therapeutic catheterizations in the most recent year.
- c. An applicant must project that the proposed service will perform a minimum of 300 therapeutic catheterization procedures annually within three years of initiation of services, without reducing the cardiac catheterizations performed at existing comprehensive catheterization programs in the service area below the minimum thresholds of 300 therapeutic procedures and 500 diagnostic procedures at each facility.
- d. The physicians must be experienced interventionalists who perform a minimum of 75 elective PCI cases per year and preferably at least 11 PCI procedures for STEMI each year. Ideally, operators with an annual procedure volume of fewer than 75 procedures per year should only work at institutions with an activity level of more than 600 procedures per year. Operators who perform fewer than 75 procedures per year should develop a defined mentoring relationship with a highly experienced operator who has an annual procedural volume of at least 150 procedures.

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

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

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

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

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

j. Applicants must provide documentation to show that guidelines for determining patients appropriate for PCI procedures in a setting without on-site open heart backup consistent with standards of the American College of Cardiology have been developed and will be maintained.

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

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

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

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

n. An applicant for provision of elective PCI without on-site surgical backup agrees, as a condition for issuance of its Certificate of Need for such service, to

discontinue therapeutic catheterization services and surrender the Certificate of Need for that service if they have failed to achieve 200 therapeutic catheterizations per year by the expiration of the first three years of operation of such services.

Not applicable. This project does not involve the provision of emergent and elective PCI without on-site cardiac backup.

Comprehensive Catheterization Services

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

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

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

Not applicable. This project does not involve a comprehensive catheterization laboratory.

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

Not applicable. This project does not involve a comprehensive catheterization laboratory.

Pediatric Catheterization Services

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

a. All existing facilities have performed at a combined use rate of 80% of capacity for the most recent year; and

b. An applicant must project that the proposed service will perform a minimum of 500 diagnostic equivalent procedures annually within three years of initiation of services.

Not applicable. This project does not involve pediatric catheterization services.

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

Not applicable. This project does not involve pediatric catheterization services.

13. Documentation of need for the proposed service:

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

According to the American Heart Association¹, the following are known or suspected heart conditions which diagnostic cardiac catheterization can be performed:

- Coronary artery disease (including heart attack)
- Heart valve problems
- Decreased heart function
- Congenital heart disease
- Elevated pressures in the heart chambers and/or great vessels
- Abnormal cardiac output (volume of blood flowing through the heart)
- Heart muscle inflammation, infection, or rejection (in the transplanted heart), for which catheterization is performed to obtain small pieces of tissue for microscopic examination (biopsy)

A list of the Top 25 primary diagnoses for inpatient hospitalizations of Berkeley County residents in 2014 is included in **Attachment 5**. This list shows that of the top five DRGs related to inpatient hospitalization of Berkeley County residents, two are cardiac diagnoses. In fact, three of the top fourteen reasons for inpatient hospitalization of

¹ <http://circ.ahajournals.org/content/107/17/e111.full#sec-6>

Berkeley County patients are fall into cardiac diagnoses including, heart failure, cardiac dysrhythmias, and acute myocardial infarction.

According the Office of Revenue and Fiscal Affairs, from 2012 to 2014, close to 1,000 Berkeley County residents per year required either inpatient or outpatient diagnostic cardiac catheterization. This data is shown in **Exhibit 17** below. Without an existing provider of this service in Berkeley County, many of these residents have been forced to drive close to 45 minutes, if not longer for this service. With the establishment of an inpatient hospital in Berkeley County, the transport of some inpatients in need of diagnostic catheterization would result in unnecessary delays in diagnosis and added expense for these patients.

Exhibit 17
Inpatient and Outpatient Discharges for Berkeley County
Residents Having a Diagnostic Catheterization Procedure

	2012	2013	2014
Inpatient	519	506	429
Outpatient	430	443	468
Total	949	949	897

Source: Office of Revenue and Fiscal Affairs

In addition, **Exhibit 13** which outlines the projected utilization for the proposed project also demonstrates the potential candidates for this service which are already treated at Roper or St. Francis Hospital that would be treated more conveniently and closer to home with less expense and travel should the proposed project be approved.

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

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

Not applicable. The applicant hospital is not yet built. However, the number of Berkeley County patients who received diagnostic cardiac catheterization in Years 2012-2014 is presented in **Exhibit 17** directly above. In addition, **Exhibit 18** below shows the number of patients originating from the primary service area who received diagnostic cardiac catheterizations in the Roper St. Francis Healthcare System for years 2012-2014.

Exhibit 18
2012-2015 Primary Service Area Patients Receiving Diagnostic
Cardiac Catheterizations at Roper and St. Francis Hospitals

	2012	2013	2014	2015
Berkeley County - All Zips	281	289	303	292
Dorchester County				
29420	35	27	27	27
29472	12	10	9	5
29483	61	57	59	62
29485	36	39	35	42
29456*	0	0	0	0
Charleston County				
29406	54	40	43	46
29410*	0	0	0	0
29418	52	49	51	60
29420*	0	0	1	0
29456*	0	0	0	0
Total for Primary Service Area Only	531	511	528	534

Source: Roper St. Francis Health System Internal Data

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

No additional patients will be generated through changes in referral patterns, physician recruitment, or other circumstances as a result of this project. As stated and demonstrated previously, this project is intended to address the need of the existing Roper St. Francis referral base that would otherwise be referred to an existing Roper St. Francis cath lab, but would be more conveniently served at Roper St. Francis Hospital - Berkeley.

Patients from the proposed service area, as appropriate, would be shifted from the existing labs within the Roper St. Francis Healthcare System to Roper St. Francis Hospital - Berkeley. The estimated shift and resulting utilization at Roper St. Francis Hospital - Berkeley was presented above in **Exhibit 13**.

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

Existing and projected patient origin information and referral patterns for the Roper St. Francis Health System are provided and detailed in **Exhibit 13** above.

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

(a) criteria for referral of patients on both a routine and an emergency back-up basis;

(b) regular communications between cardiologists performing catheterizations and surgeons to whom patients are referred;

(c) acceptability of diagnostic results from the cardiac catheterization service to the receiving surgical service to the greatest extent possible to prevent duplication of services; and

(d) development of linkages with the receiving institution's peer review mechanism.

These criteria were incorporated into the patient transfer agreement between Roper St. Francis Hospital - Berkeley and Roper Hospital, the open heart surgery provider within the healthcare system, included in Attachment 5.

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

Roper St. Francis Hospital - Berkeley will adopt and utilize the same standards that are currently being utilized by Roper Hospital for the provision of diagnostic cardiac catheterization services, which is the American College of Cardiology Appropriate Use Criteria for Diagnostic Catheterization provided in Attachment 5. The description of patient criteria to include referral arrangements for high-risk patients is described in detail in the transfer agreement with Roper Hospital which is included in Attachment 5.

16. Cardiac catheterization services should be staffed by a minimum of two physicians licensed by the State of South Carolina who possess the qualifications specified by the governing body of the facility. Protocols should be established that govern initial and continuing granting of clinical staff privileges to physicians to perform diagnostic, therapeutic and/or pediatric catheterizations. Applicants

must provide documentation that one or more interventional cardiologists will be required to respond to a call in a timely manner consistent with the hospital Medical Staff bylaws and clinical indications. In addition, standards should be established to assure that each physician using the service would be involved in adequate numbers of applicable types of cardiac catheterization procedures to maintain proficiency.

A minimum of two qualified physicians will staff the proposed cardiac catheterization lab. The system has nineteen cardiologists on staff, all licensed in South Carolina and board certified in cardiovascular diseases. The cardiologists who will staff the cath lab are on Roper's staff and they collectively perform over 3,000 caths per year. Their quality and appropriateness are measured using the ACC Cath PCI database which measures their relations to their peers. We are currently above average in all measured categories of quality and processes.

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

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

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

Roper St. Francis Hospital - Berkeley will report annual data and share outcomes as appropriate to external entities as outlined in this Standard.

B12. Discuss alternative facilities and/or services considered including the advantages and disadvantages of each alternative. Include a statement as to why this project alternative was adopted.

Two alternative options that were considered included:

Maintain the Status Quo

Maintaining the current situation means Berkeley County residents remain without this service. It results in a continuation of Roper St. Francis-aligned patients living in the new hospital's primary service area required to travel to the Peninsula or West Ashley for a diagnostic cardiac catheterization. Taking into account the forecasted population growth and how it will exacerbate the existing traffic/ travel situation, maintaining the status quo is not ideal.

Initiate Service at Mount Pleasant Hospital and Close the Lab at Bon Secours St. Francis Xavier Hospital

Mount Pleasant Hospital was viewed as a simpler transport to get patients downtown to Roper for cardiac services than the Berkeley Hospital in Goose Creek.

B13. Discuss any serious problems, such as costs, availability, or accessibility in obtaining care of the type proposed, experienced by patients in the absence of this project.

Diagnostic cardiac catheterization is one standard of care for the diagnosis of cardiovascular disease. In the absence of this project, access issues would result. Roper St. Francis-aligned patients in Berkeley and Dorchester counties would likely be referred and/or transferred to Roper Hospital on the Peninsula, a considerable drive (approximately 35 – 60 minutes depending on time of day and/or traffic) for a diagnostic cardiac catheterization. With traffic and travel times already an issue throughout the Tri-County area, and with the forecast population growth expected to further exacerbate the traffic/travel situation, it is our position that without the proposed project these access limitations will become even more of an issue.

There is the potential for service availability to become an issue. Roper Hospital has three catheterization labs where diagnostic and therapeutic caths are performed. These labs operated at 93% capacity in 2015 (3,334 equivalents). While the majority of this project's projected volume is a re-direction of Roper patients to the new hospital, in the absence of this project capacity issues at Roper could result which would extend the scheduling of outpatient caths. The project will not only enhance access, but establish the necessary resources within Berkeley County to meet the growing needs of the local service area population.

B14. Where a project effects an increase or decrease in bed capacity, provide annual occupancy rates for the facility based on licensed beds, for the past three years by category (i.e. general acute, psychiatric, obstetric, nursing home, etc.).

N/A

B15. Identify the method of financing the cost of the project, including the start-up costs. Provide documentation that the applicant can obtain such financing. Alternative sources and/or methods of financing must be identified and the method chosen demonstrated to be the most feasible option.

Hospital bond proceeds will be used to fund this project, as attested by Ms. Julie Graudin, CPA, in her letter included in Attachment 6.

B16. For an addition to an existing facility or service, provide a current annual budget and at least a three fiscal year projected budget for both the overall facility and the proposed project. The projections must be developed by an accountant. For a new facility or service, provide a projected annual budget for not less than three fiscal years following the completion of the proposed project. The projections must be attested to by an accountant. These budgets must at a minimum include how proposed charges, proposed cost of service, utilization, depreciation, reimbursement rates and contractual adjustments were calculated. Any assumptions made in the application must be specifically noted shown.

Attachment 6 includes a forecasted statement of operations for the project and the hospital (both with and without the project).

B17. Provide a list of proposed charges for the project. The charges provided may be used for comparison with the average charges in the final completion report as required in Section 607.3.b.

Charges at Roper St. Francis Healthcare are applied to all member hospitals. Charges for these services in 2016 are as follows:

Right Heart Cardiac Cath \$6,572

Left Heart Cardiac Cath: \$11,461

Combined Right and Left Heart Cardiac Cath: \$14,045

Note that routine annual charge increases are anticipated and applied hospital-wide to stay abreast of an ever-increasing expense structure, and will be applied / in effect by the time Roper St. Francis Hospital – Berkeley begins providing the proposed service.

B18. Document that the proposed project is economically feasible, both immediately and long-term. In the case of existing facilities, what impact will the proposed project have on patient charges and cost per unit of service?

To gauge the economic feasibility, refer to both the project and hospital pro-formas located in Attachment 6. The project will not result in increased charges; however, as stated above routine annual charge increases are anticipated (and applied hospital-wide) to stay abreast of an ever-increasing expense structure (e.g. nursing labor expense, pharmaceutical expenses, new technology, etc.).

B19. State how the project will foster cost containment and improve quality of care through the promotion of such services as ambulatory and home health care, preventive health care, promotion of shared services, economies of scale, and design and construction economies.

One aspect of fostering cost containment relates to the diagnostic cath itself. Early diagnosis via this tool can prevent the progression of heart and/or artery disease, which, if left undiagnosed and/or untreated would result in higher health care acuity and costs.

The project should improve quality of care by streamlining care delivery. Redirected patients will benefit from the increased convenience of having this service at their local RSF hospital.

An associated preventive health care program is already in place. Roper St. Francis offers The Healthy Lifestyle Program, a cardiac care program, to eligible individuals with at least one of five cardiovascular risk factors. It is designed to help improve heart health and overall well-being, and may even reduce the amount of needed prescription medications. It is led by Cardiologist, Dr. Ciccone, along with a dietician and certified personal trainer. The cardiologist does a cardiac risk evaluation. The six-month program helps the individual make better food choices and outlines a lasting, customized exercise program. It also includes a variety of educational sessions and support group opportunities.

Finally, one planned design and construction economy entails locating the cath lab proximate to the operating rooms in order to leverage pre and post op care services.

B20. In the case of projects involving additional long-term care beds, discuss how the plans of other agencies, organizations, or programs responsible for providing and financing long-term care have been considered.

N/A.

B21. Provide a three-year projected manpower budget in full-time equivalents (FTE's) detailing the existing and proposed nursing, other professional, and non-professional personnel required for the staffing of the new project.

Title	Year 1 Proposed # FTEs	Year 2 Proposed # FTEs	Year 3 Proposed # FTEs
Lab Tech	2.0	2.0	2.0
CV Nurse	1.0	1.0	1.0

B22. Provide the number of existing and proposed medical staff by specialty, to include physicians employed by, or with admission privileges to, the facility. Include the name of the Chief of the Medical Staff, if available.

The medical staff development plan for the hospital scheduled to open in 2019 is currently underway, and the Chief of the Medical Staff hasn't been named. Two cardiologists will staff the proposed cath lab.

B23. Indicate those physicians who have expressed a willingness to utilize the proposed services or to refer patients to the facility for the provision of services.

Roper St. Francis Physician Partners employs three cardiologists and the healthcare system has nineteen cardiologists on staff. Within the primary service area Lowcountry Cardiology Associates (5 physicians) has an office in North Charleston and in Moncks Corner, and Coastal Cardiology, PA (6 physicians) has an office in Moncks Corner. Cardiologists from both of these two (independent) groups will staff the lab. Their physician letters of support are included in Attachment 7.

Given a number of referrals are likely to originate from primary care physicians throughout the primary service area, a description of recent and planned growth of Roper St. Francis Physician Partners employed primary care physicians follows. In August of 2015 it celebrated the grand opening of three new Primary Care Partner and Express Care locations (Monday – Friday 8a-9p and weekend hours on Saturday and Sunday with same co-pay as visiting a PCP) in Summerville, consisting of eight physicians. Combined with the other existing practices in North Charleston, Moncks Corner, and Goose Creek, there are nineteen primary care physicians. Roper St. Francis continues to extend access to its broad network of physicians and services to the north areas in preparation for its new hospital. In April of 2016 it announced the lease of five former Nason buildings, two of which are located in North Charleston and one in Summerville. The plan is to convert three of the properties into Express Care locations and consideration is being given to which services to offer at the other two sites. The first site will open in August as an Express Care at 5133 Ladson Road in Summerville. While Roper St. Francis is strategically preparing for its new hospital opening within its physician network, non-affiliated physicians practicing in the primary service area are also likely to refer to and/or utilize the lab. Project support letters from physicians including both cardiologists and primary care physicians have been included in Attachment 7.

B24. Discuss the availability of health manpower resources for the provision of the proposed services, including the contemplated program and plan for recruiting and training personnel.

The project will require three FTEs, and we do not anticipate any difficulty in filling these positions. System-wide staffing strategies for recruitment focus on local newspaper advertising, career fairs, direct mailing and targeted university program recruitment. For specialized occupations and nursing positions, Roper St. Francis Healthcare has effectively promoted its unique staffing models, compensation rates, continuing education and facility location to attract quality personnel. When necessary, a targeted recruitment effort for hard to fill positions will begin well in advance of service initiation and/or licensure.

In terms of training, Roper St. Francis Healthcare has a structured general orientation program which is required for all new hires, as well as a department-specific orientation. Employees must participate in the system's annual mandatory education programs which are tracked on-line for each employee. Courses require a passing grade. Departments conduct competency training each year for clinical positions. In addition, our Professional Development Department provides ongoing training programs to ensure staff has the requisite knowledge and skills to effectively perform his/her duties. Roper St. Francis Healthcare provides additional opportunity to employees to further their career through a Tuition Assistance program. Lean Six Sigma Green Belt certifications are earned via training provided by our Quality, Innovation and Patient Safety Department. Managers attend Leadership Development Institute quarterly for their personal development and performance, and all new managers are required to attend a week long course, Taking the Helm, a new manager orientation provided by Human Resources.

B25. Describe the previous experience of the applicant in the proposed health care field. If the applicant has no prior experience, specify the anticipated sources of technical assistance, either from specific individuals or organizations.

The Roper St. Francis Healthcare system, a 657-bed system, includes three licensed hospitals. Roper Hospital was founded in 1850 as the first community hospital in the Carolinas. Bon Secours St. Francis Xavier Hospital opened in 1882 as St. Francis Xavier Infirmary, the first Catholic hospital in South Carolina. Bon Secours St. Francis Xavier Hospital is one of three Magnet Hospitals (the ultimate credential for high quality nursing) in South Carolina. The third hospital, Mount Pleasant Hospital, opened in 2010. A Certificate of Need was issued in January of 2016 to Roper St. Francis Hospital – Berkeley for the construction of a 50-bed hospital in Berkeley County via a bed transfer from Roper Hospital. This will be the system's fourth hospital.

The system also has a number of facilities / sites extending throughout the Tri-County area, which include three licensed surgery centers, two freestanding emergency departments, a home health agency, an outpatient hospice program, and a number of diagnostic centers. Roper St. Francis Healthcare is the Low country's only private, not-for-profit health care system, and is dedicated to its mission of "Healing All People with Compassion, Faith and Excellence". The system employs a network of more than 230 physicians, and has a medical staff of nearly 900 physicians covering numerous specialties.

Roper St. Francis has made significant strides in recent months to offer additional access to its broad network of physicians and services. The Boeing Preferred Partnership option launched January 1, 2016, for more than 6,000 Boeing teammates and their eligible dependents. The new Preferred Partnership option is offered exclusively through the doctors and hospitals of the Roper St. Francis Health Alliance, the first clinically integrated network (CIN) in the tri-county area. This is the first time a healthcare system has partnered with a large private employer in the Lowcountry to improve and maintain the health of employees and their family members.

The new hospital will benefit greatly from the system's experience and existing comprehensive range of heart and vascular services from screening and diagnosis to treatment and rehabilitation in one integrated facility. The Roper St. Francis Heart & Vascular Center located within Roper Hospital is the leading provider of adult cardiovascular services in Charleston. It includes the following components:

- Minimally Invasive Surgery Center
- Valve Clinic
- Accredited Vascular Lab
- Cardiac Imaging including stress testing, EKG, EEG
- Wound Care Management
- Hyperbaric & Undersea Medicine
- Electrophysiology
- Outpatient Vascular Clinic

- Endocrinology Services
- Smoking Cessation
- Cardiovascular prevention and screenings
- Cardiac Wellness and Rehabilitation
- Automated External Defibrillator training
- Hybrid Operating Room (under construction)
- Cardiovascular Intensive Care Unit

Designation by the Society of Cardiovascular Patient Care as an accredited Chest Pain Center, Roper Hospital's emergency room, the Heart & Vascular Center, and emergency medical personnel are able to coordinate care and reduce deaths from heart disease. In addition, all five Roper St. Francis emergency rooms include a chest pain center. Roper St. Francis Hospital – Berkeley will have referral arrangements with Roper Hospital for high-risk patients and a helipad in the event air ambulance services are needed.

B26. Discuss the impact of the project on the clinical training programs of health professional schools particularly the extent to which these schools will have access to the services for training.

Roper St. Francis Healthcare has clinical affiliation agreements with a number of schools throughout the state and beyond. Although not all-inclusive, a list of affiliations is summarized in the table below:

School	Program
Armstrong Atlantic State University	radiologic sciences program
Centura College	medical assisting program
Charleston Southern University	nursing program
Clemson	recreation therapy program
Des Moines University	physician assistant program
Duke University	nursing program
Elon University	physical therapy program
Emory University	nursing education program; wound ostomy continence
Francis Marion University	nursing program
Greenville Technical College	RN refresher program; medical imaging sciences and health information management program
Horry Georgetown Technical College	phlebotomy program
Lowcountry Regional Emergency Medical Services Council	EMT/paramedic program
Medical University of South Carolina	medical residency program; nursing program; health professions program; dentistry program; graduate studies program
Midlands Technical College	ultrasound technology program
Miller-Motte Technical College	surgical technology program; health information technology program; medical assisting program
Orangeburg-Calhoun Technical College	radiology program
Palmetto School of Ultrasound	ultrasound technology program
Pitt Community College	CT/MRI/nuclear medicine programs
Regis University	nursing program
South Carolina State University	nursing program
South University	pharmacy and nursing programs
Southeastern Institute	medical assistant program
University of Georgia	dietetic internship program

Trident Technical College	nursing program; physical therapy and occupational therapy programs; medical records coding; pharmacy tech; respiratory tech; medical lab tech; radiology tech; medical assistant program and EMT/paramedic program
University of Alabama at Birmingham	nursing program
UNC at Chapel Hill	physical therapy and radiologist assistant programs
University of South Carolina	nursing program; physical therapy and speech therapy programs; and social work
Wake Forest University	physician assistant program
Walden University	nursing program
Winthrop University	dietetic internship program

Updated August of 2015

At this time training programs will not have access to the proposed catheterization lab.

B27. Provide documentation of policies and procedures to assure the quality of healthcare services by addressing patient safety and quality indicators, as applicable. Documents may include, but are not limited to, measures of patient care, patient safety, healthcare-acquired infections and the following of best practices established by recognized organizations. Applicable quality standards in the South Carolina Health Plan must be addressed.

Patient Safety Indicators

The Joint Commission provides standards to assist in patient care and safety processes. In 2002 it established the National Patient Safety Goals Program, with goals focusing on problems in healthcare and how to solve them. Our response to The Joint Commission's 2015 National Patient Safety Goals (NPSG) follows:

Identify Patients Correctly

NPSG.01.01.01: Does the organization use at least two patient identifiers when providing care, treatment and services?

- ❖ Policy #76- Patient Identification- Patient's name and date of birth
- ❖ Policy # 04-4400-07-01 Medication Administration- Two patient identifiers prior to administering medications
- ❖ Policy - Obtaining and Labeling of Specimens- Containers used for blood and other specimens need to be labeled in the presence of the patient

NPSG.01.03.01: Does the organization eliminate transfusion errors related to patient misidentification?

- ❖ Policy – Blood and Blood Product Administration- Matches the blood to the order and the patient, and uses a two person identification process

Improve Staff Communication

NPSG.02.03.01: Does the organization report critical results in a timely basis?

❖ Nursing Policy #7 Timely Reporting of Critical Results of Tests and Diagnostic Procedures

- The time to report should not exceed 1 hour from resulting to reporting to nurse on unit and to the physician.
- If a patient has recurring critical results of one test (i.e. Troponin), subsequent results that are improving do not need to be called to physician.
- If an abnormal result is known to the Physician the result does not need to be called, unless lab value worsens (i.e. WBC on a Neutropenic patient).
- Results that are being treated by physicians order or per protocol do not need to be called to physician (i.e. PTT for Heparin Protocol)
- Results of Radiology reports verifying correct placement of a device do not need to be called to the Physician (i.e. ICD, pacemaker, ET tube, feeding tubes, central lines).
- ❖ Lab Policy- Reporting of Critical Laboratory Values
- ❖ Radiology Policy- Procedure for Critical Test Results

Use Medicines Safely

NPSG.03.04.01: Does the organization label all medications on and off the sterile field in procedural settings?

❖ Policy #108 Medication Labeling on and off the Sterile Field

❖ Policy # 02-4400-07-333 Labeling of Non Pharmacy Prepared Medications and Vaccines

- All medication that are not immediately administered need to be labeled.
- Label must include : Name, Dose, Preparation date
- Discard any unlabeled medications.

NPSG.03.05.01: Does the organization reduce the likelihood of patient harm associated with the use of Anticoagulants?

❖ Policy #111 Anticoagulation Management

- Use approved protocol for initiation and maintenance of therapy
- Baseline/ Ongoing monitoring: (check INR prior to starting a patient on warfarin, Monitor for Renal dysfunction)
- Dietary receives a list daily of any patient receiving warfarin to ensure no drug-food interactions
- Provide education regarding anticoagulation therapy to the patient at Discharge. Education prints automatically at the time of discharge from HCS.

NPSG.03.06.01: Does the organization maintain and communicate accurate patient medication information?

❖ Policy #11 Medication Reconciliation- Admission through Discharge

Use Alarms Safely

NPSG.06.01.01: How does the organization improve the safety of critical alarm systems?

Roper St. Francis Healthcare has chosen:

- Tele Alarms
- Ventilator Alarms
- IV Pump Alarms

Prevent Infection

NPSG.07.01.01: How does the organization comply with the CDC and WHO guidelines for Hand Hygiene?

- ❖ IC Policy- Hand Hygiene
- ❖ Monitor unit compliance

NPSG.07.03.01: How does the organization implement evidenced based practices to prevent health care associated infections due to multidrug-resistant organisms?

❖ IC Policy- Multi Drug Resistant Organisms

NPSG.07.04.01: How does the organization implement evidenced based practices to prevent central line infections?

❖ Nursing Policy- Care of Central Venous Line - Line is monitored for need to continue use

NPSG.07.05.01: How does the organization implement evidenced based practices for preventing surgical site infections?

❖ Follows SCIP Guidelines for hair removal, antibiotic selection and administration

NPSG.07.06.01: How does the organization implement evidenced based practices to prevent indwelling catheter associated urinary tract infections?

❖ Follows evidenced based guidelines for securing catheters, maintaining sterility, and removal of catheters.

❖ Monitor patients daily for need for Foley catheter. Remove as soon as possible using the Foley Removal Protocol.

Quality Indicators

Roper St. Francis Healthcare has a Center for Patient Safety which consists of staff dedicated to serving the organization's quality and patient safety needs. The Center produces a monthly quality scorecard that tracks performance measures related to the patient experience, outcomes, ambulatory care, and other metrics (e.g. teammate injuries) and identifies major areas to focus.

B28. Provide any additional information that would assist the department in evaluating this project.

Not Applicable

C1. An Indigent Care Plan as required by the Board of Health and Environmental Control. It shall address at minimum, the following:

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

The Roper St. Francis Healthcare nondiscrimination policy (to be extended to Roper St. Francis Hospital – Berkeley) which applies to Roper Hospital, St. Francis Hospital, and Mount Pleasant Hospital, any departments owned or operated by these Hospitals, as well as Roper St. Francis Physician Partners, Roper St. Francis Worksite Partners, and Roper St. Francis Medshare does not exclude, deny benefits to, or otherwise discriminate against any person on the ground of race, color, or national origin, or on the basis of disability or age in admission to, participation in, or receipt of the services and benefits under any of its programs and activities, whether carried out by the facilities named above directly or through a contractor or any other entity with which the facilities' names above arranges to carry out its programs and activities.

With regards to ability to pay, it is the policy of Roper St. Francis Healthcare to provide patient care in accordance with the Emergency Medical Treatment and Active Labor Act (EMTALA), Consolidated Omnibus Budget Reconciliation Act (COBRA), Centers for Medicare & Medicaid Services (CMS), The Joint Commission (TJC), and other federal, state, and local regulations regarding the treatment and transfer of patients experiencing a medical emergency. The system's Financial Assistance Program offers financial assistance and medical indigency adjustments to patients who meet the established guidelines.

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

Refer to the response provided in "a" above.

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

Not Applicable

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

Projections begin in 2019, given the hospital's anticipated licensure will occur in 2019.

RSF Hospital - Berkeley	2019	2020
Total Patient Revenue	\$52,436,329	\$96,175,681
Charity Care Expense	\$1,153,599	\$2,115,865
Percentage	2%	2%

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

Projected charity care in conjunction with community outreach programs at Roper St. Francis Healthcare member hospitals is anticipated to meet many of the community's needs. The health system intends to continue working with local and state leaders in efforts to better address the indigent care issues in conjunction with health care reform.

Roper St. Francis Healthcare is committed to public service as part of its mission - "Healing All People With Compassion, Faith, and Excellence". The following summarizes Roper St. Francis Healthcare's \$56,827,475 in community benefit for 2015:

- Charity care at cost totaled \$46,479,148
- Community outreach programs including grants benefitting the community totaled \$5,128,121
 1. The system served 96,984 citizens via health fairs and community events.
 2. Roper St. Francis Healthcare employees showed their commitment to the community by providing 90,589 hours of staff time to support community and health related initiatives, including sponsorship of approximately 120 community events and participation in 75 requested community health fairs and screenings.
 3. Monetary donations, contributions of paid employee time and donations of supplies and equipment are a few ways Roper St. Francis Healthcare supports organizations that are consistent with its mission. Organizations sponsored in 2015 included (but are not limited to): Access Health, Barrier Island Free Clinic, Spinal Cord Injury Program, Our Lady of Mercy Outreach Center Prenatal Clinic, and Ryan White Program.
- Unreimbursed Medicaid cost \$4,686,835
- Community investment \$533,371

Initiatives to Address Area Indigent Care Issues and Improve Community Health:

Roper St. Francis Healthcare conducted a 2013 Community Health Needs Assessment (CHNA) for all three member hospitals as required for not-for-profit hospitals to comply with the Affordable Care Act. It identifies local health and medical needs, and provides a plan to indicate how Roper St. Francis Healthcare will respond to these needs. This effort will be conducted at least once every three years, and Roper St. Francis is in the process of updating this CHNA for 2016. Roper St. Francis chose the following six issues as priorities to implement for its current CHNA, and the ongoing assessment and monitoring confirm that these are the major priorities of focus:

- Access to services and coverage for the uninsured and underinsured
- Mental health
- Maternal and child health
- Prevention/wellness/outreach
- High prevalence of chronic disease
- Coordination of care across settings

The Community Needs Assessment Team has developed implementation strategies for each health priority identified above. The implementation plan is updated every year and the 2016 document is available. Strategies are clearly defined, and a matrix of which areas each hospital campus will address included.

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

The CareAlliance Health Services Board of Directors is responsible for the charity care programs at member hospitals and allocates funding on an annual basis for indigent and uncompensated care.

C2. A map of sufficiently large scale to be meaningful, indicating the location of the project site and its geographical area.

Refer to Attachment 3.

C3. A plot plan of the project site showing existing buildings, roads, parking areas, walks, service and entrance courts, existing utilities, and other natural land features necessary for adequate analysis of site conditions.

An intersection map denoting the hospital's location is included in Attachment 3. A plot plan showing roads, parking areas, etc. won't be available until July, given the hospital's main entrance is being reoriented to Highway 176 (requiring significantly less disturbance to the natural features of the land) with a secondary entrance from US 17-A.

C4. A legal description of the project site indicating its physical characteristics and existing easements.

Refer to Exhibit A of the Deed included in Attachment 8.

C5. A square foot program of space and/or equipment elements, and scale drawings describing the existing space and proposed alterations and additions.

Refer to Attachment 3.

C6. Documentation from the appropriate zoning authorities that the proposed site is or can be zoned for the intended use.

Not applicable as this is a hospital service addition

C7. Documentation from appropriate sources that utilities supplied to the site are adequate for the project to include electricity, gas, water, and sewerage.

Not applicable as this is a hospital service addition

C8. Endorsement from the community that the project is desirable. This may include but is not limited to members of the medical community, citizen's groups, and other health and social service disciplines in the community.

Project support letters have been included in Attachment 7.

C9. Documentation that the proposed project has been approved by the health facility's planning committee and governing body.

Reference Attachment 9.

C10. For the facilities or services not licensed by the Department of Health and Environmental Control, provided documentation of coordination and support from the appropriate licensing agency.

Not applicable

Part D. Assurances

Roper St. Francis Hospital - Berkeley assures each of the following where applicable:

1. That the applicant has or will have a fee simple title or such other estate or interest in the site including necessary easements and rights-of-way, sufficient to assure use and possession for the purpose of the construction and operation of the facility.
2. That approval by the department of the final drawings and specifications, which will be prepared by an architectural and/or engineer legally registered under the laws of the State of South Carolina, will be obtained.
3. That the applicant will submit to the Department for prior approval changes that substantially alter the scope of work, function, utilities, major items of equipment, safety or cost of the facility during construction.
4. That the applicant will cause the project to be completed in accordance with the Certificate of Need application.
5. That the applicant will cause the project to be completed in accordance with approved plans and specifications by maintaining competent and adequate architectural and engineering services throughout the construction administration phase of the project. That, at the completion of the project, the architect of record shall be required to issue a statement that to the best of his knowledge and belief, based upon available records, supplemental documents, and periodic observation of the work, the project was constructed according to those documents approved by the Department.
6. That the facility will be operated and maintained in accordance with the standards prescribed by law and regulations for the maintenance and operation of such facilities.
7. That the applicant understands that the Certificate of Need shall become void at the end of the specified time period from the date of issuance unless otherwise extended under Chapter 6 of these regulations.
8. That the Department or its authorized representatives may at any time during the course of construction and upon the completion of the project make an on-site inspection of the construction and equipment to check for compliance of the construction in accordance with the application for which the Certificate of Need was issued.
9. That the controlling interest in any health care facility shall not be sold or leased or otherwise disposed of unless the Certificate of Need has been fulfilled.

10. That the applicant will notify the Department in writing that the contractual agreement has been completed. For a construction project, the letter shall indicate that a construction contract specifying the beginning and completion dates of the project, has been signed by both parties. For service projects, the letter must indicate that equipment purchase orders with estimated delivery dates have been properly negotiated.
11. That the applicant will notify the Department in writing of the date that a new or expanded services has been implemented, completed or terminated.
12. That the applicant will provide monthly progress reports and a final completion report which contains the information required by Section 607 of these regulations.

Attachments

- 1: Affidavit of Publication
- 2: Cost Estimates
Architect's Scope Narrative
- 3: Maps
Schematics and Space Program
- 4: CAHS Organizational Chart
- 5: Need Analysis Supporting Documentation
- 6: Accountant's Letter
Financials
- 7: Project Support Letters
- 8: Legal Description
- 9: Resolution of Board Approval

Attachment 1
Affidavit of Publication

ROPER HOSPITAL
316 CALHOUN STREET
CHARLESTON SC 29401

AFFIDAVIT OF PUBLICATION

The Post and Courier

State of South Carolina

County of Charleston

Personally appeared before me the undersigned advertising clerk of the above indicated newspaper published in the city of Charleston, county and state aforesaid, who, being duly sworn, says that the advertisement of

(copy attached)

appeared in the issues of said newspaper on the following day(s):

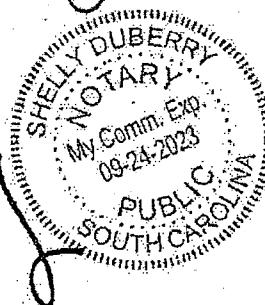
04/28/16 Thu PC 04/30/16 Sat CNW
04/29/16 Fri PC
04/30/16 Sat PC
04/28/16 Thu CNW
04/29/16 Fri CNW

at a cost of \$74.28
Account# 113469
Order# 1448940
P.O. Number

Subscribed and sworn to before
me this 2nd day
of May
A.D. 2016

Stephanie Kruger
advertising clerk

NOTARY PUBLIC, SC
My commission expires



CON.0080

Attachment 2
Cost Estimates
Architect's Scope Narrative

Budget Item	Cost
GE Imaging System	\$936,494.00
CVPACS and Hemo System Merge	\$113,845.00
Boston Scientific IVUS system	\$97,650.00
St Jude FFR system	\$111,000.00
Intercom system	
Medtronic Temporary Pulse generator	\$3,604.00
Oxicom Whole blood Oximeter	\$7,040.00
Datascope Intra-aortic balloon pump console	\$59,483.00
I-Stat	\$7,400.00
Medrad contrast injector	\$82,376.00
Blanket warmer	\$6,951.00
Surgical tables	\$0.00
IMPELLA console	\$49,118.00
Drug pyxis	\$4,350.00
Lead aprons	\$400.00
Bovie	\$24,689.00
Lead shield	\$4,200.00
Surgical lights	\$157,799.35
Crashcart	\$14,152.61
Mayo stand	\$640.00
Lead racks	\$881.83
Zoll Defibrillator	\$10,177.84
Radial arm board	\$0.00
storage cart	\$4,800.00
IV pumps	\$4,762.00
EKO's console	\$14,400.00
Patient lift/moving equipment	\$6,704.00

\$1,722,917.63

\$146,448.00

\$1,869,365.63



GE Healthcare

Date: 05-05-2016
 Quote #: PR4-C70069
 Version #: 1

Roper Hospital
 316 Calhoun St
 Charleston SC 29401-1113

Attn: Michael Grayson
 Charleston
 SC 29401

Date: 05-05-2016

Quote Summary Heading

Qty	Description	Ext List Price	Ext Sell Price
1	IGS 520 Single Plane		
	IGS 520 Single Plane	\$1,798,385.00	\$936,494.30
Quote Summary:			
Total List Price:			\$1,798,385.00
Total Discount: (47.93%)			(\$861,890.70)
Total Extended Selling Price:			\$936,494.30
Total Quote Net Selling Price			\$936,494.30

Summary Note:



GE Healthcare

Date: 05-05-2016
 Quote #: PR4-C70069
 Version #: 1

Roper Hospital
 316 Calhoun St
 Charleston SC 29401-1113

Attn: Michael Grayson
 Charleston
 SC 29401

Customer Number: 1-231PL4
 Quotation Expiration Date: 08-03-2016

This Agreement (as defined below) is by and between the Customer and the GE Healthcare business ("GE Healthcare"), each as identified herein. Agreement is defined as this Quotation and the terms and conditions set forth in either: (i) the Governing Agreement identified below, or (ii) if no Governing Agreement is identified, the following documents:

- 1) This Quotation that identifies the Product offerings purchased or licensed by Customer;
- 2) The following documents, or applicable, if attached to this Quotation: (i) GE Healthcare Warranty; (ii) GE Healthcare Additional Terms and Conditions; (iii) GE Healthcare Product Terms and Conditions; and (iv) GE Healthcare General Terms and Conditions.

In the event of conflict among the foregoing items, the order of precedence is as listed above.

This Quotation is subject to withdrawal by GE Healthcare at any time before acceptance. Customer accepts by signing and returning this Quotation or by otherwise providing evidence of acceptance satisfactory to GE Healthcare. Upon acceptance, this Quotation and the related terms and conditions listed above for the Governing Agreement, if any, shall constitute the complete and final agreement of the parties relating to the products identified in this Quotation.

No agreement or understanding, oral or written in any way purporting to modify this Agreement, whether contained in Customer's purchase order or shipping release forms, or elsewhere, shall be binding unless hereafter agreed to in writing by authorized representatives of both parties.

Governing Agreement:	Premier
Terms of Delivery:	FOB Destination
Billing Terms:	80% delivery / 20% installation
Payment Terms:	Net Due in 30 Days
Total Quote Net Selling Price:	\$936,494.30

INDICATE FORM OF PAYMENT:

If "GE HFS Loan" or "GE HFS Lease" is NOT selected at the time of signature, then you may NOT elect to seek financing with GE Healthcare Financial Services (GE HFS) to fund this arrangement after shipment.

☐ Cash/Third Party Loan
☐ GE HFS Lease
☐ GE HFS Loan
☐ Third Party Lease (please identify financing company) _____

By signing below, each party certifies that it (i) has received a complete copy of this Quotation, including the GE Healthcare terms, conditions and warranties, and (ii) has not made any handwritten or electronic modifications. Manual changes or mark-ups on this Agreement (except signatures in the signature blocks and an indication in the form of payment section below) will be void.

Each party has caused this agreement to be executed by its duly authorized representative as of the date set forth below.

CUSTOMER

Authorized Customer Signature _____ Date _____

Print Name _____ Print Title _____

Purchase Order Number (if applicable) _____

GE HEALTHCARE

Joseph Riley _____ 05-05-2016

Signature _____ Date _____

Product Sales Specialist

Email: Joseph.Riley@ge.com

Office: +1 843 813 4894

Mobile: 843.813.4894

Fax: 205.449.9808



GE Healthcare

Date: 05-05-2016
 Quote #: PR4-C70069
 Version #: 1

Total Quote Selling Price	\$936,494.30
Trade-In and Other Credits	\$0.00
Total Quote Net Selling Price	\$936,494.30

To Accept this Quotation

Please sign and return this Quotation together with your Purchase Order To:

Joseph Riley:
 Office: +1 843 813 4894
 Mobile: 843.813.4894
 Email: Joseph.Riley@ge.com
 Fax: 205.449.9808

Payment Instructions

Please Remit Payment for invoices associated with this quotation to:

GE Healthcare
 P.O. Box 96483
 Chicago, IL 60693

To Accept This Quotation

- Please sign the quote and any included attachments (where requested).
- If requested, please indicate your form of payment.
- If you include the purchase order, please make sure it references the following information:
 - The correct Quote number and version number above
 - The correct Remit To information as indicated in "Payment Instructions" above
 - The correct SHIP TO site name and address
 - The correct BILL TO site name and address
 - The correct Total Quote Net Selling Price as indicated above

Upon submission of a purchase order in response to this quotation, GE Healthcare requests the following to evidence agreement to contract terms:
 Signature page on quote filled out with signature and P.O. number.

*****OR*****

Verbiage on the purchase order must state one of the following: (i) Per the terms of Quotation # _____; (ii) Per the terms of GPO# _____; (iii) Per the terms of MPA # _____; or (iv) Per the terms of SAA # _____. Include the applicable quote/agreement number with the reference on the purchase order.

In addition, source of funds (choice of: Cash/Third Party Loan or GE HFS Lease or GE HFS Loan or Third Party Lease through _____), must be indicated, which may be done on the quote signature page (for signed quotes), on the purchase order (where quotes are not signed) or via a separate written source of funds statement (if provided by GE Healthcare).



GE Healthcare

Date: 05-05-2016
Quote #: PR4-C70069
Version #: 1

05-05-2016

GPO Agreement Reference Information

Customer: Michael Grayson
Contract Number: PLEASE SEE PREMIER CONTRACT # BELOW
Start Date:
End Date: 06/30/2019

Billing Terms: 80% delivery / 20% Installation
Payment Terms: Net Due In 30 Days
Shipping Terms: FOB Destination

For a copy of the GPO contract or summary, please go to your GPO Membership login page premierconnect.premierinc.com. If a copy of the contract is not available on your membership page, please contact your GPO client manager.

Offer subject to the Terms and Conditions of the applicable Group Purchasing Agreements currently in effect between GE Healthcare and Premier Purchasing Partners, L.P. include PP-CA-261 (CV) and PP-CA-258 (Invasive Cardiology).



GE Healthcare

Date:
Quote #:
Version #:

05-05-2016
PR4-C70069
1

Item No.	Qty	Catalog No.	Description	Ext Sell Price
	1		IGS 520 Single Plane	
1	1	S18921EH	INNOVA-IGS 520 WITH OMEGA V Long Table	\$530,715.00
2	1	S18061TP	SmartBox for Omega Tables	\$2,500.00
3	1	S18061TW	Smart Handle for Omega Tables	\$2,500.00
4	1	S18061RE	Omega V Table Foot End Rail Extender	\$2,500.00
5	1	S18061TX	2nd Remote TSSC for Omega Tables	\$2,500.00
6	1	S18461MX	Large Display In-Room Monitor	\$105,000.00
7	1	S18391LZ	Large Display Monitor Suspension with 36 meter cable	\$20,000.00
8	1	S18111PV	Power Cord for LDM	Incl.
9	1	S18751PY	3KVA UPS for LDM, 110 volt	Incl.
10	1	S18461LM	Link Set for Recording System	\$2,400.00
11	1	S18461MC	Link Set for CA1000	\$1,900.00
12	1	S18461AD	Analog to Digital Converter Kit	\$1,525.00
13	1	S18461LP	Link Set for PACS	\$1,900.00
14	1	S18461LV	Link Set for IVUS Volcano	\$1,200.00
15	1	S18461LH	Link Set for EP Mapping	\$1,900.00
16	1	S18461LW	Link Set for AW, Innova 3D, and Innova CT	\$5,500.00
17	1	S18461LG	Link Set for Digital and Analog Ultrasound	\$2,550.00
18	1	S18461LZ	Link Set for Open 1	\$1,900.00
19	1	S1876PE	Main Power Disconnect Panel - UPS Ready	\$13,149.50
20	1	S18751PW	UPS INTERFACE	\$900.00
21	1	S1875PK	Innova IQ-20KVA UPS	\$12,500.00
22	1	S18101CH	UL Coolix SMC Auto-Transformer	\$1,150.00

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GE Healthcare

 Date:
 Quote #:
 Version #:

 05-05-2016
 PR4-C70069
 1

Item No.	Qty.	Catalog No.	Description	Ext. Sell Price
23	1	S18751CB	Cardiac Analysis Package on DL Digital System	\$14,000.00
24	1	S18921EE	PCI ASSIST	\$55,000.00
25	1	S18721AF	Administration Package	\$5,000.00
26	1	S18751FS	FluoroStore with Fluoroloop	\$7,500.00
27	1	S18751SA	In-room Browser	\$2,500.00
28	1	S18751CH	InnovaChase 5 fps Peripheral Bolus Chase with DRM Option	\$10,000.00
29	1	S18921NB	Standard Positioning and Anti-Collision Package	Incl.
30	1	S18921LA	Dose & IQ Optimization Package for IGS520	\$35,000.00
31	1	E7018HA	Mark 7 Arterion injector on integrated pedestal with installation and warranty (GE Innova package)	\$36,000.00
32	1	E4502SS	NR - X-Ray Warning and Room Lighting Control Panel	\$1,740.00
33	1	E6220J	VIS-A-VIS Vitaling Intercom System for X-ray	\$9,600.00
34	1	E7009CA	Innova 2100/2121 Detector Drapes (20/box)	\$79.20
35	1	E7060A	Omega Foot End Table Rail	\$1,440.00
36	1	E6415J	X-Ray Table Clamp for Remote Panning Handle	\$520.00
37	1	E8016AY	GE Angio/Cardiac Slicker for Omega V Tables - 132 in.	\$276.00
38	1	E6420BJ	HB-1 Armboard	\$960.00
39	1	E6420BK	HB-1 Armboard Pad	\$96.00
40	1	E8015JB	Omega V Tempurpedic Table Pad (1 in. Thick, 131 in. L)	\$1,260.00
41	1	E7018JZ	Mavig 2.5m Track without Cable Spooler	\$2,560.00
42	1	E3053CC	2.5m Cable Spooler (requires E3053CM)	\$679.20
43	1	E3053CM	Cable Holders and Stoppers for Ceiling Track	\$279.20
44	1	E3053BC	Portegra2 360 Ceiling Column w/ Carriage - 58 cm.	\$2,288.80



GE Healthcare

 Date:
 Quote #:
 Version #:

 05-05-2016
 PR4-C70069
 1

Item No.	Qty.	Catalog No.	Description	Ext. Sell Price
45	1	E3053CH	Contour Shield 76 x 61 cm (with center connect)	\$5,199.20
46	1	E3053HB	LED130, focusable LED examination lamp	\$6,700.00
47	1	E3053JB	Movig Double-Pivot, Flexible Lower Body Protector	\$4,367.20
48	2	E7058AB	GE Anti-Fatigue Floor Mat (Gray 3x5 x 5/8")	\$760.00
49	1	W0101CV	8 Days Interventional X-ray Advanced Applications On-site System Training	\$18,500.00
50	1	S18101SP	Installation Template	Incl.
51	1	S18101SM	Vascular Base Plate Assembly	Incl.
52	1	S18751CD	MAC Lab Cable 70 inches	Incl.
53	1	S18941CG	CABLES SYSTEMS GROUPE 1 M	Incl.
54	1	S18941GK	CABLES SYSTEMS GROUPE 2 M	Incl.
55	1	S18941CE	Group 3 Cable - Standard Length	Incl.
56	1	S18741EY	Group 4 - 5 Cable	Incl.
57	1	S18741PG	Innova Lift Dolly	Incl.
58	1	S18101SX	Rails and Cable Drapes	Incl.
59	1	S18121TB	X-ray Digital Detector Coolant Kit	Incl.
60	1	S18101SF	Above Grade and Through Bolts	Incl.
61	1	S18111SB	9 ft. 6 inch Inboard Monitor Bridge	Incl.
62	1	S18111SH	Long Sleeve for 3 Monitor Support	Incl.
63	1	S18121RD	In Board Rails, 228 inch/579 cm	Incl.

Quote Summary:

Total List Price:	\$1,798,385.00
Total Discount: (47.93%)	(\$861,890.70)
Total Extended Selling Price:	\$936,494.30

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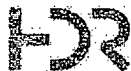
GE Healthcare

Date:
Quote #:
Version #:05-05-2016
PR4C70069
1

Item No.	Qty.	Catalog No.	Description	Ext. Sell Price
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Total Quote Net Selling Price**\$936,494.30**

(Quoted prices do not reflect state and local taxes if applicable. Total Net Selling Price
Includes Trade In allowance, if applicable.)



April 27, 2016

Mr. Scott Broome, FACHE
Roper St. Francis
316 Calhoun Street
Charleston, SC 29401

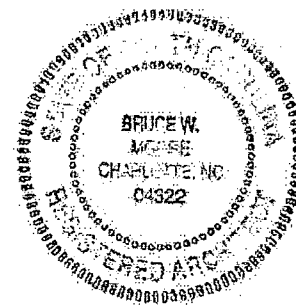
RE: **Certificate of Need**
Roper St. Francis Berkeley Hospital – Cardiac Cath / Special Procedures

Dear Mr. Broome:

This is to certify that I have reviewed the Construction Costs for the referenced project. Based upon my review and comparison of this project with similar projects, I believe the costs indicated are a reasonable estimate of the Construction Costs to be expected on a project of the scope defined. The **Anticipated Construction Cost** is **\$770,000** which includes \$48,230 for estimated Architectural and Engineering Fees. The construction cost and floor area summary is as follows:

	<u>Amount</u>	<u>Square Footage</u>	<u>Cost / SF</u>
Construction Costs	\$643,072	1,600	\$401.92
Subtotal	\$643,072	1,600	\$401.92
Architectural and Engineering Fees	\$ 48,230		
Signage	\$ 4,502		
Other Professional Fees	\$ 9,646		
Project Contingency	\$ 64,550		
Total Construction	\$770,000		

Bruce William Moore, AIA
South Carolina License No. 4322



hdrinc.com

440 S. Church Street, Charlotte, NC 28202
T 704.338.9700 F 704.338.6766

CON.0091

Attachment 3
Maps
Schematics and Space Program

Proposed Site

SC Highway A

J01-093

R845

J01-094

5 Miles from Summerville

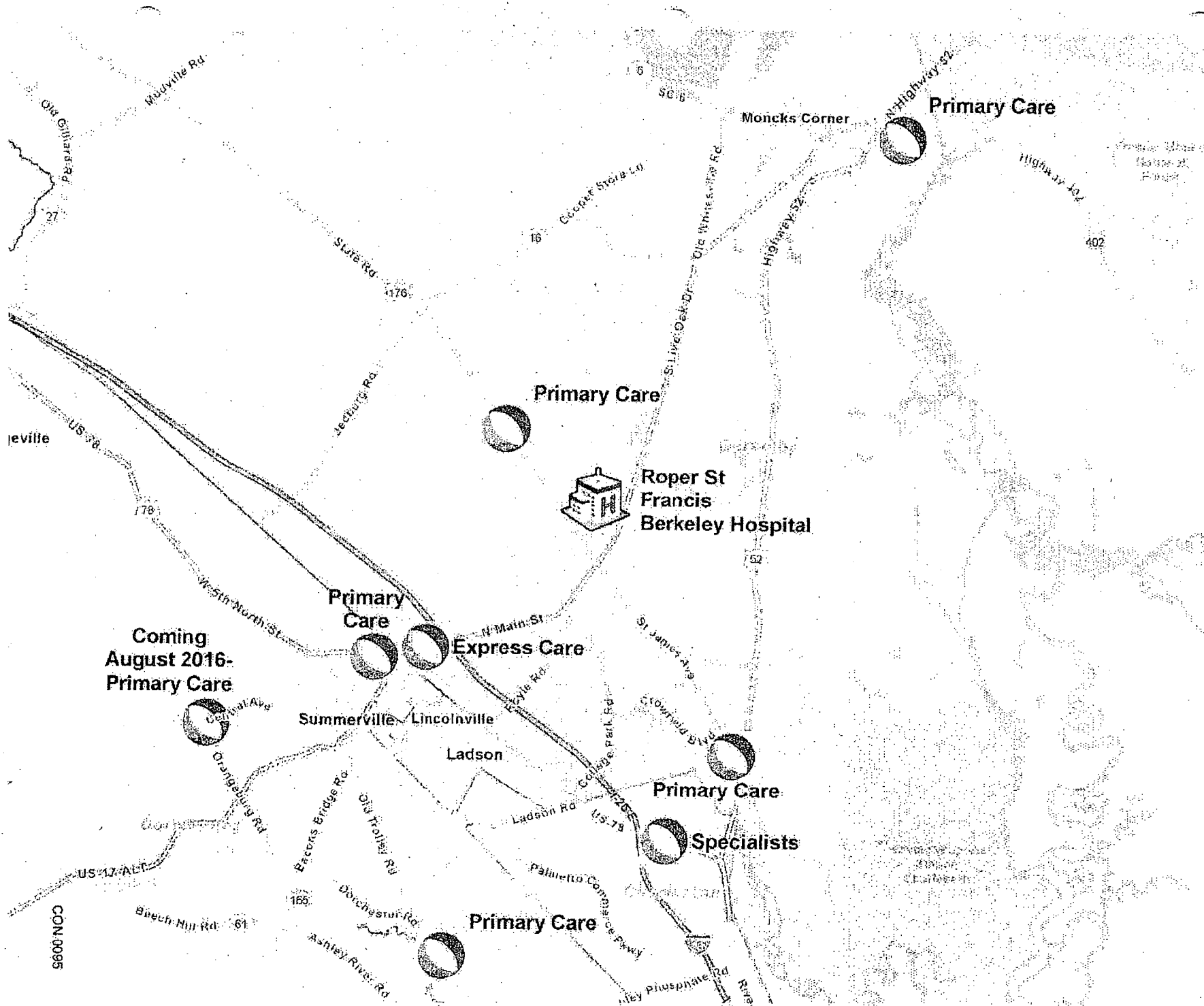
12 Miles from Moncks Corner

7 Miles from Goose Creek

**Roper St Francis
Berkeley Hospital**

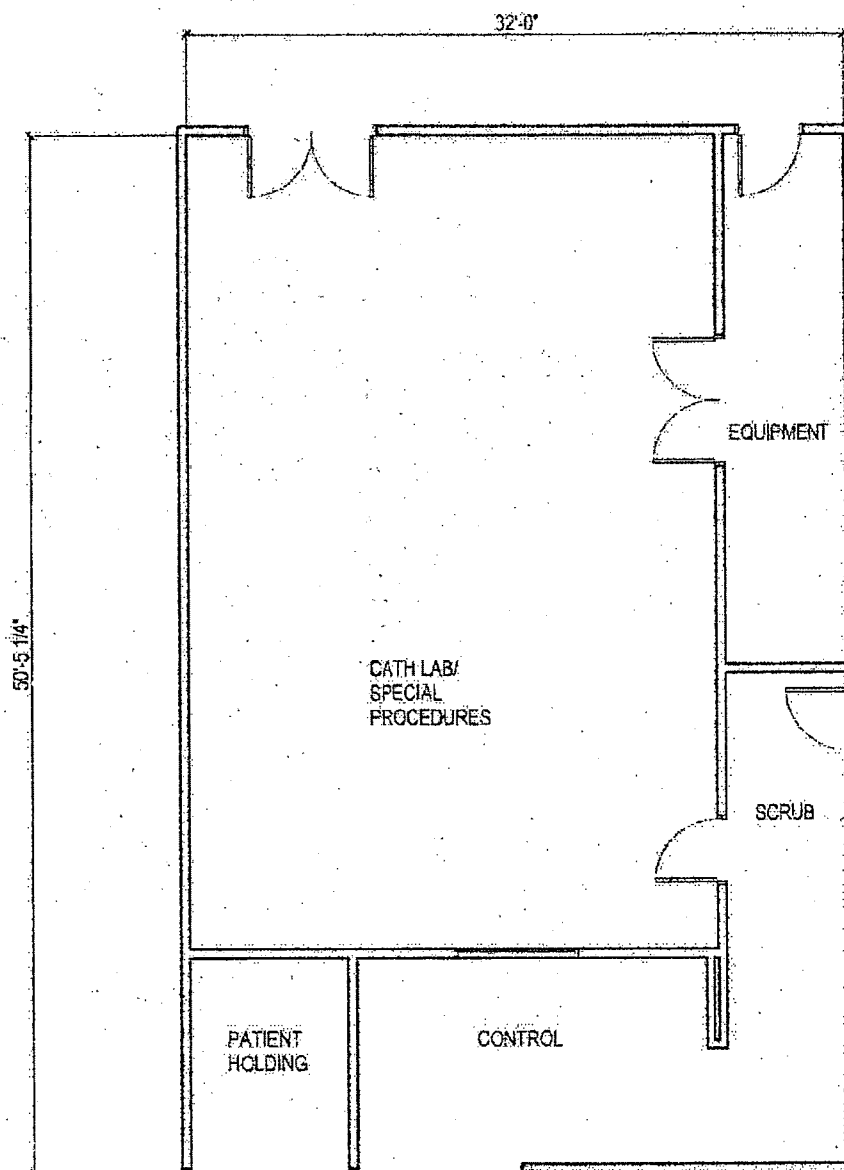
R846

J01-095



CON 0095

R847



**CATH/ SPECIAL PROCEDURES ROOM
SCHEMATIC FLOOR PLAN**

RSF BERKELEY HOSPITAL
SCALE: 1/8" = 1'-0"

CON.0096



Room/Area	Unit	NSF	Total NSF	Comments
-----------	------	-----	--------------	----------

Invasive Cardiology / Special Procedures

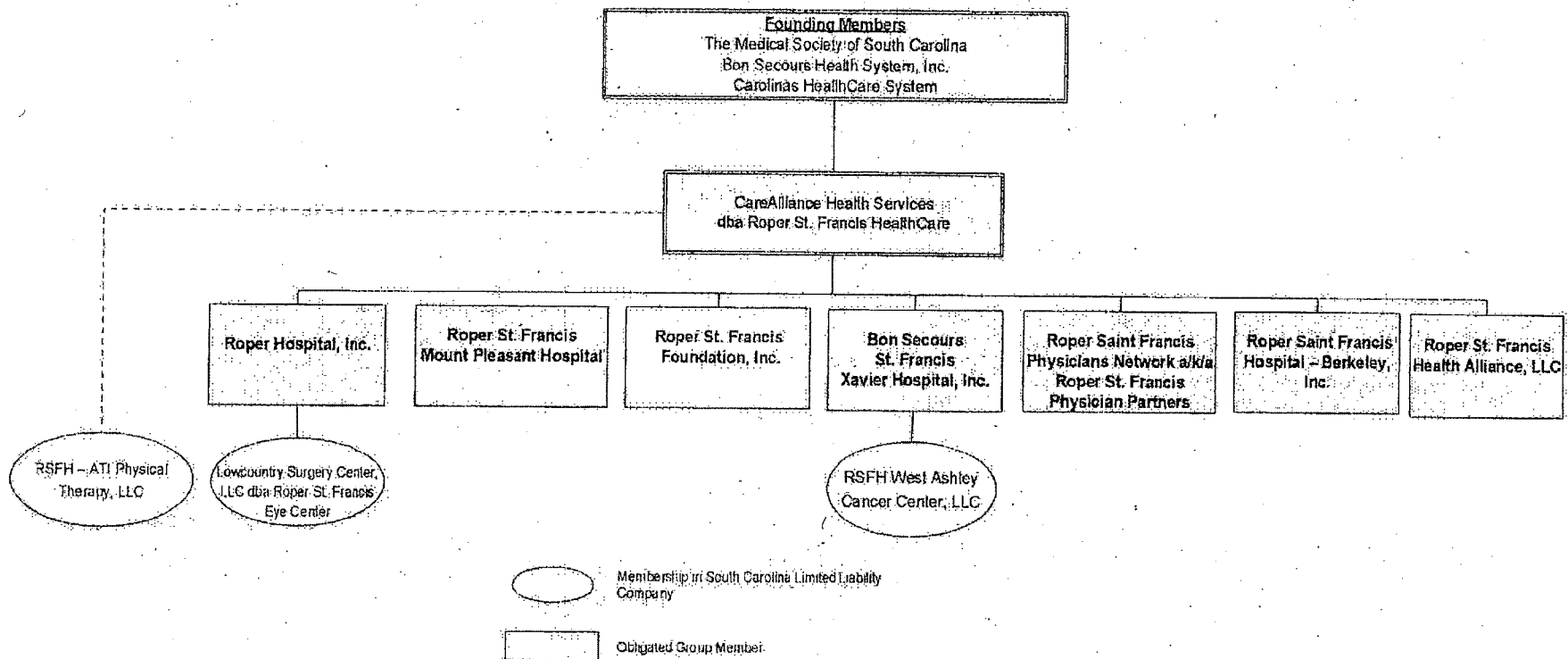
Interventional Room	1	900	900	
Control Room	1	100	100	
Computer Room	1	100	100	
Patient Holding/Recovery Cubicle	1	80	80	
Scrub Station	1	20	20	
Laser Imager/Processor Station	1	60	60	
Tech Work Area	1	40	40	
Support and Circulation	1	300	300	

Subtotal

1,600

Attachment 4
CAHS Organizational Chart

**Organizational Chart
CareAlliance Health Services d/b/a
Roper St. Francis Healthcare**



J01-099

Version 1.01.001

CON 0099

R851

Attachment 5

Need Analysis Supporting Documentation

PATIENT TRANSFER AGREEMENT

THIS PATIENT TRANSFER AGREEMENT (the "Agreement") is made effective as of the ___ day of May, 2016 ("Effective Date"), by and between **Roper Hospital, Inc.** ("RHI"), a nonprofit corporation organized and governed under the laws of the State of South Carolina and exempt from taxation pursuant to Sections 501(c)(3) and 509 of the Internal Revenue Code of 1986, as amended, and **Roper St. Francis Hospital – Berkeley, Inc.** a nonprofit corporation organized and governed under the laws of the State of South Carolina and exempt from taxation pursuant to Sections 501(c)(3) and 509 of the Internal Revenue Code of 1986, as amended, ("Transferor"). RHI and Transferor are hereafter sometimes singularly referred to as a "Party" and together referred to as the "Parties".

RECITALS:

WHEREAS, RHI is a tertiary hospital in Charleston, South Carolina with provides a comprehensive cardiovascular services, including screenings, diagnosis, cardiac and cardiothoracic surgery (including open-heart surgery) and rehabilitation services.

WHEREAS, Transferor is a non-profit hospital proposing to build and operate a cardiac catheterization laboratory on its primary campus in Berkeley County at .

WHEREAS, the Parties desire to work in a coordinated and cooperative fashion o enhance the quality and continuity of care for their patients and desire to facilitate appropriate patient transfers (as defined hereafter) between their respective facilities for individuals who need specialized and/or emergency care that is beyond the medical capability of the Transferor and establish protocols, policies and procedures for timely transfer, continuity of care and appropriate transport of these individuals both to and from RHI;

WHEREAS, RHI is willing to accept such transfers as required by law and under the terms and conditions as set forth in this Agreement;

WHEREAS, Transferor is willing to initiate such transfers to RHI as required by law and under the terms and conditions as set forth in this Agreement;

NOW, THEREFORE, in consideration of the mutual promises and covenants set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereby covenant, stipulate and agree as follows:

ARTICLE I. RECITALS

SECTION 1.1 The above recitals are true and correct and are incorporated herein by reference.

ARTICLE II. DEFINITIONS

1. **Recitals.** The above recitals are true and correct and are incorporated herein by reference.

2. Acceptance of Transfers. RHI agrees to accept the transfer, from the Facility to RHI, of patients who are in need of acute medical care, emergency medical services and other services, to include radiology and diagnostic imaging services, more appropriately provided by RHI. Such transfers shall be made in accordance with the terms of this Agreement. RHI shall not be required to accept the transfer of any patient during natural disasters or other emergencies, except for emergency treatment to the extent the receiving party has the capacity to provide such treatment.

3. Exchange of Information. Upon execution of this Agreement, and upon reasonable request thereafter, each party shall provide detailed information in writing to the other party respecting (i) the services it offers to patients; (ii) its admission policies and procedures; (iii) the names or titles of the persons authorized to initiate and accept the transfer of patients on behalf of such party; and (iv) the location where patients being transferred will be received at its premises. Each party shall provide at least ten (10) days prior written notice to the other party of any change in the services provided or its admission policies and procedures, and shall use reasonable efforts to provide written notice of any changes in authorized personnel or other information provided pursuant to this Agreement.

4. Authorization to Transfer. Each transfer shall be initiated by order of the patient's attending physician except in emergencies in which case the transferring party shall promptly notify the attending physician of the transfer. When the need for a transfer has been identified, the transferring party shall immediately notify the receiving party of the need to transfer the patient, the patient's current condition and treatment plan, and such other information as may be relevant to determining whether transfer to the receiving party is the most appropriate treatment option for the patient and whether the patient can be adequately cared for by the receiving party. The receiving party will use reasonable efforts to promptly admit the patient, provided the transfer is medically appropriate, all conditions for admission are met, bed space is available to accommodate the patient and the patient can be adequately cared for by the receiving party. Prior to moving the patient, the transferring party must receive confirmation from the receiving party that it can accept the patient. Transfers between the parties shall be based solely upon the considerations set forth herein, without regard to race, religion, gender, sexual orientation, color, national or ethnic origin, age or handicapping condition.

5. Communications between Providers. Each party agrees that, when a transfer is required for surgery, it will encourage regular communications between the cardiologist performing catheterizations and surgeons to whom the patients are referred.

6. Patient Consent. The transferring party shall obtain the patient's consent for all non-emergency transfers prior to making the transfer. If the patient does not have the capacity to consent to the transfer, the transferring party shall obtain the consent of the person authorized by law to consent to treatment for the patient. Each party shall use reasonable efforts to afford each patient the opportunity to choose his or her health care providers.

7. Assignment of Staff Physician. In the event the patient's attending physician does not have staff privileges at the facilities of the receiving party, the receiving party shall assist the

attending physician in making a prompt referral of the patient to an appropriate member of the receiving party's medical staff.

8. Patient Transport. The transferring party shall be responsible for the safe transport of the patient with adequate personnel, equipment and supplies. The receiving party shall not be responsible for the patient's care until the patient is admitted by the receiving party.

9. Patient Records, Diagnostic Records and Personal Effects. The transferring party agrees to send with each patient at the time of transfer or, in the case of emergency, as promptly as possible after the transfer, pertinent medical and other information necessary to continue the patient's treatment without interruption together with essential identifying and administrative information, including any required transfer forms. This information shall include the items enumerated in Schedule A attached hereto. Each party agrees to supplement such information as necessary for the maintenance of the patient during transport and treatment of the patient upon arrival at the receiving party. The records described above shall be placed in the custody of the person in charge of the transporting medium who shall sign a receipt for the medical records and the patient's valuables and personal effects and in turn shall obtain a receipt from the receiving party when it receives the records and the patient's valuables and personal effects. The parties agree that, to the extent possible under the particular circumstances, diagnostic results from the cardiac catheterization services will be provided to RHI and be used to prevent duplication of services.

10. Confidentiality of Patient Information. Except upon the express written consent of the other Party, RHI and the Transferor agree not to disclose any of the terms of this Agreement and any Confidential Information (as defined hereafter) that concerns or relates to the obligations and operations of each Party under the terms of this Agreement, to persons other than to the following: (i) physicians and patient care personnel at either Party solely for purposes of patient care; (ii) members of state or federal survey, licensing or accrediting agencies; (iii) the Joint Commission on the Accreditation of Healthcare Organizations ("JCAHO"); (iv) any third party reimbursement entity having the right and need to know; and (v) parties entitled to such information in conjunction with judicial, administrative, and other similar legal proceedings in which such information is not privileged and must be disclosed. For purposes of this Agreement, the term "Confidential Information" shall be defined to include, but not be limited to, all RHI and Transferor patient information, the terms of this Agreement, all policies and information relating to the medical, clinical, and administrative operations of RHI and the Transferor, all RHI and Transferor financial information (including, but not limited to, charges for services or procedures performed at either Party or other entities owned or affiliated with either Party, managed care contracting procedures and strategies, managed care reimbursement rates, and third party payer reimbursement procedures), RHI's or Transferor's strategic, business, and marketing plans, credentialing information, utilization information, terms of any facility agreements, relationships with vendors, and terms of other agreements to which RHI or Transferor is a party. This provision shall not be applicable to information made public through any means, other than an act or omission of RHI or Transferor, including, but not limited to, RHI's, either Party's breach of this Agreement.

Both Parties are fully aware that the Confidential Information includes protected health

information ("PHI") that each Party provides to the other in connection with their performance under this Agreement and each Party covenants that upon termination or expiration of this Agreement, any and all Confidential Information in its possession and control, whether on computer tapes, listings, or in any other format whatsoever, and any information derived from the Confidential Information, including PHI, will be returned to the other Party according to the requirements of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). RHI and Transferor contractually recognize the confidentiality of all PHI each may receive pursuant to the terms of this Agreement. Each Party will use appropriate safeguards to prevent the use or disclosure of PHI except as permitted by this Agreement, and shall immediately report to the other Party any use or disclosure of PHI not permitted by this Agreement. Each Party agrees to comply fully with the Standards for Privacy of Individually Identifiable Health Information implementing the privacy requirements of the Administrative Simplification subtitle of HIPAA set forth at 45 CFR Parts 160 and 164, and those required by the Health Information Technology for Economic and Clinical Health Act, Public Law 111-005 (the "HITECH Act") as applicable to each Party's performance of its obligations under this Agreement. Each Party further agrees to implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the PHI each creates, receives, maintains or transmits pursuant to the terms of this Agreement and shall report to the other Party any incident that compromises the security of the PHI. Each Party shall ensure that any of its respective subcontractors or agents who have access to PHI pursuant to the terms of this Agreement shall implement reasonable and appropriate safeguards to protect such PHI. The parties agree to maintain the confidentiality of patient records and other information provided by either party to the other in connection with the transfer of any patient pursuant to this Agreement. Each party shall comply with all state and federal regulations protecting the confidentiality of patient records and shall promptly notify the other party of any efforts made to obtain access to patient records provided by such party. Each party agrees to cooperate with any effort by the other party to resist in judicial proceedings efforts made to obtain access to patient records provided by such party.

11. Compliance with Applicable Laws, Regulations, Rulings or Standards. Both Parties will abide by the CareAlliance Health Services d/b/a Roper St. Francis Healthcare Code of Conduct. The parties agree to comply with all standards and amendments thereto, of all entities which govern, regulate, and/or accredit the parties, including, but not limited to, federal, state, and local government agencies, as well as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). The parties specifically agree to comply with all provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), together with all rules, regulations, and amendments promulgated as a result of that Act, including the HITECH Act. Failure of Provider to comply with these laws, rules, or regulations, may result in immediate termination of this contract by CareAlliance Health Services with no further obligations due to Provider. The parties further agree that to the extent such changes in applicable laws, regulations, rulings or standards, substantially affect the provisions of this Agreement or make privileges and immunities available, whether related to billing for reimbursement, peer review, or otherwise, the parties shall execute such written amendments to this Agreement as may be necessary to assure continued compliance with such laws, regulations, rulings, and standards, to preserve the continuous viability of the provisions of this Agreement and to take advantage of such privileges and immunities. In the event that there are subsequent changes or clarifications

of statutes, rules or regulations that either party determines must be complied with to ensure proper reimbursement from third parties, to protect/preserve their tax-exempt status or of tax-exempt bonds issued with respect thereto, or otherwise to ensure compliance with all applicable statutes, rules and regulations, each Party shall notify the other in writing of any actions it reasonably deems are necessary to comply with such changes, and the receiving party shall promptly take such actions and/or agree to modify this Agreement as is/are necessary to ensure such compliance.

12. Quality Services. RHI agrees to use only personnel with appropriate credentials, education and licensure to perform Services. All Physicians performing services shall be on the RHI Medical Staff and Subject to the RHI Medical Staff Rules and Regulations. All Services provided under this Agreement are subject to monitoring for quality and safety in accordance with applicable guidelines of the Joint Commission. Monitoring by transferor may include, but is not limited to: (i) direct observation of care provided by Vendor and/or its agents and employees; (ii) audit of documents and/or documentation related to the Services; (iii) review of incident reports and other quality and safety records related to the Services; (iv) collection of data related to the efficacy of the Services; and/or (v) review of patient satisfaction results. The parties agree to create future linkages with RHIs peer review mechanism in order to provide safe and effective services to its patients.

13. Collection of Fees. Each party (or a designated subsidiary or affiliate of such party) will arrange for the billing and collection of all fees for services rendered by such party to patients transferred to it by the other party. All fees shall be the property of the party which provided the services to the patient. If a party receives payment for any services provided by the other party, it shall promptly deliver such payment to the party who provided the services. The transferring party shall provide written notice of the transfer to each insurer, third party payor or government sponsored health benefit program, and to any other party responsible for payment for health care services provided to the patient, at the time the patient is transferred to the receiving party.

14. Covenants. Each party agrees to: (i) maintain its licensure within the State of South Carolina to offer services to patients as contemplated herein; (ii) to maintain in effect a reasonable amount of professional and premises liability insurance coverage and to provide evidence of such coverage to the other party upon reasonable request; (iii) to continue its participation as a provider of the patient services contemplated herein in government sponsored health benefit programs, including Medicare and Medicaid; and (iv) comply with all policies and procedures of government funded health benefit programs and other health insurance plans in which it participates, all JCAHO accreditation standards, and all governmental laws, regulations, rules and requirements applicable to the provision of services to patients as contemplated herein.

15. Indemnification. Each party hereby agrees to indemnify, defend and hold harmless the other party, its agents and employees, from all claims, fines, demands, suits, actions or costs, including legal and other professional fees, or any other liability relating to or arising out of the acts or omissions of the indemnifying party, its agents or employees, in the course of providing services to its patients and any patients transferred to it by the other party, including services provided in connection with the transfer of any of its patients to the other party. Each party shall notify the other party in writing within three days following the date it receives actual notice of

any incident or alleged injury which is likely to result in a claim against the other party. Such notice shall include the names, addresses and phone numbers of all persons who were present and the date, time, location and circumstances of the incident. The parties shall cooperate in the defense of any claims arising out of or in connection with the transfer of any patient pursuant to this Agreement.

16. Term. The initial term of this Agreement shall be for three (3) years beginning the Effective Date of this Agreement, subject, however, to earlier termination as provided herein. Following expiration of the initial term, this Agreement may be extended for up to two additional consecutive terms of one (1) year each, by written agreement of the parties at least thirty (30) days prior to the expiration date of the then current term.

17. Termination for Cause. Either party may terminate this Agreement immediately by written notice to the other party upon the occurrence of any of the following events: (a) limitation, revocation, suspension or nonrenewal of the other party's license to provide services to patients as contemplated by this Agreement; (b) any lapse in the other party's professional or premises liability insurance coverage or failure to maintain coverage as required by this Agreement; (c) upon any finding that the other party: (i) has been debarred, excluded or otherwise declared ineligible for participation in any government sponsored health benefit program; (ii) is the subject of any action or investigation to debar or exclude it from participation in any government sponsored health benefit program; or (iii) is charged with or convicted of any criminal offense related to the delivery of health care services; (d) failure by the other party to abide by any other provision of this Agreement within fifteen (15) days after written notice; or (e) the other party is convicted, enters plea of guilty, nolo contendere or an agreement to perform community service in lieu of a plea, to a charge of theft, fraud, violation of drug laws, sexual misconduct, or to an offense that adversely affects the reputation of the party seeking to terminate this Agreement, or which reasonably could create concern on the part of patients, the public or employees of such party.

18. Referrals. Nothing in this agreement shall be construed as limiting the rights of either party to contract with any other health care provider for the rendition of services to its patients, on either a limited or general basis, while this Agreement is in effect. This Agreement is not intended to influence the judgment of either party or any physician affiliated with either party in choosing the medical facility appropriate for the treatment and care of any patient. Neither party shall receive any compensation or benefit in return for referrals, if any are made. The parties specifically do not intend to (a) violate the Medicare and Medicaid Patient and Program Protection Act of 1987, 42 U.S.C. § 1320a-7b(b), commonly referred to as the *Anti-Kickback Statute*, the Ethics in Patient Referrals Act, 42 U.S.C. § 1395nn, commonly referred to as *Stark II* or the South Carolina Provider Self-Referral Act of 1993, S.C. Code §44-113-10 et. seq., or (b) engage in any transaction subject to the Penalty Excise Tax on Excess Benefit Transactions with Tax Exempt Hospitals, 26 U.S.C. § 4958, commonly referred to as *Intermediate Sanctions*.

19. Business Interruption: If all or a substantial portion of the operations of either party are interrupted by war, fire, labor troubles, riots, the elements, earthquakes, acts of God, eminent domain, or other force majeure, the provisions of this Agreement will be suspended for the duration of the interruption. If the interruption continues for more than thirty (30) days, the

affected party shall have the right to terminate this Agreement by written notice to the other party. This Agreement shall automatically terminate in the event that the patient services contemplated by this Agreement are no longer offered by a party following the interruption.

20. Medicare Access to Books and Records. To the extent required by federal law and regulation, and until the expiration of four (4) years after the furnishing of services pursuant to this Agreement, the each party shall make available, upon written request by the Secretary of the Department of Health and Human Services, or upon written request by the Comptroller General of the United States, or any of their duly authorized representatives, a copy of this Agreement and books, documents and records of such party necessary to certify the nature and extent of the costs incurred by the other party for any services provided hereunder. No disclosure under this paragraph shall be construed as a waiver of any legal right to which the disclosing party may be entitled.

21. Notices. All notices shall be in writing directed to a party at its address as set forth below. Either party may designate a new address by written notice to the other party. All notices shall be effective upon receipt when sent via facsimile or express mail service, and three days after mailing when mailed postage prepaid by United States registered or certified mail, return receipt requested.

To RHI:

Roper St. Francis Healthcare
125 Doughty St., Suite 720
Charleston, SC 29403
Attn: Legal Department

To Transferor:

Roper St. Francis Healthcare
125 Doughty St., Suite 720
Charleston, SC 29403
Attn: Legal Department

22. Assignment. This Agreement may not be assigned by either party without the prior written consent of the other party except that RHI may assign this Agreement to any affiliated entity.

23. Interpretation. This Agreement contains the entire understanding of the parties with respect to its subject matter and supersedes all prior agreements and understandings with respect thereto. This Agreement may be amended only by a written instrument executed by each party. The invalidity, illegality or unenforceability of any provision hereof shall not render invalid, illegal or unenforceable any other provision hereof. This Agreement shall inure to the benefit of, and be binding upon, the parties hereto and their successors and permitted assigns.

24. Waiver Limitation. No failure or delay in exercising any right, power or remedy hereunder shall constitute a waiver, forfeiture or other impairment of such right, power or remedy. Except as expressly provided herein to the contrary, the rights, powers and remedies herein are cumulative rather than exclusive and may be exercised concurrently or consecutively in any order.

25. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of South Carolina. Venue for any action hereunder shall be in Charleston County, South Carolina.

IN WITNESS WHEREOF, the parties have executed this as of the day and year first written above in a manner sufficient to bind themselves.

Roper/St. Francis Hospital - Berkeley, Inc.

By: Allen Carroll

Print Name: Allen Carroll

Title: Regional CEO

Roper Hospital, Inc.

By: MJC

Print Name: Matthew J. Severance

Title: CEO

SCHEDULE A

Records and Information to Accompany Patients
At the Time of Transfer to Another Facility

In emergencies, provide such records and information as is possible under the circumstances, and deliver any additional information as soon as possible following the transfer.

- a. Patient's name, address, age and patient identification number;
- b. Person authorized to consent to treatment for the patient if the patient is or should become incapacitated, including that person's name, street address, and telephone number;
- c. Physician referral or transfer orders;
- d. Patient consent to transfer;
- e. Current medical diagnosis and treatment plan;
- f. Patient history;
- g. Condition giving rise to the need for transfer;
- h. Condition at the time of transfer;
- i. Vital signs — including Glasgow coma Score — at time of transfer;
- j. Treatment provided to the patient, including medications given and route of administration;
- k. Laboratory and x-ray findings, appropriate laboratory specimens, and x-ray films;
- l. Fluids given, by type and volume;
- m. Name and phone number of the physician making the referral or transfer;
- n. Name and phone number of the physician at receiving facility who has been contacted about the patient;
- o. Advance directives, if any, executed by the patient; and
- p. Inventory of the patient's personal effects and any valuables accompanying the patient during the transfer.

APPROPRIATE USE CRITERIA

ACCF/SCAI/AATS/AHA/ASE/ASNC/HFSA/HRS/SCCM/SCCT/SCMR/STS 2012 Appropriate Use Criteria for Diagnostic Catheterization

A Report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, Society for Cardiovascular Angiography and Interventions, American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Heart Failure Society of America, Heart Rhythm Society, Society of Critical Care Medicine, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and Society of Thoracic Surgeons

Diagnostic Catheterization Writing Group

Manish R. Patel, MD, FACC, *Co-Chair*
Steven R. Bailey, MD, FACC, FSCAI, FAHA, *Co-Chair*

Robert O. Bonow, MD, MACC, MACP, FAHA
Charles E. Chambers, MD, FACC, FSCAI*
Paul S. Chan, MD, MSc

Gregory J. Dehmer, MD, FACC, FSCAI, FACP, FAHA
Ajay J. Kirtane, MD, SM, FACC, FSCAI
L. Samuel Wann, MD, MACC
R. Parker Ward, MD, FACC, FASE, FASNC

*Society for Cardiovascular Angiography and Interventions Representative

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Steven R. Bailey, MD, FACC, FSCAI, FAHA, *Writing Group Liaison*

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Susan G. Lakoski, MD, MS¶

D. Elizabeth Le, MD, FACC, FASE#
John R. Lesser, MD, FACC, FSCAI, FSCCT**
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Andrea M. Russo, MD, FACC, FHR§§
Matthew J. Sorrentino, MD, FACC‡‡
Mathew R. Williams, MD, FACC|||
John B. Wong, MD, FACP‡‡

†American College of Physicians Representative; ‡Heart Failure Society of America Representative; §American Society of Nuclear Cardiology Representative; ||Society of Critical Care Medicine Representative; ¶American Heart Association Representative; #American Society of Echocardiography Representative; **Society of Cardiovascular Computed Tomography Representative; ††Society for Cardiovascular Magnetic Resonance Representative; ‡‡American College of Cardiology Foundation Representative; §§Heart Rhythm Society Representative; |||American Association for Thoracic Surgery/Society of Thoracic Surgeons Representative

This document was approved by the American College of Cardiology Foundation Board of Trustees in February 2012.

The American College of Cardiology Foundation requests that this document be cited as follows: Patel MR, Bailey SR, Bonow RO, Chambers CE, Chan PS, Dehmer GJ, Kirtane AJ, Wann LS, Ward RP. ACCF/SCAI/AATS/AHA/ASE/ASNC/HFSA/HRS/SCCM-SCCT/SCMR/STS 2012 appropriate use criteria for diagnostic catheterization: a report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, Society for Cardiovascular Angiography and Interventions, American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Heart Failure Society of America, Heart Rhythm Society, Society of Critical Care Medicine, Society of Cardiovascular Computed

Tomography, Society for Cardiovascular Magnetic Resonance, and Society of Thoracic Surgeons. J Am Coll Cardiol 2012;59:1995-2027

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CON-0111

**Appropriate
Use Criteria
Task Force**Michael J. Wolk, MD, MACC, *Chair*

Steven R. Bailey, MD, FACC, FSCAI, FAHA

Pamela S. Douglas, MD, MACC, FAHA,

FASE

Robert C. Hendel, MD, FACC, FAHA,

FASNC

Christopher M. Kramer, MD, FACC, FAHA

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Manesh R. Patel, MD, FACC

Leslee Shaw, PhD, FACC, FASNC

Raymond F. Strainback, MD, FACC, FASE

Joseph M. Allen, MA

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Abstract

The American College of Cardiology Foundation, in collaboration with the Society for Cardiovascular Angiography and Interventions and key specialty and subspecialty societies, conducted a review of common clinical scenarios where diagnostic catheterization is frequently considered.

The indications (clinical scenarios) were derived from common applications or anticipated uses, as well as from current clinical practice guidelines and results of studies examining the implementation of noninvasive imaging appropriate use criteria. The 166 indications in this document were developed by a diverse writing group and scored by a separate independent technical panel on a scale of 1 to 9, to designate appropriate use (median 7 to 9), uncertain use (median 4 to 6), and inappropriate use (median 1 to 3).

Diagnostic catheterization may include several different procedure components. The indications developed focused primarily on 2 aspects of diagnostic catheterization. Many indications focused on the performance of coronary angiography for the detection of coronary artery disease with other procedure components (e.g., hemodynamic measurements, ventriculography) at the discretion of the operator. The majority of the remaining indications focused on hemodynamic measurements to evaluate valvular heart disease, pulmonary hypertension, cardiomyopathy, and other conditions, with the use of coronary angiography at the discretion of the operator. Seventy-five indications were rated as appropriate, 49 were rated as uncertain, and 42 were rated as inappropriate.

The appropriate use criteria for diagnostic catheterization have the potential to impact physician decision making, healthcare delivery, and reimbursement policy. Furthermore, recognition of uncertain clinical scenarios facilitates identification of areas that would benefit from future research.

Preface

In an effort to respond to the need for the rational use of cardiovascular services, including imaging and invasive procedures in the delivery of high-quality care, the American College of Cardiology Foundation (ACCF) in collaboration with other professional organizations has undertaken a process to determine the appropriate use of cardiovascular procedures for selected patient indications.

Appropriate use criteria (AUC) publications reflect an ongoing effort to critically and systematically create, review,

and categorize clinical situations where diagnostic tests and therapeutic procedures are utilized by physicians caring for patients with cardiovascular disease. The process is based on understanding the technical capabilities of the procedures examined. The diversity of clinical disease present makes it difficult to be comprehensive, but the indications presented hopefully identify common scenarios encompassing the majority of situations encountered in contemporary practice. Given the breadth of information conveyed, the indications do not directly correspond to the *Ninth Revision of the International Classification of Diseases* system as these codes do not include clinical information, such as symptom status.

The ACCF and the Society for Cardiovascular Angiography and Interventions (SCAI) believe that careful blending of a broad range of clinical experiences and available evidence-based information will help guide a more efficient and equitable allocation of healthcare resources in cardiovascular care and invasive catheterization. The ultimate objective of the AUC is to improve patient care and health outcomes in a cost-effective manner while recognizing that some ambiguity and nuance is intrinsic to clinical decision making. Therefore, the AUC should not be considered substitutes for sound clinical judgment and practice experience. However, when the clinical judgment and practice patterns routinely conflict with AUC ratings, further evaluation of the specific clinical circumstances should be considered.

The AUC development process itself is also evolving. Given the iterative nature of the process and incorporation of new information about the role for diagnostic and therapeutic interventions, readers are counseled that comparison of individual appropriate use ratings developed at different times over the past several years may not reflect the comparative utility of different modalities for a given indication, as the ratings may vary over time. Cardiac catheterization plays a central role in the care of patients with cardiovascular disease, and guidance around the rationale and evidence based use of the procedure is the goal of the current document.

We are grateful to the technical panel and its moderator, Pamela S. Douglas, MD, MACC, FAHA, FASE, a professional group with a wide range of skills and insights, for their thoughtful and thorough deliberation of the merits of diagnostic catheterization for various indications. We would also like to thank the 28 individuals who provided a careful review of the draft of indications, the parent AUC Task Force, and the ACCF staff, specifically Joseph M. Allen and Lea Binder for their exceptionally skilled support in the generation of this document.

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1. Introduction

The ACCF, in collaboration with SCAI and several other professional organizations, developed common clinical scenarios where diagnostic cardiac catheterization is frequently considered. The indications, as presented in these clinical scenarios, were derived from common presentations or anticipated uses, as well as from current clinical practice guidelines. The 166 indications in this document were developed by a writing group with diverse clinical expertise and scored by a separate independent technical panel on a scale of 1 to 9, to designate appropriate use (median scores 7 to 9), uncertain use (median scores 4 to 6), and inappropriate use (median scores 1 to 3).

The AUC for diagnostic catheterization has the potential to impact physician decision making, healthcare delivery, and reimbursement policy. Furthermore, it is hoped that recognition of uncertain clinical scenarios facilitates identification of areas that could benefit from future research.

This report addresses the appropriate use of diagnostic catheterization. Improvements in cardiovascular imaging technology and an expanding array of noninvasive diagnostic tools and therapeutic options for patients with cardiovascular disease have led to many more choices than in the past. As the field advances, the healthcare community needs to understand how to best incorporate this technology into daily clinical care. ACCF and SCAI are dedicated to this effort.

2. Methods

The indications included in this publication cover a variety of cardiovascular signs and symptoms as well as clinical judgments as to the likelihood of cardiovascular findings. Within each main disease category, a standardized approach was used to capture a significant number of clinical scenarios without making the list of indications excessive. The term "indication" is used interchangeably with "clinical scenario" in the document for brevity and does not imply that imaging should necessarily be done. Diagnostic catheterization may include several different procedure components. The indications developed focused primarily on 2 aspects of diagnostic catheterization. Many indications focused on the performance of coronary angiography for the detection of coronary artery disease (CAD), with other procedure components (e.g., hemodynamic measurements, ventriculography) performed at the discretion of the operator. The majority of the remaining indications focused on hemodynamic measurements to evaluate valvular heart disease, pulmonary hypertension, cardiomyopathy, and other conditions, with the addition of coronary angiography at the discretion of the operator.

The spectrum of cardiovascular disease was addressed as it would apply to the standard adult catheterization laboratory. The writing group did not consider invasive evaluations of complex adult congenital heart disease in this document, with the belief that such complex cases would be

best performed by individuals with considerable specialized expertise and at institutions with sufficient patient volume. Recommendations in this area are addressed in separate subspecialty publications. Additionally, invasive procedures such as endomyocardial biopsy, pericardiocentesis, or right heart catheterization not performed in the catheterization laboratory are not covered in this document.

The indications were constructed by a varied group of experts in both invasive and noninvasive diagnostic cardiac imaging. Subsequent modifications in the indications were made based on discussions with the task force and feedback from independent reviewers. Wherever possible, indications were mapped to relevant clinical guidelines and key publications/references (see Online Appendix).

A detailed description of the methods used for rating the selected clinical indications is found in a previous publication, "ACCF Proposed Method for Evaluating the Appropriateness of Cardiovascular Imaging" (1). Briefly, this process combines evidence-based medicine and practice experience by engaging a technical panel in a modified Delphi exercise. The technical panel first rated the indications independently, after which the results were summarized and the panel convened for a face-to-face meeting to discuss each indication. At this meeting, panel members were provided with their scores and a blinded summary of their peers' scores. After the meeting, panel members once again independently rated each indication to determine the final scores.

Although panel members were not provided explicit cost information to help determine their ratings, they were asked to implicitly consider costs as an additional factor in their evaluation of appropriate use. In rating these criteria, the technical panel was asked to assess whether the use of the test for each indication is appropriate, uncertain, or inappropriate, and was provided with the following definition of appropriate use:

An appropriate diagnostic cardiac catheterization (left heart, right heart, ventriculography, and/or coronary angiography) is one in which the expected incremental information combined with clinical judgment exceeds the negative consequences by a sufficiently wide margin for a specific indication that the procedure is generally considered acceptable care and a reasonable approach for the indication.

Each member of the technical panel assigned a score to each indication, and the scores of the technical panel were tabulated for the final ratings and assigned an appropriateness rating as follows:

Median Score 7 to 9

Appropriate test for specific indication (test is generally acceptable and is a reasonable approach for the indication).

Median Score 4 to 6

Uncertain for specific indication (test may be generally acceptable and may be a reasonable approach for indication). Uncertainty also implies that more research

and/or patient information is needed to classify the indication definitively.

Median Score 1 to 3

Inappropriate test for that indication (test is not generally acceptable and is not a reasonable approach for the indication).

The division of these scores into 3 levels of appropriateness should be viewed as a continuum. It is important to emphasize that the category of "uncertain" is a distinct category and *must not be considered either "appropriate" or "inappropriate" or lumped together with the other categories when characterizing appropriateness ratings*. A rating of uncertain will exist if: 1) there is considerable diversity in the ratings among individual members of the technical panel indicating a wide range of opinions; 2) there is insufficient clinical information provided in the clinical scenario for the raters to reach a firm conclusion about appropriateness; or 3) there is a lack of specific information in the medical literature to make a firm recommendation regarding appropriateness. The uncertain category designation should encourage investigators to perform definitive research whenever possible. A designation of "uncertain" does not imply that the test should not be used in a specific clinical scenario. Many other factors known by the clinician and difficult to characterize within the structure of the AUC could affect a decision to perform or not perform a procedure in a specific patient. It is anticipated that the AUC reports will continue to be revised as further data are generated and information from the implementation of the criteria is accumulated. The writing group recognizes that a large portion of routine medical care would be rated as uncertain when held to the standards of the AUC and therefore hope this rating is correctly interpreted and can be placed in proper context.

To prevent bias in the scoring process, the technical panel was deliberately comprised of a minority of specialists in cardiac catheterization. Specialists, although offering important clinical and technical insights, might have a natural tendency to rate the indications within their specialty as more appropriate than nonspecialists. In addition, care was taken in providing objective, nonbiased information, including guidelines and key references, to the technical panel.

The level of agreement among panelists as defined by RAND (2) was analyzed based on the BIOMED rule for a panel of 14 to 16 members. As such, agreement is defined as an indication where 4 or fewer panelists' ratings fell outside the 3-point region containing the median score.

Disagreement was defined as where at least 5 panelists' ratings fell in both the appropriate and the inappropriate categories. Any indication having disagreement was categorized as uncertain regardless of the final median score.

3. Assumptions

To limit inconsistencies in interpretation, specific assumptions were used by the writing group in drafting indications

and by the technical panel when rating the clinical indications for the appropriate use of diagnostic catheterization.

1. The clinical scenarios were rated based on published literature and clinical practice guidelines regarding the risks and benefits of diagnostic catheterization, if available. In general, there are few randomized trials specifically examining diagnostic catheterization as a procedure. However, diagnostic catheterization was used within the study design of many randomized trials in which specific therapies were tested. Specific patient groups not well represented in the literature are not presented in the current clinical scenarios. However, the writing group recognizes that decisions about diagnostic catheterization in such patients are frequently required. Examples of such patients include those with end-stage renal disease, advanced age, or malignancy.
2. All patients are attempting to achieve optimal care, including guideline-based risk factor modification for primary or secondary prevention in cardiovascular patients unless specifically noted (3-7).
3. Despite the best efforts of the clinician, all patients may not achieve target goals for risk factor modification. However, a plan of care to address risk factors is assumed to be occurring in patients represented in the indications. For patients with chronic stable angina, the writing group recognizes that there is a wide variance in the medical therapy for angina.
4. Operators performing diagnostic catheterization have appropriate clinical training and experience and have satisfactory outcomes as assessed by quality assurance monitoring (8,9).
5. Diagnostic catheterization (left heart, right heart, and/or coronary angiography) is performed in a manner consistent with established standards of care (8,9).
6. All indications for diagnostic catheterization were considered with the following important assumptions:
 - a. All indications were first evaluated on the basis of the available medical literature.
 - b. In many cases, studies published in the medical literature provide minimal information about the role of the test in clinical decision making.
 - c. Appropriate use criteria development requires a risk/benefit trade-off as determined by individual patient indications. Radiation exposure should be considered in risk estimates.
 - d. No circumstances exist that would preclude cardiac catheterization (e.g., severe coagulopathy, patient refusal).
7. A complete clinical history and physical exam has been completed by a qualified clinician such that the clinical status of the patient can be assumed to be valid as stated in the indication (e.g., asymptomatic patient is truly asymptomatic for the condition in question and that sufficient questioning of the patient has been undertaken).

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8. Cost was be considered implicitly in the appropriate use determination.
9. For each indication, the rating reflected whether diagnostic catheterization is reasonable for the patient and not whether it is preferred over another modality.
10. The category of "uncertain" was used when insufficient clinical data are available for a definitive categorization or there is substantial disagreement regarding the appropriateness of that indication. Those scenarios designated as uncertain reflect variations in clinical practice patterns. The designation of "uncertain" should not be used as grounds for denial of reimbursement.
11. All procedures presented are to be considered for clinical indications and not part of a research protocol.
12. All prior noninvasive testing was adequately completed.

4. Definitions

Definitions of terms used throughout the indication set are listed here. These definitions were provided to and discussed with the technical panel prior to rating of indications.

Stress Testing and Risk of Findings on Noninvasive Testing: Stress testing is commonly used for both diagnosis (possible/presumed) and risk stratification of patients with established CAD. Using criteria defined for traditional exercise stress tests (10,11):

- **Low-risk stress test findings:** associated with a cardiac mortality of <1% per year
- **Intermediate-risk stress test findings:** associated with a 1% to 3% per year cardiac mortality
- **High-risk stress test findings:** associated with a >3% per year cardiac mortality

Symptomatic/Ischemic Equivalent: Chest Pain Syndrome, Anginal Equivalent, or Ischemic Electrocardiogram (ECG) Abnormalities: Any constellation of clinical findings that the physician believes is consistent with CAD manifestations. Examples of such findings include, but are not limited to, chest pain, chest tightness, chest burning, shoulder pain, left arm pain, jaw pain, new ECG abnormalities, or other symptoms/findings suggestive of CAD. Clinical presentations in the absence of chest pain (e.g., dyspnea with exertion or reduced/worsening effort tolerance) that are thought to be consistent with CAD may also be considered to be an ischemic equivalent.

Clinical Classification of Chest Pain:

- **Typical Angina (Definite):** defined as 1) substernal chest pain or discomfort that is 2) provoked by exertion or emotional stress and 3) relieved by rest and/or nitroglycerin (12).
- **Atypical Angina (Probable):** chest pain or discomfort that lacks 1 of the characteristics of definite or typical angina.

- **Nonanginal Chest Pain:** chest pain or discomfort that meets 1 or none of the typical angina characteristics.

Grading of Angina Pectoris by the Canadian Cardiovascular Society Classification System (13):

Class I: ordinary physical activity does not cause angina, such as walking, climbing stairs. Angina occurs with strenuous, rapid, or prolonged exertion at work or recreation.

Class II: slight limitation of ordinary activity. Angina occurs on walking more than 2 blocks on the level and climbing more than 1 flight of ordinary stairs at a normal pace and in normal condition.

Class III: marked limitations of ordinary physical activity. Angina occurs on walking 1 or 2 blocks on the level and climbing 1 flight of stairs in normal conditions and at a normal pace.

Class IV: inability to carry on any physical activity without discomfort—anginal symptoms may be present at rest.

Pretest Probability of Coronary Artery Disease: Symptomatic (Ischemic Equivalent) Patients: Once the physician determines that symptoms are present that may represent CAD, the pretest probability of CAD should be assessed. There are a number of risk algorithms (14,15) available that can be used to calculate this probability. Clinicians should be familiar with those algorithms that pertain to the populations they encounter most often. In rating the appropriateness of cardiac catheterization for specific indications, the following probabilities, as calculated from any of the various available validated algorithms, should be applied (10):

- **Very low pretest probability:** <5% pretest probability of CAD
- **Low pretest probability:** between 5% and 10% pretest probability of CAD
- **Intermediate pretest probability:** between 10% and 90% pretest probability of CAD
- **High pretest probability:** >90% pretest probability of CAD

The method recommended by the ACCF/AHA guidelines for chronic stable angina (10) is provided as one example of a method used to calculate pretest probability and is a modification of a previously published literature review (16). Please refer to Table A and the clinical classification of chest pain definition angina characteristics. It is important to note that other historical factors or ECG findings (e.g., prior infarction) can affect pretest probability, although these factors are not accounted for in Table A. Similarly, while not incorporated into the algorithm, other CAD risk factors may also affect pretest likelihood of CAD. Detailed nomograms are available that incorporate the effects of a history of prior infarction, ECG Q waves and ST- and T-wave changes, diabetes, smoking, and hypercholesterolemia (17).

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Table A. Pretest Probability of CAD by Age, Gender, and Symptoms*

Age (Yrs)	Gender	Typical/Definite Angina Pectoris	Atypical/Probable Angina Pectoris	Nonanginal Chest Pain	Asymptomatic
<39	Men	Intermediate	Intermediate	Low	Very low
	Women	Intermediate	Very low	Very low	Very low
40-49	Men	High	Intermediate	Intermediate	Low
	Women	Intermediate	Low	Very low	Very low
50-59	Men	High	Intermediate	Intermediate	Low
	Women	Intermediate	Intermediate	Low	Very low
>60	Men	High	Intermediate	Intermediate	Low
	Women	High	Intermediate	Intermediate	Low

High: >90% pretest probability; Intermediate: between 10% and 90% pretest probability; Low: between 5% and 10% pretest probability; Very low: <5% pretest probability. *Modified from the ACC/AHA Exercise Testing Guidelines to reflect all age ranges (13).

CAD = coronary artery disease.

Global CAD Risk: It is assumed that clinicians will use current standard methods of global risk assessment such as those presented in the National Heart, Lung, and Blood Institute report on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III [ATP III]) (19) or similar national guidelines.

Absolute risk is defined as the probability of developing CAD over a given time period. The ATP III report estimates the absolute risk for CAD over the next 10 years. CAD risk refers to 10-year risk for any hard cardiac event (e.g., myocardial infarction or CAD death). However, acknowledging that global absolute risk scores may have not been evaluated in certain populations (e.g., women, younger men, minority populations), clinical judgment must be applied in assigning categorical risk thresholds in such subpopulations.

- **Low global CAD risk**

Defined by the age-specific risk level that is below average. In general, low risk will correlate with a 10-year absolute CAD risk <10%. However, in women and younger men, low risk may correlate with 10-year absolute CAD risk <6%.

- **Intermediate global CAD risk**

Defined by the age-specific risk level that is average. In general, moderate risk will correlate with a 10-year absolute CAD risk range of 10% to 20%. Among women and younger men, an expanded intermediate risk range of 6% to 20% may be appropriate.

- **High global CAD risk**

Defined by the age-specific risk level that is above average. In general, high risk will correlate with a 10-year absolute CAD risk of >20%. CAD equivalents (e.g., diabetes mellitus, peripheral arterial disease) can also define high risk.

Duke Treadmill Score (20): The equation for calculating the Duke treadmill score (DTS) is $DTS = \text{exercise time in minutes} - (5 \times \text{ST-segment deviation}) - (4 \times \text{exercise angina})$, with 0 = none, 1 = nonlimiting, and 2 = exercise-limiting.

The score typically ranges from -25 to +15. These values correspond to low-risk (with a score of $\geq +5$), moderate-risk (with scores ranging from -10 to +4), and high-risk (with a score of ≤ -11) categories.

ECG—Uninterpretable: Refers to ECGs with resting ST-segment depression (≥ 0.10 mV), left bundle branch block (LBBB), pre-excitation (Wolf-Parkinson-White Syndrome), or paced rhythm.

Adjunct Invasive Diagnostic Testing:

- **Fractional flow reserve (FFR)**

An invasive diagnostic tool used to provide physiological measurements as an adjunct to coronary angiography for the determination of lesion severity and to assist in decisions about revascularization. FFR is calculated using the ratio of the mean arterial pressure distal to a stenosis to the mean aortic pressure during maximal hyperemia. FFR measurements <0.75 are associated with ischemia on exercise testing and adjunct imaging (echo or nuclear) with high sensitivity (88%), specificity (100%), and overall accuracy (93%). FFR measurements >0.80 are associated with negative ischemic results with a predictive accuracy of 95%. Routine measurement of FFR in patients with multivessel coronary artery disease who are undergoing PCI with drug-eluting stents with deferral of lesions with FFR >0.80 has been shown to significantly reduce the rate of the composite endpoint of death, nonfatal myocardial infarction, and repeat revascularization at 1 year (21).

- **Intravascular ultrasound**

An invasive diagnostic test performed as an adjunct to diagnostic catheterization to provide an ultrasound-based anatomic assessment that extends beyond conventional angiography. This technique is used to identify lesion and vessel characteristics and obtain basic measurements for diagnostic and interventional application (minimal and maximal

luminal diameters, cross-sectional area, and plaque area).

Evaluating Perioperative Risk for Noncardiac Surgery: See Figure A, "Stepwise Approach to Perioperative Cardiac Assessment," from the ACCF/AHA 2009 perioperative guidelines (22). According to the algorithm, once it is determined that the patient does not require urgent surgery, the clinician should determine the

patient's active cardiac conditions (see Table B) and/or perioperative risk predictors (see Table C). If any active cardiac conditions and/or major risk predictors are present, Figure A suggests consideration of guideline-based care that may include coronary angiography and postponing or canceling noncardiac surgery. Once perioperative risk predictors are assessed, the surgical risk and the patient's functional status should be used to establish the need for noninvasive testing.

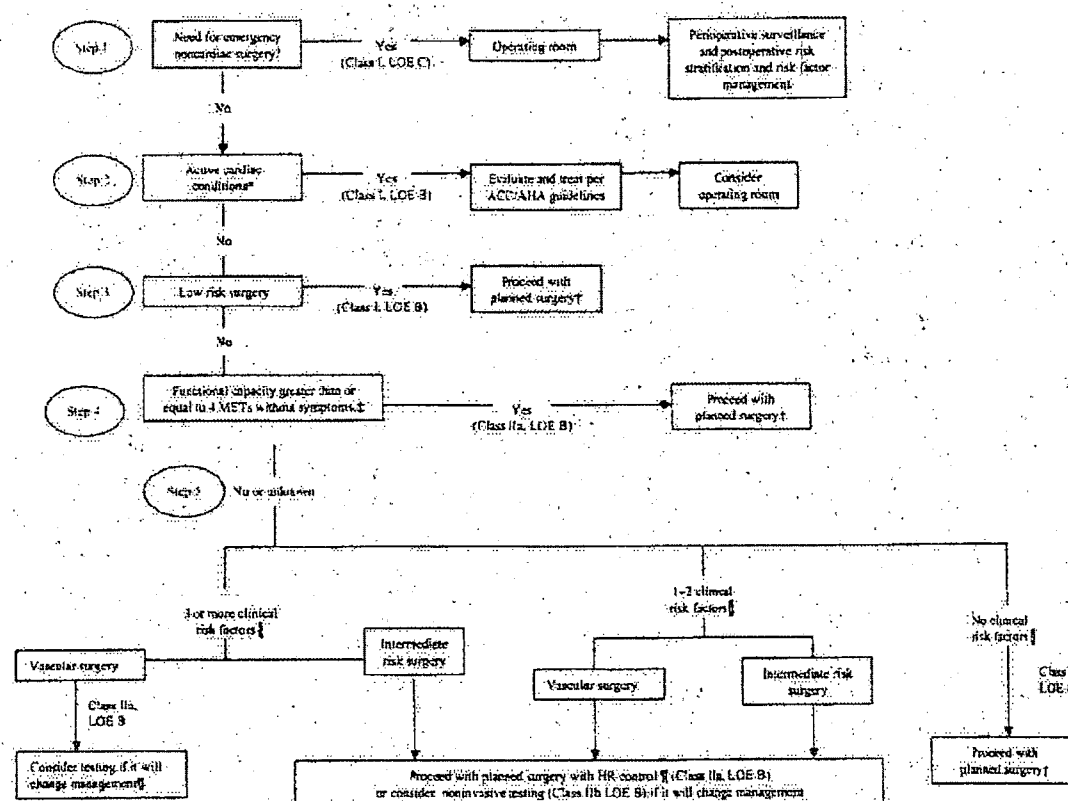


Figure A. Stepwise Approach to Perioperative Cardiac Assessment

Cardiac evaluation and care algorithm for noncardiac surgery based on active clinical conditions, known cardiovascular disease, or cardiac risk factors for patients ≥ 50 years of age. HR = heart rate; LOE = level of evidence; MET = metabolic equivalent. Modified from Fleisher et al. (22).

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Table 8. Active Cardiac Conditions for Which the Patient Should Undergo Evaluation and Treatment Before Noncardiac Surgery (Class I; Level of Evidence: B)

Condition	Examples
Unstable coronary syndromes	Unstable or severe angina* (CCS class III or IV)† Recent MI‡
Decompensated HF (NYHA functional class IV; worsening or new-onset HF)	
Significant arrhythmias	High-grade atrioventricular block Mobitz II atrioventricular block Third-degree atrioventricular heart block Symptomatic ventricular arrhythmias Supraventricular arrhythmias (including atrial fibrillation) with uncontrolled ventricular rate (HR >100 beats/min at rest) Symptomatic bradycardia Newly recognized ventricular tachycardia
Severe valvular disease	Severe aortic stenosis (mean pressure gradient >40 mm Hg, aortic valve area <1.0 cm ² , or symptomatic) Symptomatic mitral stenosis (progressive dyspnea on exertion, exertional presyncope, or HF)

*According to Campeau 13; may include atypical angina in patients who are unusually sedentary. The American College of Cardiology National Database Library defines recent MI as >7 days but ≤1 month within 30 days.

CCS = Canadian Cardiovascular Society; HF = heart failure; HR = heart rate; MI = myocardial infarction; NYHA = New York Heart Association.
Reprinted from Fleisher et al. (22).

Table C. Perioperative Clinical Risk Factors *

- History of ischemic heart disease
- History of compensated or prior heart failure
- History of cerebrovascular disease
- Diabetes mellitus (requiring insulin)
- Renal insufficiency (creatinine >2.0)

*As defined by the ACCF/AHA guidelines on perioperative cardiovascular evaluation and care for noncardiac surgery (22). Note that these are not standard coronary artery disease risk factors.
ACCF = American College of Cardiology Foundation; AHA = American Heart Association.

5. Abbreviations

ACS = acute coronary syndrome
AV = atrioventricular
CABG = coronary artery bypass grafting surgery
CAD = coronary artery disease
ECG = electrocardiogram
FFR = fractional flow reserve
LBBB = left bundle branch block
LV = left ventricular

6. Results of Ratings

The final ratings for diagnostic catheterization are listed by indication in Tables 1.1, 1.2, 1.3, 1.4, 1.5, 1.6, 1.7, 2.1, 2.2, 2.3, to 3.1. The final score reflects the median score of the 17

technical panel members and has been labeled according to the 3 appropriate use categories of appropriate (median 7 to 9), uncertain (median 4 to 6), and inappropriate (median 1 to 3). Tables 4, 5, and 6 present the same indications by the appropriate use categories.

7. Diagnostic Catheterization Appropriate Use Criteria (by Indication)

A. CAD Assessment

1. **Coronary Angiography With or Without Left Heart Catheterization and Left Ventriculography**
Coronary angiography is widely used to evaluate patients with known or suspected CAD. Depending on the clinical circumstances and prior testing, coronary angiography may be coupled with the measurement of left ventricular (LV) pressures (left heart catheterization) and/or the evaluation of LV systolic function and wall motion (left ventriculography).

The indications developed in Section A relate to appropriateness of coronary angiography. A decision about the performance of left heart catheterization and left ventriculography is left to the discretion of the operator and the patient's primary physician.

Table 1.1. Suspected or Known ACS

Indication		Appropriate Use Score (1-9)		
1.	• Cardiogenic shock due to suspected ACS	A (9)		
2.	• STEMI or suspected STEMI	A (9)		
Risk Score (e.g., TIMI, GRACE)		Low	Intermediate	High
3.	• UA/NSTEMI	A (7)	A (8)	A (9)
4.	• Suspected ACS with newly diagnosed LV wall motion abnormality or newly diagnosed resting myocardial perfusion defect	A (7)	A (8)	A (9)

A = appropriate; ACS = acute coronary syndrome; GRACE = Global Registry of Acute Coronary Events; LV = left ventricular; STEMI = ST-elevation myocardial infarction; TIMI = Thrombolysis in Myocardial Infarction; UA/NSTEMI = unstable angina/non-ST elevation myocardial infarction.

Table 1.2. Suspected CAD: No Prior Noninvasive Stress Imaging (No Prior PCI, CABG, or Angiogram Showing $\geq 50\%$ Angiographic Stenosis)

Indication		Appropriate Use Score (1-9)
Asymptomatic		
5.	• Low global CAD risk	I (1)
6.	• Intermediate global CAD risk	I (3)
7.	• High global CAD risk	U (4)
Symptomatic		
8.	• Low pretest probability	I (3)
9.	• Intermediate pretest probability	U (6)
10.	• High pretest probability	A (7)

A = appropriate; CABG = coronary bypass grafting surgery; CAD = coronary artery disease; I = intermediate; PCI = percutaneous coronary intervention; U = uncertain.

Table 1.3. Suspected CAD: Prior Noninvasive Testing (No Prior PCI, CABG, or Angiogram Showing $\geq 50\%$ Angiographic Stenosis)

Indication		Appropriate Use Score (1-9)	
		Pretest Symptom Status	
ECG Stress Testing		Asymptomatic	Symptomatic
11.	• Low-risk findings (e.g., Duke treadmill score ≥ 5)	I (1)	U (4)
12.	• Intermediate-risk findings (e.g., Duke treadmill score 4 to -10)	U (4)	U (6)
13.	• High-risk findings (e.g., Duke treadmill score ≤ -11)	A (7)	A (8)
14.	• Other high-risk findings (ST-segment elevation, hypotension with exercise, ventricular tachycardia, prolonged ST-segment depression)	A (7)	A (9)
Stress Test With Imaging (SPECT MPI, Stress Echocardiography, Stress PET, Stress CMR)		Pretest Symptom Status	
		Asymptomatic	Symptomatic
15.	• Low-risk findings (e.g., $<5\%$ ischemic myocardium on stress SPECT MPI or stress PET, no stress-induced wall motion abnormalities on stress echo or stress CMR)	I (2)	U (4)
16.	• Intermediate-risk findings (e.g., 5% to 10% ischemic myocardium on stress SPECT MPI or stress PET, stress-induced wall motion abnormality in a single segment on stress echo or stress CMR)	U (4)	A (7)
17.	• High-risk findings (e.g., $>10\%$ ischemic myocardium on stress SPECT MPI or stress PET, stress-induced wall motion abnormality in 2 or more segments on stress echo or stress CMR)	A (7)	A (9)
18.	• Other high-risk findings (e.g., T1D, significant stress-induced LV dysfunction)	A (7)	A (8)
19.	• Discordant findings (e.g., low-risk prior imaging with ongoing symptoms consistent with ischemic equivalent)	Not rated	A (7)
20.	• Discordant findings (e.g., low-risk stress imaging with high-risk stress ECG response or stress-induced typical angina)	U (5)	A (7)
21.	• Equivocal/uninterpretable findings (e.g., perfusion defect vs. attenuation artifact, uninterpretable stress imaging)	U (5)	A (7)
22.	• Fixed perfusion defect on SPECT MPI or a persistent wall motion abnormality on stress echo consistent with infarction without significant ischemia ($<5\%$ ischemic myocardium)	U (4)	U (6)
23.	• Baseline resting LV dysfunction (i.e., LVEF $\leq 40\%$) AND • Evidence (e.g., PET, CMR, delayed thallium uptake, dobutamine echo) of myocardial viability in dysfunctional segment	A (7)	A (8)

Table 1.3. Continued

Indication		Appropriate Use Score (1-9)	
Echocardiography (TTE)		Pretest Symptom Status	
		Asymptomatic	Symptomatic
24.	Newly recognized LV systolic dysfunction (i.e., LVEF $\leq 40\%$) with an unknown etiology	U (5)	A (8)
25.	Newly recognized LV systolic dysfunction (i.e., LVEF 41% to 49%) with an unknown etiology	U (5)	A (8)
26.	New regional wall motion abnormality with an unknown etiology and normal LV systolic function	U (5)	A (7)
27.	Suspected significant ischemic complication related to CAD (e.g., ischemic mitral regurgitation or VSD)	A (9)	
Coronary Calcium Score		Pretest Symptom Status	
		Asymptomatic	Symptomatic
28.	Agatston score <100	I (1)	Not rated
29.	Agatston score 100-400	I (2)	Not rated
30.	Agatston score 400-1,000	I (3)	Not rated
31.	Agatston score $>1,000$	I (3)	Not rated
Coronary CTA		Pretest Symptom Status	
		Asymptomatic	Symptomatic
32.	Lesion $<50\%$ non-left main	I (3)	U (4)
33.	Lesion $\geq 50\%$ non-left main	U (4)	A (7)
34.	Lesion $\geq 50\%$ left main	Not rated	A (9)
35.	Lesions $\geq 50\%$ in more than 1 coronary territory	U (5)	A (7)
36.	Lesion of unclear severity, possibly obstructive (non-left main)	U (4)	A (7)
37.	Lesion of unclear severity, possibly obstructive (left main)	A (7)	A (8)
38.	Lesion $<50\%$ with extensive partly calcified and non-calcified plaque	I (3)	U (5)
CMR		Pretest Symptom Status	
		Asymptomatic	Symptomatic
39.	Area of delayed gadolinium myocardial enhancement of unknown etiology	I (3)	Not rated

*Coronary calcium score only rated for asymptomatic patients as these patients are the population in which it is used.

A = appropriate; CABG = coronary bypass grafting surgery; CAD = coronary artery disease; CMR = cardiovascular magnetic resonance; CTA = computed tomography angiography; ECO = electrocardiogram; I = inappropriate; LV = left ventricular; LVEF = left ventricular ejection fraction; PET = positron emission tomography; SPECT MPI = single-photon emission computed tomography myocardial perfusion imaging; ID = transient ischemic dilation; TTE = transthoracic echocardiography; U = uncertain; VSD = ventricular septal defect.

Table 1.4. Adjunctive Invasive Diagnostic Testing in Patients Undergoing Appropriate Diagnostic Coronary Angiography

Indication		Appropriate Use Score (1-9)		
		Unexpected Angiographic Finding or No Prior Noninvasive Testing	Prior Testing = No Ischemic Findings	Prior Testing = Concordant Ischemic Findings
FFR for Lesion Severity				
40.	Angiographically indeterminate severity left main stenosis (defined as 2 or more orthogonal views contradictory whether stenosis $\geq 50\%$)	A (7)	A (7)	A (7)
41.	Nonobstructive disease by angiography (non-left main) $<50\%$	I (3)	I (2)	U (5)
42.	Angiographically intermediate disease (non-left main) 50% to 69%	A (7)	U (6)	A (7)
43.	Angiographically obstructive significant disease (non-left main) $\geq 70\%$ stenosis	A (7)	A (7)	I (3)
IVUS for Lesion Severity				
44.	Angiographically indeterminate left main stenosis (defined as 2 or more orthogonal views contradictory whether stenosis $\geq 50\%$)	A (7)	A (7)	A (7)
45.	Nonobstructive disease by angiography (non-left main) $<50\%$	I (3)	I (3)	U (6)
46.	Angiographically intermediate disease (non-left main) 50% to 69%	U (5)	U (5)	U (6)
47.	Angiographically obstructive significant disease (non-left main) $\geq 70\%$ stenosis	U (4)	U (5)	I (5)
IVUS—Examination of Lesion or Artery Morphology				
48.	Coronary lesions or structures difficult to characterize angiographically (e.g., aneurysm, extent of calcification, stent fracture, stent apposition, stent expansion, dissections) or for sizing of vessel before stent placement			A (8)

*Concordance refers to noninvasive imaging studies that demonstrate evidence of abnormal myocardial perfusion that is in the same distribution as a coronary artery stenosis, or degree of regional disease that is similar to clinical impression.

A = appropriate; FFR = fractional flow reserve; I = inappropriate; IVUS = intravascular ultrasound; U = uncertain.

Table 1.5. Patients With Known Obstructive CAD (e.g., Prior MI, Prior PCI, Prior CABG, or Obstructive Disease on Invasive Angiography)

Indication		Appropriate Use Score (1-9)	
Medically Managed Patients		Asymptomatic/Controlled Symptoms OR Unchanged Findings	Worsening or Limiting Symptoms AND Worsening Findings
49.	• Low-risk noninvasive findings	I (2)	U (6)
50.	• Intermediate-risk noninvasive findings	U (4)	A (7)
51.	• High-risk noninvasive findings	A (7)	A (9)
Post Revascularization (PCI or CABG)			
52.	• Asymptomatic or stable symptoms		I (3)
53.	• Low-risk noninvasive findings		U (6)
	• Worsening or limiting symptoms		A (7)
54.	• Intermediate-risk noninvasive findings		A (7)
	• Worsening or limiting symptoms		A (8)
55.	• High-risk noninvasive findings		A (8)
	• Worsening or limiting symptoms		A (9)
Post Revascularization (PCI)			
56.	• Asymptomatic		U (5)
	• Prior unprotected left main PCI		

I = appropriate; CABG = coronary bypass grafting surgery; CAD = coronary artery disease; I = inappropriate; MI = myocardial infarction; PCI = percutaneous coronary intervention; U = uncertain

Table 1.6. Arrhythmias

Indication		Appropriate Use Score (1-9)		
Etiology Unclear After Initial Evaluation				
57.	• Resuscitated cardiac arrest with return of spontaneous circulation			A (8)
58.	• VF or sustained VT with or without symptoms			A (8)
59.	• Nonsustained VT (<5 beats VT)			U (5)
	• Normal LV systolic function			
No Prior Noninvasive Assessment of Ischemia With Normal Systolic Function				
CHD Risk		Low	Intermediate	High
60.	• Syncope	I (2)	U (4)	U (6)
61.	• New-onset atrial fibrillation or flutter	I (2)	I (3)	U (5)
62.	• Heart block (e.g., second-degree type II or third-degree AV block) OR	I (2)	I (3)	U (5)
	• Symptomatic bradyarrhythmias			
63.	• Newly diagnosed LBBB	U (4)	U (5)	U (6)

I = appropriate; AV = atrioventricular; CHD = coronary heart disease; I = inappropriate; LBBB = left bundle branch block; LV = left ventricular; U = uncertain; VF = ventricular fibrillation; VT = ventricular tachycardia

Table 1.7. Preoperative Coronary Evaluation for Noncardiac Surgery in Stable Patients

Indication		Appropriate Use Score (1-9)	
64.	• Low-risk surgery		I (2)
65.	• ≥ 4 METS functional capacity without symptoms		I (2)
66.	• Prior to solid organ transplantation		U (5)
<4 METS Functional Capacity, No Noninvasive Testing Performed, With or Without Clinical Risk Factors Present (Preoperative Clinical Risk Factors: Ischemic Heart Disease, Heart Failure, Cerebrovascular Disease, Insulin-Requiring Diabetes Mellitus, Renal Insufficiency Or >2.0)			
Procedure Planned		Intermediate-Risk Surgery	Vascular Surgery
67.	• No risk factors	I (2)	I (3)
68.	• 1 to 2 risk factors	I (3)	U (4)
69.	• ≥ 3 risk factors	U (4)	U (5)

Or = oral; I = appropriate; I = inappropriate; METS = metabolic equivalents; U = uncertain

B. Assessment for Conditions Other Than Coronary Artery Disease

2. **Right and Left Heart Catheterization or Right Heart Catheterization Alone With or Without Left Ventriculography and Coronary Angiography**
Right and left heart catheterization (including the measurement of cardiac output and intracardiac oxygen saturations) is used to evaluate a variety of conditions. The syndrome of heart failure may or may not be present in these clinical scenarios. Depending on the clinical circumstances and prior testing, coronary angiography, left or right ventriculography, and additional angiography such as supravalvular aortography may be coupled with hemodynamic measurements. A decision about the need for coronary angiography in addition to the hemodynamic study should be at the discretion of the operator and the patient's primary physician.

2.1. Valvular Disease

Patients with valvular heart disease can be challenging to evaluate, and these challenges are even greater in the setting of multivalve involvement. Failure to intervene with appropriate therapies at the correct time can result in the permanent impairment of heart function and a poor prognosis. The evaluation of valvular disease should start with a careful history and physical examination and is then augmented by noninvasive imaging, most frequently echocardiography. One of the challenges faced by clinicians occurs when the clinical impression of valve lesion severity based on the history and physical exam differs from that derived from an imaging test. The presence of concordant or conflicting impressions may affect the decision to perform an

invasive evaluation and this is tested in the table below. For patients in whom valve surgery is planned, the indication for cardiac catheterization is covered in Indication 70.

Table 2.1 only considers isolated lesions of left-sided valves and does not consider mixed disease of a valve (e.g., aortic stenosis and regurgitation) or multivalve disease. Invasive evaluation may be necessary in these settings but often requires the assessment of several other variables such as LV function and should be at the discretion of the clinician. Scenarios were not developed for isolated or mixed disease of the tricuspid or pulmonic valve because they are relatively uncommon in adults and, when present, are often associated with left-sided valve lesions.

2.2. Cardiomyopathies

A variety of conditions present with signs and/or symptoms of heart failure. Right heart catheterization alone or combined right and left heart catheterization (including the measurement of cardiac and pulmonary pressures, cardiac output, vascular resistance, and intracardiac oxygen saturations) is used to evaluate many of these conditions. Depending on the clinical circumstances and prior testing, coronary angiography, left or right ventriculography, and additional angiography may be coupled with these hemodynamic measurements. The indications developed below relate to appropriateness of the right and left heart catheterization. A decision about the performance of coronary angiography should be at the discretion of the operator and the patient's primary physician.

Table 2.1. Valvular Disease

Indication		Appropriate Use Score (1-5)
70.	• Preoperative assessment before valvular surgery	A (7)
71.	• Pulmonary hypertension out of proportion to the severity of valvular disease	A (8)
72.	• Left ventricular dysfunction out of proportion to the severity of valvular disease	A (8)
Chronic Native or Prosthetic Valvular Disease Asymptomatic Related to Valvular Disease		
73.	• Mild or moderate mitral stenosis	I (2)
74.	• Severe mitral stenosis	U (6)
75.	• Mild or moderate mitral regurgitation	I (2)
76.	• Severe mitral regurgitation	U (5)
77.	• Mild or moderate aortic stenosis	I (2)
78.	• Severe aortic stenosis	U (4)
79.	• Mild or moderate aortic regurgitation	I (2)
80.	• Severe aortic regurgitation	U (5)

Table 2.1. Continued

Indication		Appropriate Use Score (1-9)	
Chronic Native or Prosthetic Valvular Disease Symptomatic Related to Valvular Disease			
Noninvasive Imaging for Valvular Disease		Concordant With Clinical Impression of Severity	Conflicting With Clinical Impression of Severity
81.	• Mild or moderate mitral stenosis	I (2)	A (7)
82.	• Severe mitral stenosis	I (3)	A (7)
83.	• Mild or moderate mitral regurgitation	I (2)	A (7)
84.	• Severe mitral regurgitation	I (3)	A (7)
85.	• Mild or moderate aortic stenosis	I (3)	A (7)
86.	• Severe aortic stenosis	I (3)	A (8)
87.	• Equivocal aortic stenosis/low gradient aortic stenosis • May include pharmacological challenge (e.g., dobutamine)	Not rated	A (8)
88.	• Mild or moderate aortic regurgitation	I (2)	A (7)
89.	• Severe aortic regurgitation	I (3)	A (8)
90.	• Acute moderate or severe mitral or aortic regurgitation	U (4)	A (8)

A = appropriate; I = inappropriate; U = uncertain.

Table 2.2. Pericardial Diseases

Indication		Appropriate Use Score (1-9)
91.	• Suspected pericardial tamponade	A (8)
92.	• Suspected or clinical uncertainty between constrictive vs. restrictive physiology	A (8)

A = appropriate.

Table 2.3. Cardiomyopathies

Indication		Appropriate Use Score (1-9)
93.	• Known or suspected cardiomyopathy with or without heart failure	A (7)
94.	• Re-evaluation of known cardiomyopathy • Change in clinical status or cardiac exam or to guide therapy	A (7)
95.	• Suspected arrhythmogenic right ventricular dysplasia • Assessment of right ventricular morphology	U (5)

A = appropriate; U = uncertain.

3. Right Heart Catheterization

In several clinical situations, the performance of right heart catheterization (hemodynamics

and cardiac output) alone is used. This can be performed in the cardiac catheterization laboratory.

Table 3.1. Pulmonary Hypertension or Intracardiac Shunt Evaluation

Indication		Appropriate Use Score (1-9)
96.	• Known or suspected intracardiac shunt with indeterminate shunt anatomy or shunt fraction	A (8)
Evaluation of Pulmonary Hypertension		
97.	• Suspected pulmonary artery hypertension • Equivocal or borderline elevated estimated right ventricular systolic pressure on resting echo study	A (7)
98.	• Suspected pulmonary hypertension • Elevated estimated right ventricular systolic pressure on resting echo study	A (7)
99.	• Resting pulmonary hypertension • Determine response to pulmonary vasodilators given in cath lab	A (8)
100.	• Resting pulmonary hypertension • Determine response after initiation of drug therapy	A (7)
101.	• Post heart transplant patient • With or without the performance of endomyocardial biopsy	A (7)
102.	• Indeterminate intravascular volume status • Etiology unclear after initial evaluation	A (7)

A = appropriate.

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8. Diagnostic Catheterization Appropriate Use Criteria (by Appropriate Use Rating)

Table 4. Appropriate Indications (Median Score 7-9)

Indication	Appropriate Use Score (1-9)
Suspected Acute Coronary Syndrome	
1. • Cardiogenic shock due to suspected ACS	A (9)
2. • STEMI or suspected STEMI	A (9)
3. • UA/NSTEMI • Low-risk score (e.g., TIMI, GRACE)	A (7)
3. • UA/NSTEMI • Intermediate-risk score (e.g., TIMI, GRACE)	A (8)
3. • UA/NSTEMI • High-risk score (e.g., TIMI, GRACE)	A (9)
4. • Suspected ACS with newly diagnosed LV wall motion abnormality or newly diagnosed resting myocardial perfusion defect • Low-risk score (e.g., TIMI, GRACE)	A (7)
4. • Suspected ACS with newly diagnosed LV wall motion abnormality or newly diagnosed resting myocardial perfusion defect • Intermediate-risk score (e.g., TIMI, GRACE)	A (8)
4. • Suspected ACS with newly diagnosed LV wall motion abnormality or newly diagnosed resting myocardial perfusion defect • High-risk score (e.g., TIMI, GRACE)	A (9)
Suspected CAD: No Prior Noninvasive Stress Imaging (No Prior PCI, CABG, or Angiogram Showing ≥50% Angiographic Stenosis)	
10. • High pretest probability • Symptomatic	A (7)
Suspected CAD: Prior Noninvasive Testing (No Prior PCI, CABG, or Angiogram Showing ≥50% Angiographic Stenosis)	
ECG Stress Testing	
13. • High-risk findings (e.g., Duke treadmill score ≤ -11) • Asymptomatic	A (7)
13. • High-risk findings (e.g., Duke treadmill score ≤ -11) • Symptomatic	A (9)
14. • Other high-risk finding (ST-segment elevation, hypotension with exercise, ventricular tachycardia, prolonged ST-segment depression) • Asymptomatic	A (7)
14. • Other high-risk finding (ST-segment elevation, hypotension with exercise, ventricular tachycardia, prolonged ST-segment depression) • Symptomatic	A (9)
Stress Test With Imaging (SPECT MPI, Stress Echocardiography, Stress PET, Stress CMR)	
16. • Intermediate-risk findings (e.g., 5% to 10% ischemic myocardium on stress SPECT MPI or stress PET, stress-induced wall motion abnormality in a single segment on stress echo or stress CMR) • Symptomatic	A (7)
17. • High-risk findings (e.g., >10% ischemic myocardium on stress SPECT MPI or stress PET, stress-induced wall motion abnormality in 2 or more segments on stress echo or stress CMR) • Asymptomatic	A (7)
17. • High-risk findings (e.g., >10% ischemic myocardium on stress SPECT MPI or stress PET, stress-induced wall motion abnormality in 2 or more segments on stress echo or stress CMR) • Symptomatic	A (9)
18. • Other high-risk finding (e.g., T1D, significant stress-induced LV dysfunction) • Asymptomatic	A (7)
18. • Other high-risk finding (e.g., T1D, significant stress-induced LV dysfunction) • Symptomatic	A (8)
19. • Discordant findings (e.g., low-risk prior imaging with ongoing symptoms consistent with ischemic equivalent) • Symptomatic	A (7)
20. • Discordant findings (e.g., low-risk stress imaging with high-risk stress ECG response or stress-induced typical angina) • Symptomatic	A (7)
21. • Equivocal/uninterpretable findings (e.g., perfusion defect vs. attenuation artifact, uninterpretable stress imaging) • Symptomatic	A (7)

Table 4. Continued

Indication	Appropriate Use Score (1-9)
23. • Baseline resting LV dysfunction (i.e., LVEF $\leq 40\%$) AND • Evidence (e.g., PET, CMR, delayed thallium uptake, dobutamine echo) of myocardial viability in dysfunctional segment • Asymptomatic	A (7)
23. • Baseline resting LV dysfunction (i.e., LVEF $\leq 40\%$) AND • Evidence (e.g., PET, CMR, delayed thallium uptake, dobutamine echo) of myocardial viability in dysfunctional segment • Symptomatic	A (8)
Echocardiography (TTE)	
24. • Newly recognized LV systolic dysfunction (i.e., LVEF $\leq 40\%$) with an unknown etiology • Symptomatic	A (8)
25. • Newly recognized LV systolic dysfunction (i.e., LVEF 41% to 49%) with an unknown etiology • Symptomatic	A (8)
26. • New regional wall motion abnormality with an unknown etiology and normal LV systolic function • Symptomatic	A (7)
27. • Suspected significant ischemic complication related to CAD (e.g., ischemic mitral regurgitation or VSD)	A (9)
Coronary CTA	
33. • Lesion $\geq 50\%$ non-left main • Symptomatic	A (7)
34. • Lesion $\geq 50\%$ left main • Symptomatic	A (8)
35. • Lesions $\geq 50\%$ in more than 1 coronary territory • Symptomatic	A (7)
36. • Lesion of unclear severity, possibly obstructive (non-left main) • Symptomatic	A (7)
37. • Lesion of unclear severity, possibly obstructive (left main) • Asymptomatic	A (7)
37. • Lesion of unclear severity, possibly obstructive (left main) • Symptomatic	A (8)
Adjunctive Invasive Diagnostic Testing in Patients Undergoing Appropriate Diagnostic Coronary Angiography	
FFR for Lesion Severity	
40. • Angiographically indeterminate severity left main stenosis (defined as 2 or more orthogonal views contradictory whether stenosis $> 50\%$) • Unexpected angiographic finding or no prior noninvasive testing	A (7)
40. • Angiographically indeterminate severity left main stenosis (defined as 2 or more orthogonal views contradictory whether stenosis $> 50\%$) • Prior testing = no ischemic findings	A (7)
40. • Angiographically indeterminate severity left main stenosis (defined as 2 or more orthogonal views contradictory whether stenosis $> 50\%$) • Prior testing = concordant ischemic findings	A (7)
42. • Angiographically intermediate disease (non-left main) 50% to 69% • Unexpected angiographic finding or no prior noninvasive testing	A (7)
42. • Angiographically intermediate disease (non-left main) 50% to 69% • Prior testing = concordant ischemic findings	A (7)
43. • Angiographically obstructive significant disease (non-left main) $\geq 70\%$ stenosis • Unexpected angiographic finding or no prior noninvasive testing	A (7)
43. • Angiographically obstructive significant disease (non-left main) $\geq 70\%$ stenosis • Prior testing = no ischemic findings	A (7)
IVUS for Lesion Severity	
44. • Angiographically indeterminate severity left main stenosis (defined as 2 or more orthogonal views contradictory whether stenosis $> 50\%$) • Unexpected angiographic finding or no prior noninvasive testing	A (7)
44. • Angiographically indeterminate severity left main stenosis (defined as 2 or more orthogonal views contradictory whether stenosis $> 50\%$) • Prior testing = no ischemic findings	A (7)
44. • Angiographically indeterminate severity left main stenosis (defined as 2 or more orthogonal views contradictory whether stenosis $> 50\%$) • Prior testing = concordant ischemic findings	A (7)

Table 4. Continued

Indication		Appropriate Use Score (1-9)
IVUS—Examination of Lesion or Artery Morphology		
48.	• Coronary lesions or structures difficult to characterize angiographically (e.g., aneurysm, extent of calcification, stent fracture, stent apposition, stent expansion, dissections) or for sizing of vessel before stent placement	A (8)
Patients With Known Obstructive CAD (e.g., Prior MI, Prior PCI, Prior CABG, or Obstructive Disease on Invasive Angiography)		
Medically Managed Patients		
50.	• Intermediate-risk noninvasive findings • Worsening or limiting symptoms and worsening findings	A (7)
51.	• High-risk noninvasive findings • Asymptomatic/controlled symptoms or unchanged findings	A (7)
51.	• High-risk noninvasive findings • Worsening or limiting symptoms and worsening findings	A (9)
Post Revascularization (PCI or CABG)		
54.	• Intermediate-risk noninvasive findings • Worsening or limiting symptoms	A (7)
55.	• High-risk noninvasive findings • Worsening or limiting symptoms	A (8)
Arrhythmias		
Etiology Unclear After Initial Evaluation		
57.	• Resuscitated cardiac arrest with return of spontaneous circulation	A (8)
58.	• VF or sustained VT with or without symptoms	A (8)
Valvular Disease		
70.	• Preoperative assessment before valvular surgery	A (7)
71.	• Pulmonary hypertension out of proportion to the severity of valvular disease	A (8)
72.	• Left ventricular dysfunction out of proportion to the severity of valvular disease	A (8)
Chronic Native or Prosthetic Valvular Disease Symptomatic Related to Valvular Disease		
81.	• Mild or moderate mitral stenosis • Noninvasive imaging for valvular disease conflicting with clinical impression of severity	A (7)
82.	• Severe mitral stenosis • Noninvasive imaging for valvular disease conflicting with clinical impression of severity	A (7)
83.	• Mild or moderate mitral regurgitation • Noninvasive imaging for valvular disease conflicting with clinical impression of severity	A (7)
84.	• Severe mitral regurgitation • Noninvasive imaging for valvular disease conflicting with clinical impression of severity	A (7)
85.	• Mild or moderate aortic stenosis • Noninvasive imaging for valvular disease conflicting with clinical impression of severity	A (7)
86.	• Severe aortic stenosis • Noninvasive imaging for valvular disease conflicting with clinical impression of severity	A (8)
87.	• Equivocal aortic stenosis/low gradient aortic stenosis • May include pharmacological challenge (e.g., dobutamine) • Noninvasive imaging for valvular disease conflicting with clinical impression of severity	A (8)
88.	• Mild or moderate aortic regurgitation • Noninvasive imaging for valvular disease conflicting with clinical impression of severity	A (7)
89.	• Severe aortic regurgitation • Noninvasive imaging for valvular disease conflicting with clinical impression of severity	A (8)
90.	• Acute moderate or severe mitral or aortic regurgitation • Noninvasive imaging for valvular disease conflicting with clinical impression of severity	A (8)
Pericardial Diseases		
91.	• Suspected pericardial tamponade	A (8)
92.	• Suspected or clinical uncertainty between constrictive vs. restrictive physiology	A (8)
Cardiomyopathies		
93.	• Known or suspected cardiomyopathy with or without heart failure	A (7)
94.	• Re-evaluation of known cardiomyopathy • Change in clinical status or cardiac exam or to guide therapy	A (7)
Pulmonary Hypertension or Intracardiac Shunt Evaluation		
96.	• Known or suspected intracardiac shunt with indeterminate shunt anatomy or shunt fraction	A (8)

Table 4. Continued

Indication		Appropriate Use Score (1-9)
Evaluation of Pulmonary Hypertension		
97.	• Suspected pulmonary artery hypertension • Equivocal or borderline elevated estimated right ventricular systolic pressure on resting echo study	A (7)
98.	• Suspected pulmonary hypertension • Elevated estimated right ventricular systolic pressure on resting echo study	A (7)
99.	• Resting pulmonary hypertension • Determine response to pulmonary vasodilators given in cath lab	A (9)
100.	• Resting pulmonary hypertension • Determine response after initiation of drug therapy	A (7)
101.	• Post heart transplant patient • With or without the performance of endomyocardial biopsy	A (7)
102.	• Indeterminate intravascular volume status • Etiology unclear after initial evaluation	A (7)

A = appropriate; ACS = acute coronary syndrome; CABG = coronary bypass grafting surgery; CAD = coronary artery disease; CMR = cardiovascular magnetic resonance; CTA = computed tomography angiography; ECG = electrocardiogram; FR = fractional flow reserve; GRACE = Global Registry of Acute Coronary Events; IVUS = intravascular ultrasound; LV = left ventricular; LVEF = left ventricular ejection fraction; MI = myocardial infarction; PET = positron emission tomography; PCI = percutaneous coronary intervention; SPECT-MPI = single-photon emission computed tomography myocardial perfusion imaging; STEMI = ST-elevation myocardial infarction; TID = transient ischemic dilation; TIMI = Thrombolysis in Myocardial Infarction; TTE = transthoracic echocardiography; U/NSTEMI = unstable angina/non-ST-elevation myocardial infarction; VF = ventricular fibrillation; VSD = ventricular septal defect; VT = ventricular tachycardia.

Table 5. Uncertain Indications (Median Score 4-6)

Indication		Appropriate Use Score (1-9)
Suspected CAD: No Prior Noninvasive Stress Imaging (No Prior PCI, CABG, or Angiogram Showing $\geq 50\%$ Angiographic Stenosis)		
7.	• High global CAD risk • Asymptomatic	U (4)
9.	• Intermediate pretest probability • Symptomatic	U (6)
Suspected CAD: Prior Noninvasive Testing (No Prior PCI, CABG, or Angiogram Showing $\geq 50\%$ Angiographic Stenosis)		
ECG Stress Testing		
11.	• Low-risk findings (e.g., Duke treadmill score ≥ 5) • Symptomatic	U (4)
12.	• Intermediate-risk findings (e.g., Duke treadmill score 4 to -10) • Asymptomatic	U (4)
12.	• Intermediate-risk findings (e.g., Duke treadmill score 4 to -10) • Symptomatic	U (6)
Stress Test With Imaging (SPECT-MPI, Stress Echocardiography, Stress PET, Stress CMR)		
15.	• Low-risk findings (e.g., $<5\%$ ischemic myocardium on stress SPECT-MPI or stress PET, no stress-induced wall motion abnormalities on stress echo or stress CMR) • Symptomatic	U (4)
16.	• Intermediate-risk findings (e.g., 5% to 10% ischemic myocardium on stress SPECT-MPI or stress PET, stress-induced wall motion abnormality in a single segment on stress echo or stress CMR) • Asymptomatic	U (4)
20.	• Discordant findings (e.g., low-risk stress imaging with high-risk stress ECG response or stress-induced typical angina) • Asymptomatic	U (5)
21.	• Equivocal/uninterpretable findings (e.g., perfusion defect vs. attenuation artifact, uninterpretable stress imaging) • Asymptomatic	U (5)
22.	• Fixed perfusion defect on SPECT-MPI or a persistent wall motion abnormality on stress echo consistent with infarction without significant ischemia ($<5\%$ ischemic myocardium) • Asymptomatic	U (4)
22.	• Fixed perfusion defect on SPECT-MPI or a persistent wall motion abnormality on stress echo consistent with infarction without significant ischemia ($<5\%$ ischemic myocardium) • Symptomatic	U (9)
Echocardiography (TTE)		
24.	• Newly recognized LV systolic dysfunction (i.e., LVEF $\leq 40\%$) with an unknown etiology • Asymptomatic	U (6)
25.	• Newly recognized LV systolic dysfunction (i.e., LVEF 41% to 49%) with an unknown etiology • Asymptomatic	U (5)
26.	• New regional wall motion abnormality with an unknown etiology and normal LV systolic function • Asymptomatic	U (5)

Table 5. Continued

Indication		Appropriate Use Score (1-9)
Coronary CTA		
32.	• Lesion <50% non-left main • Symptomatic	U (4)
33.	• Lesion ≥50% non-left main • Asymptomatic	U (4)
35.	• Lesions ≥50% in more than 1 coronary territory • Asymptomatic	U (5)
36.	• Lesion of unclear severity, possibly obstructive (non-left main) • Asymptomatic	U (4)
38.	• Lesion <50% with extensive partly calcified and noncalcified plaque • Symptomatic	U (5)
Adjunctive Invasive Diagnostic Testing in Patients Undergoing Appropriate Diagnostic Coronary Angiography		
FFR for Lesion Severity		
41.	• Nonobstructive disease by angiography (non-left main) <50% • Prior testing = concordant ischemic findings	U (5)
42.	• Angiographically intermediate disease (non-left main) 50% to 69% • Prior testing = no ischemic findings	U (6)
IVUS for Lesion Severity		
45.	• Non-obstructive disease by angiography (non-left main) <50% • Prior testing = concordant ischemic findings	U (6)
46.	• Angiographically intermediate disease (non-left main) 50% to 69% • Unexpected angiographic finding or no prior noninvasive testing	U (5)
46.	• Angiographically intermediate disease (non-left main) 50% to 69% • Prior testing = no ischemic findings	U (5)
46.	• Angiographically intermediate disease (non-left main) 50% to 69% • Prior testing = concordant ischemic findings	U (6)
47.	• Angiographically obstructive significant disease (non-left main) ≥70% stenosis • Unexpected angiographic finding or no prior noninvasive testing	U (4)
47.	• Angiographically obstructive significant disease (non-left main) ≥70% stenosis • Prior testing = no ischemic findings	U (5)
Patients With Known Obstructive CAD (e.g., Prior MI, Prior PCI, Prior CABG, or Obstructive Disease on Invasive Angiography)		
Medically Managed Patients		
49.	• Low-risk noninvasive findings • Worsening or limiting symptoms and worsening findings	U (6)
50.	• Intermediate-risk noninvasive findings • Asymptomatic/controlled symptoms or unchanged findings	U (4)
Post Revascularization (PCI or CABG)		
53.	• Low-risk noninvasive findings • Worsening or limiting symptoms	U (6)
Post Revascularization (PCI)		
56.	• Asymptomatic • Prior unprotected left main PCI	U (5)
Arrhythmias		
Etiology Unclear After Initial Evaluation		
59.	• Nonsustained VT (<6 beats VT) • Normal LV systolic function	U (5)
No Prior Noninvasive Assessment of Ischemia With Normal Systolic Function		
60.	• Syncope • Intermediate CHD risk	U (4)
60.	• Syncope • High CHD risk	U (6)
61.	• New-onset atrial fibrillation or flutter • High CHD risk	U (5)
62.	• Heart block (e.g., second-degree type II or third-degree AV block) OR • Symptomatic bradyarrhythmias • High CHD risk	U (5)
63.	• Newly diagnosed LBBB • Low CHD risk	U (4)

Table 5. Continued.

Indication		Appropriate Use Score (1-9)
63.	• Newly diagnosed LBBB • Intermediate CHD risk	U (5)
63.	• Newly diagnosed LBBB • High CHD risk	U (5)
Preoperative Coronary Evaluation for Noncardiac Surgery in Stable Patients		
66.	• Prior to solid organ transplantation	U (5)
<4 METS Functional Capacity, No Noninvasive Testing Performed, With or Without Clinical Risk Factors Present (Preoperative Clinical Risk Factors: Ischemic Heart Disease, Heart Failure, Cerebrovascular Disease, Insulin-Requiring Diabetes Mellitus, Renal Insufficiency Cr > 2.0)		
68.	• 1 to 2 risk factors • Vascular surgery	U (4)
69.	• ≥3 risk factors • Intermediate-risk surgery	U (4)
69.	• ≥3 risk factors • Vascular surgery	U (6)
Valvular Disease		
Chronic Native or Prosthetic Valvular Disease		
Asymptomatic Related to Valvular Disease		
74.	• Severe mitral stenosis	U (6)
76.	• Severe mitral regurgitation	U (5)
78.	• Severe aortic stenosis	U (4)
80.	• Severe aortic regurgitation	U (5)
Chronic Native or Prosthetic Valvular Disease		
Symptomatic Related to Valvular Disease		
90.	• Acute moderate or severe mitral or aortic regurgitation • Noninvasive imaging for valvular disease concordant with clinical impression of severity	U (4)
Cardiomyopathies		
95.	• Suspected arrhythmogenic right ventricular dysplasia • Assessment of right ventricular morphology	U (5)

AV = atriocentric; CABG = coronary bypass grafting surgery; CAD = coronary artery disease; CHD = coronary heart disease; CMR = cardiovascular magnetic resonance; Cr = creatinine; CTA = computed tomography angiography; ECG = electrocardiogram; FFR = fractional flow reserve; IVUS = intravascular ultrasound; LBBB = left bundle branch block; LV = left ventricular; LVEF = left ventricular ejection fraction; METS = metabolic equivalents; MI = myocardial infarction; PCI = percutaneous coronary intervention; PET = positron emission tomography; SPECT MPI = single-photon emission computed tomography myocardial perfusion imaging; TTE = transthoracic echocardiography; U = uncertain; VT = ventricular tachycardia.

Table 6. Inappropriate Indications (Median Score 1-3)

Indication		Appropriate Use Score (1-9)
Suspected CAD: No Prior Noninvasive Stress Imaging (No Prior PCI, CABG, or Angiogram Showing ≥50% Angiographic Stenosis)		
5.	• Low global CAD risk • Asymptomatic	I (1)
6.	• Intermediate global CAD risk • Asymptomatic	I (3)
8.	• Low pretest probability • Symptomatic	I (3)
Suspected CAD: Prior Noninvasive Testing (No Prior PCI, CABG, or Angiogram Showing ≥50% Angiographic Stenosis)		
ECG Stress Testing		
11.	• Low-risk findings (e.g., Duke treadmill score ≥5) • Asymptomatic	I (1)
Stress Test With Imaging (SPECT MPI, Stress Echocardiography, Stress PET, Stress CMR)		
15.	• Low-risk findings (e.g., <5% ischemic myocardium on stress SPECT MPI or stress PET, no stress-induced wall motion abnormalities on stress echo or stress CMR) • Asymptomatic	I (2)
Coronary Calcium Score		
28.	• Agatston score <100 • Asymptomatic	I (1)
29.	• Agatston score 100 to 400 • Asymptomatic	I (2)
30.	• Agatston score 400-1,000 • Asymptomatic	I (3)

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Table 6. Continued

Indication		Appropriate Use Score (1-9)
31.	• Agatston score >1,000 • Asymptomatic	I (3)
Coronary CTA		
32.	• Lesion <50% non-left main • Asymptomatic	I (1)
38.	• Lesion <50% with extensive partly calcified and noncalcified plaque • Asymptomatic	I (3)
CMR		
39.	• Area of delayed gadolinium myocardial enhancement of unknown etiology • Asymptomatic	I (3)
Adjunctive Invasive Diagnostic Testing in Patients Undergoing Appropriate Diagnostic Coronary Angiography		
FFR for Lesion Severity		
41.	• Nonobstructive disease by angiography (non-left main) <50% • Unexpected angiographic finding or no prior noninvasive testing	I (3)
41.	• Nonobstructive disease by angiography (non-left main) <50% • Prior testing = no ischemic findings	I (2)
43.	• Angiographically obstructive significant disease (non-left main) ≥70% stenosis • Prior testing = concordant ischemic findings	I (3)
IVUS for Lesion Severity		
45.	• Nonobstructive disease by angiography (non-left main) <50% • Unexpected angiographic finding or no prior noninvasive testing	I (3)
45.	• Nonobstructive disease by angiography (non-left main) <50% • Prior testing = no ischemic findings	I (3)
47.	• Angiographically obstructive significant disease (non-left main) ≥70% stenosis • Prior testing = concordant ischemic findings	I (3)
Patients With Known Obstructive CAD (e.g., Prior MI, Prior PCI, Prior CABG, or Obstructive Disease on Invasive Angiography)		
Medically Managed Patients		
49.	• Low-risk noninvasive findings • Asymptomatic/controlled symptoms or unchanged findings	I (2)
Post Revascularization (PCI or CABG)		
52.	• Asymptomatic or stable symptoms	I (1)
Arrhythmias		
No Prior Noninvasive Assessment of Ischemia With Normal Systolic Function		
60.	• Syncope • Low CHD risk	I (2)
61.	• New-onset atrial fibrillation or flutter • Low CHD risk	I (2)
61.	• New-onset atrial fibrillation or flutter • Intermediate CHD risk	I (3)
62.	• Heart block (e.g., second-degree type II or third-degree AV block) OR • Symptomatic bradyarrhythmias • Low CHD risk	I (2)
62.	• Heart block (e.g., second-degree type II or third-degree AV block) OR • Symptomatic bradyarrhythmias • Intermediate CHD risk	I (3)
Preoperative Coronary Evaluation for Noncardiac Surgery in Stable Patients		
64.	• Low-risk surgery	I (2)
65.	• ≥4 METS functional capacity without symptoms	I (2)
<4 METS Functional Capacity, No Noninvasive Testing Performed, With or Without Clinical Risk Factors Present (Preoperative Clinical Risk Factors: Ischemic Heart Disease, Heart Failure, Cerebrovascular Disease, Insulin-Requiring Diabetes Mellitus, Renal Insufficiency Cr >2.0)		
67.	• No risk factors • Intermediate-risk surgery	I (2)
67.	• No risk factors • Vascular surgery	I (3)
68.	• 1 to 2 risk factors • Intermediate-risk surgery	I (3)

Table 6. Continued

Indication		Appropriate Use Score (1-9)
Valvular Disease		
Chronic Native or Prosthetic Valvular Disease		
Asymptomatic Related to Valvular Disease		
73.	Mild or moderate mitral stenosis	1 (2)
75.	Mild or moderate mitral regurgitation	1 (2)
77.	Mild or moderate aortic stenosis	1 (2)
79.	Mild or moderate aortic regurgitation	1 (2)
Chronic Native or Prosthetic Valvular Disease		
Symptomatic Related to Valvular Disease		
81.	Mild or moderate mitral stenosis Noninvasive imaging for valvular disease concordant with clinical impression of severity	1 (2)
82.	Severe mitral stenosis Noninvasive imaging for valvular disease concordant with clinical impression of severity	1 (3)
83.	Mild or moderate mitral regurgitation Noninvasive imaging for valvular disease concordant with clinical impression of severity	1 (2)
84.	Severe mitral regurgitation Noninvasive imaging for valvular disease concordant with clinical impression of severity	1 (3)
85.	Mild or moderate aortic stenosis Noninvasive imaging for valvular disease concordant with clinical impression of severity	1 (3)
86.	Severe aortic stenosis Noninvasive imaging for valvular disease concordant with clinical impression of severity	1 (3)
88.	Mild or moderate aortic regurgitation Noninvasive imaging for valvular disease concordant with clinical impression of severity	1 (2)
89.	Severe aortic regurgitation Noninvasive imaging for valvular disease concordant with clinical impression of severity	1 (3)

AV = atriocentric; CABG = coronary bypass grafting surgery; CAD = coronary artery disease; CHD = coronary heart disease; CMR = cardiovascular magnetic resonance; Cr = creatinine; CTA = computed tomography angiography; ECG = electrocardiogram; FFR = fractional flow reserve; I = inappropriate; IVUS = intravascular ultrasound; METS = metabolic equivalents; MI = myocardial infarction; PCI = percutaneous coronary intervention; PET = positron emission tomography; SPECT/MIPI = single-photon emission computed tomography myocardial perfusion imaging.

9. Figures

	Risk Assessment		
	Low	Intermediate	High
Asymptomatic Global CAD Risk			U
Symptomatic Pretest Probability		U	A

Figure 1. Suspected CAD: No Prior Noninvasive Stress Imaging

A = appropriate; CAD = coronary artery disease; I = inappropriate; U = uncertain.

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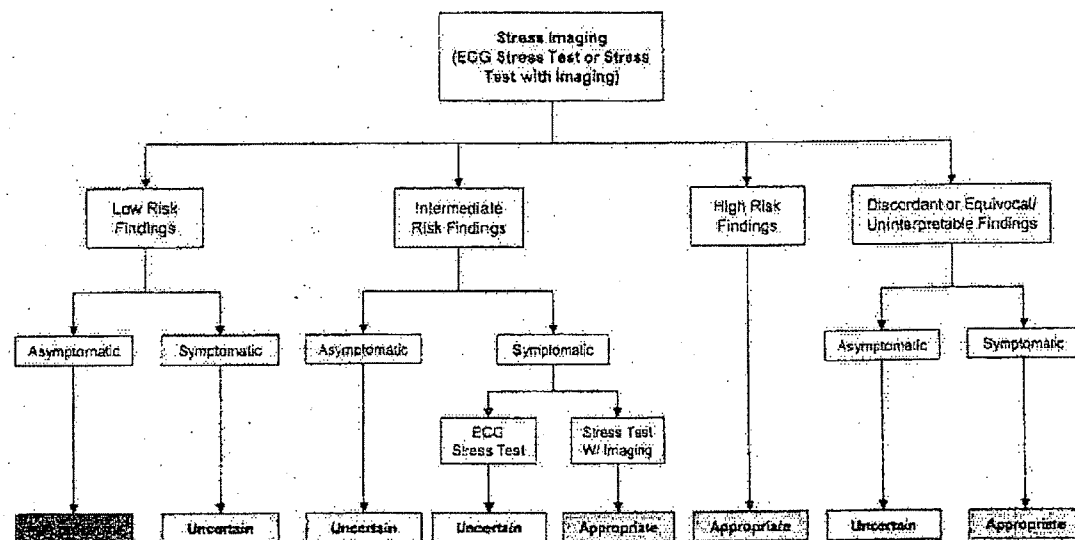


Figure 2. Suspected CAD: Prior Noninvasive Stress Testing

Indications 22 to 27 not covered in figure. CAD = coronary artery disease; ECG = electrocardiography.

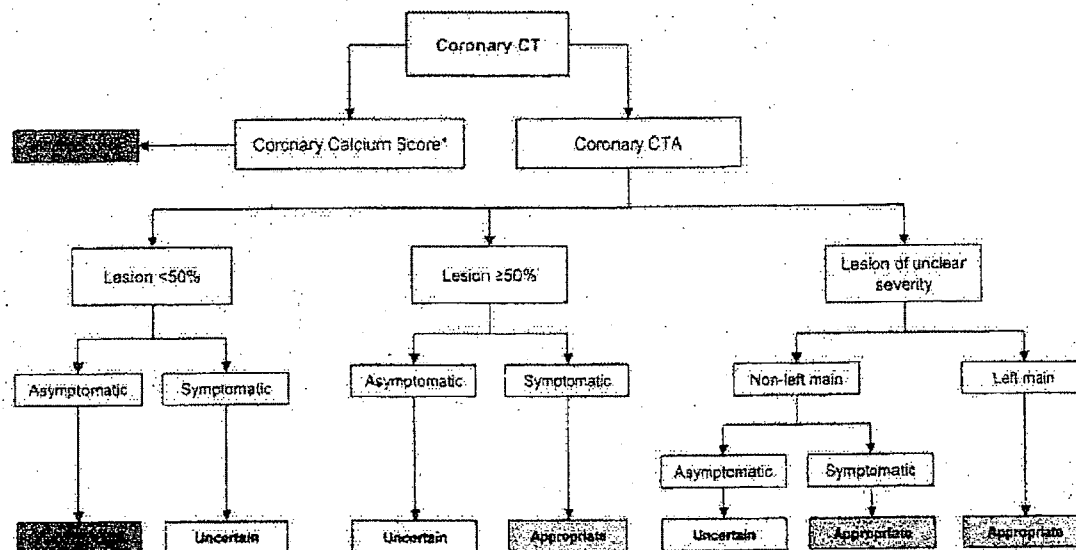


Figure 3. Suspected CAD: Prior Noninvasive Cardiac CT (Calcium Score and CTA)

*Coronary calcium score only rated for asymptomatic patients as these patients are the population in which it is used. CT = computed tomography; CTA = computed tomography angiography.

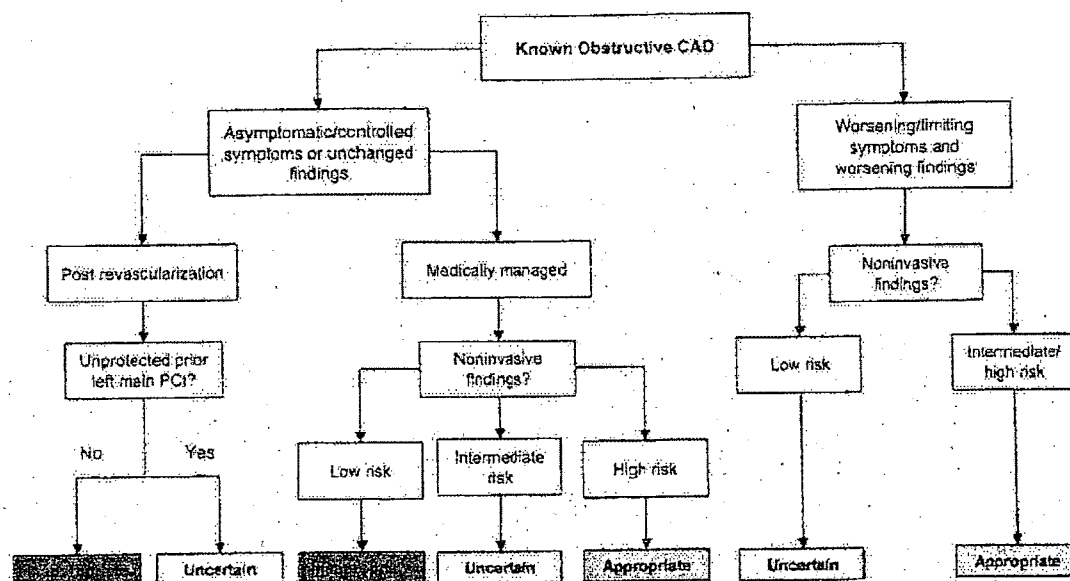


Figure 4. Patients With Known Obstructive CAD

CAD = coronary artery disease; PCI = percutaneous coronary intervention.

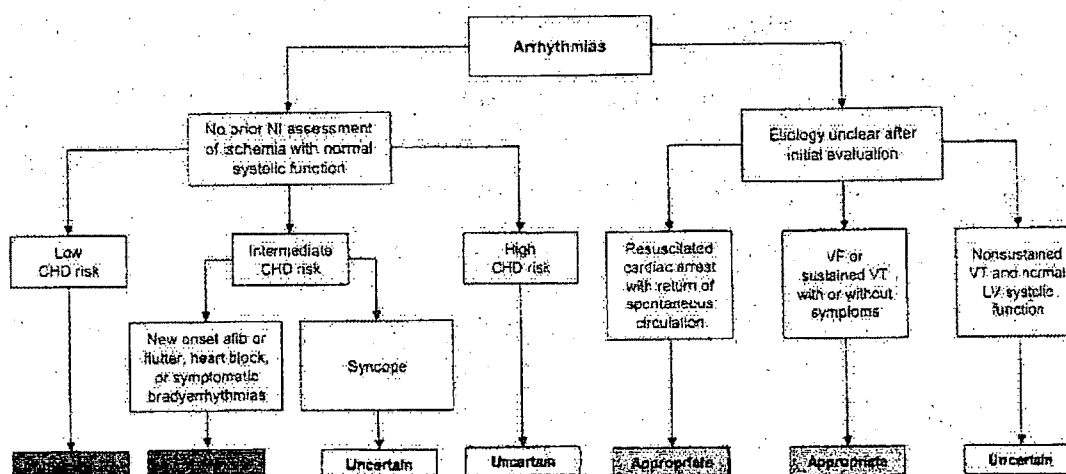


Figure 5. Evaluation of Arrhythmias

Indication 63 for newly diagnosed LBBB is not represented in this figure and was rated as "uncertain." CHD = coronary heart disease; LBBB = left bundle branch block; LV = left ventricular; NI = noninvasive; VF = ventricular fibrillation; VT = ventricular tachycardia.

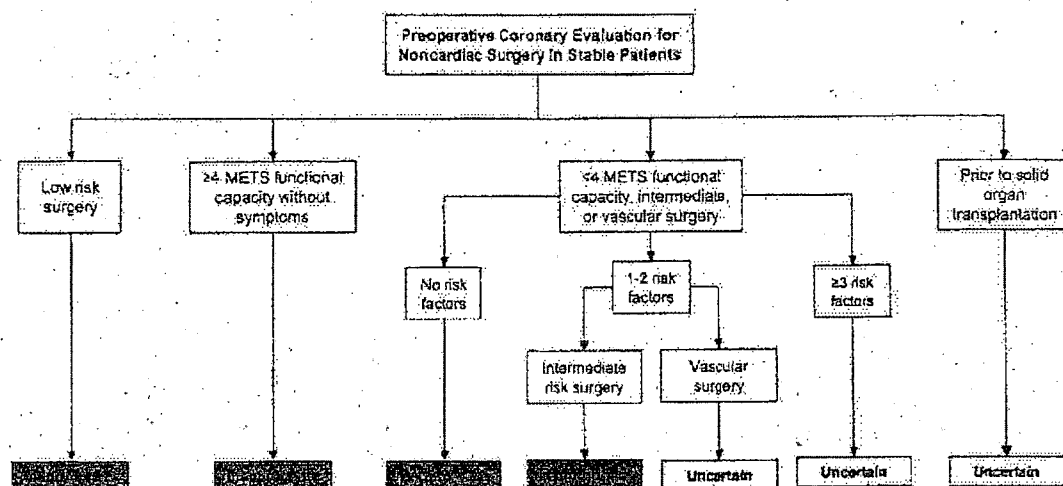


Figure 6. Preoperative Coronary Evaluation: Patients With No Prior Noninvasive Stress Testing

METS = metabolic equivalents.

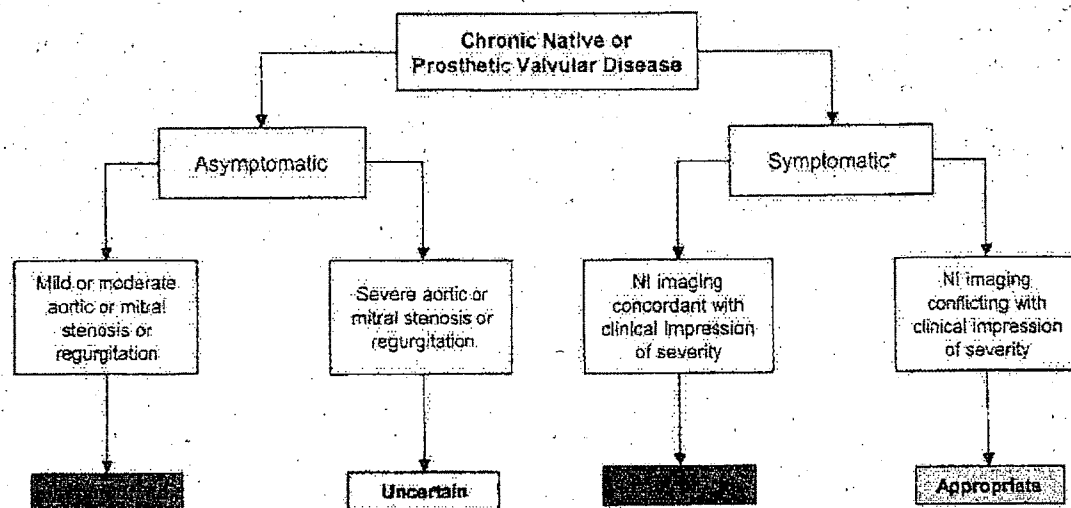


Figure 7. Evaluation of Valvular Disease

Preoperative assessment before vascular surgery is not represented in this figure and is rated "appropriate." *Indication 90 for acute moderate or severe mitral or aortic regurgitation is not represented in this figure. Rating for concordant imaging is "uncertain" and conflicting imaging is "appropriate." NI = noninvasive.

10. Discussion

Diagnostic cardiac catheterization incorporates both imaging and hemodynamic procedures aimed at providing information to document specific cardiovascular disease states as well as help care for and improve the health of patients with known or suspected heart disease. The AUC are meant to provide guidance concerning the rational and timely use of diagnostic cardiac catheterization and coronary angiography. The current document provides an evaluation of many of the indications commonly considered in clinical practice. The writing group felt that review of the recommendations by general procedures and indications would be of the highest utility to clinical practice.

10.1. Assessment for CAD

Several sets of indications were rated regarding the use of invasive coronary angiography for the evaluation of CAD. The writing group felt that the decision to include left heart catheterization, left ventriculography, and perhaps other invasive procedures with coronary angiography should be at the discretion of the operator, depending on the clinical situation, the presence or absence of noninvasive assessments of LV function and pulmonary pressures, and the perceived accuracy of these noninvasive results.

In general, these indications were grouped by the clinical suspicion for acute coronary syndromes, suspected or known obstructive CAD, use of adjunctive invasive diagnostic technologies, evaluation of arrhythmias, and preoperative evaluation. Although these scenarios represented many common clinical indications for the evaluation of CAD, the writing group acknowledges that this is not comprehensive and thus there are likely clinical scenarios encountered in practice that are not rated in this document. Nevertheless, review of these scenarios should provide clinicians guidance on the use of coronary angiography.

Overall, patients with definite or suspected acute coronary syndromes were rated as appropriate for coronary angiography. These ratings reflect the current management and risk stratification of patients with acute coronary syndrome (ACS), which usually involves defining the presence, location, and degree of coronary stenosis and is based on abundant clinical studies on the management of ACS patients that used coronary angiography. Alternatively, in patients without known CAD, referral directly for coronary angiography for the suspicion of obstructive disease was felt to be appropriate only in symptomatic patients with a high pretest probability. The remaining patients (asymptomatic patients and symptomatic patients with low or intermediate pretest probability) were felt to be uncertain or inappropriate for a management strategy that used coronary angiography as the initial diagnostic test.

In patients with prior noninvasive testing, coronary angiography was rated inappropriate for asymptomatic patients with low-risk findings. Symptomatic patients with intermediate- or high-risk findings or equivocal/discordant noninvasive findings were rated appropriate for coronary

angiography. Coronary calcium scores, regardless of severity, were rated as inappropriate indications for invasive coronary angiography in asymptomatic patients. The technical panel was not asked to rate calcium scores in symptomatic patients as this test is usually only performed in asymptomatic patients to assess risk. For patients with known CAD, asymptomatic patients following revascularization and medically managed patients with stable symptoms and low-risk noninvasive test findings were rated inappropriate in general for coronary angiography, whereas patients with high-risk noninvasive findings or those with limiting or worsening symptoms were rated as appropriate.

Several clinical scenarios related to the use of coronary angiography in the evaluation of certain cardiac arrhythmias were developed. Coronary angiography was rated as appropriate for patients resuscitated after cardiac arrest (assuming return of reasonable neurologic function) and for those with sustained VT regardless of symptoms. The other scenarios developed related to syncope, new onset atrial fibrillation/flutter, high-degree atrioventricular block, or new LBBB and were generally inappropriate for patients with a low coronary heart disease (CHD) risk and uncertain with a high CHD risk.

Scenarios for patients scheduled for noncardiac surgical procedures were also rated. In the preoperative setting for noncardiac surgery, direct catheterization and angiography was not generally considered appropriate unless the patient had significant risk factors or was undergoing transplantation of a solid organ or vascular surgery.

10.2. Assessment for Conditions Other Than CAD

Assessment of intracardiac and pulmonary pressures and other testing such as measurement of cardiac output were evaluated primarily in the setting of valvular heart disease, cardiomyopathies, and pulmonary hypertension. In the section on CAD assessment, the scenarios developed considered the use of coronary angiography and considered other procedures during the invasive evaluation (e.g., left heart catheterization, left ventriculography) as secondary to the primary purpose of the evaluation and at the discretion of the operator. In a similar format, the scenarios developed in this section rated the use of the hemodynamic evaluations and considered coronary angiography as secondary to the primary purpose of the evaluation and at the discretion of the operator.

It should be noted that, in general, for patients with planned valvular surgery, preoperative catheterization for coronary anatomy was rated as appropriate. Additionally, in patients with symptomatic and severe valvular heart disease with discordant clinical and noninvasive imaging findings, hemodynamic assessment was rated as appropriate. Specific groups such as those with low transvalvular gradient, depressed LV function or decreased cardiac output were rated as appropriate for further evaluation using hemodynamic studies.

Patients without symptoms, with mild to moderate stenosis or concordant clinical and noninvasive findings were generally rated as inappropriate for diagnostic catheterization procedures with hemodynamic assessment. Those

without symptoms but with severe disease were rated as uncertain. Asymptomatic patients with valvular heart disease were rated based on the noninvasive findings alone since discordance between a clinical impression and noninvasive findings in these patients would not be easily determined. Patients with pulmonary hypertension, either clinically suspected or documented and requiring evaluation for pharmacological therapy, were identified as appropriate for invasive hemodynamic assessment at rest as well as with provocative maneuvers (exercise or pharmacological challenge).

Specific groups such as those suspected of pericardial disease, intracardiac shunts, tamponade, suspected cardiomyopathy or patients who have received cardiac transplant were rated as appropriate for hemodynamic studies and endomyocardial biopsy.

10.3. Application of the Criteria

In their work developing and rating these clinical scenarios, the writing group and technical panel focused on the multiple goals of diagnostic cardiac catheterization and coronary angiography and common clinical scenarios seen in clinical practice. Clinical scenarios and ultimately the ratings of the technical panel were focused on obtaining information from the procedure that should help in the management of patients with suspected or known heart disease including providing needed reassurance about the clinical status of the patient. Additionally, the diagnostic catheterization AUC was written with recognition that these indications would be linked with the coronary revascularization AUC. In fact, the hope of the writing group was to develop a system that would inform patients and clinicians to increase the right patients undergoing appropriate invasive catheterization procedures before discussions and considerations around revascularization.

With these goals in mind, there are many potential applications for the AUC in this document. Decision support and educational tools should be developed. Ideally, these would translate these ratings into clinical tools used at the point of care to aid clinicians and patients in the decision to perform or undergo an invasive procedure. Figures 1 to 7 are meant to provide some initial algorithms for the overall ratings.

Facilities and payers may choose to use these criteria, either prospectively in the design of protocols or review procedures, or retrospectively for quality reports. It is hoped that payers would use these criteria to ensure that their members receive necessary, beneficial, and cost-effective cardiovascular care, rather than for other purposes. It is expected that services performed for appropriate and/or uncertain indications will receive reimbursement. In contrast, services performed for inappropriate indications may require additional documentation to justify payment because of the unique circumstances or the clinical profile that may exist in such a patient. This additional documentation should not be required for uncertain indications. It is critical to emphasize that the writing group, technical panel, AUC Task Force, and clinical community do not believe an uncertain rating justifies denial of reimbursement for these invasive

procedures. Rather, uncertain ratings are those in which the available data vary and many other factors exist that may affect the decision to perform or not perform cardiac catheterization and coronary angiography. The opinions of the technical panel often varied for these indications, reflecting that additional research is needed. Indications with high clinical volume that are rated as uncertain identify important areas for further research. The writing group and technical panel favor the collaborative interaction between patients, referring clinicians, and cardiologists in determining the need for these invasive procedures.

When evaluating physician or facility performance, AUC should be used in conjunction with efforts that lead to quality improvement. Prospective preauthorization procedures, if put in place, are most effective once a retrospective review has identified a pattern of potential inappropriate use. Because these criteria are based on current scientific evidence and the deliberations of the technical panel, they should be used prospectively to generate future discussions about reimbursement, but should not be applied retrospectively to cases completed before issuance of this report or documentation of centers/providers performing an unexpectedly high proportion of inappropriate cases as compared with their peers.

The writing group recognizes that these criteria will be evaluated during routine clinical care. To that end, specific data fields such as symptom status, presence or absence of acute coronary syndrome, history of CAD or revascularization, and type of noninvasive testing and findings will be required to determine individual appropriate use ratings. It is recognized that the characterization of symptoms is inherently subjective, and there is variability in the interpretation of many noninvasive tests. Fundamental to the application of the AUC is the understanding that the characterization of symptoms or interpretation of noninvasive tests is performed in a manner such that independent qualified reviewers would reach the same conclusions or support the conclusions of the individual physician about symptoms or noninvasive test results.

The primary objective of this report is to provide guidance regarding the use of diagnostic catheterization including coronary angiography, left heart catheterization and left ventriculography, and right heart catheterization for a diverse set of clinical scenarios. As with previous AUC documents, consensus among the raters was desirable, but an attempt to achieve complete agreement within this diverse panel would have been artificial and was not the goal of the process. Two rounds of ratings with substantial discussion among the technical panel members between the ratings did lead to some consensus among panelists. However, further attempts to drive consensus would have diluted true differences in opinion among panelists and, therefore, was not undertaken.

Future research analyzing patient outcomes for indications rated as appropriate and inappropriate will help ensure the equitable and efficient allocation of resources for cardiac catheterization. Further exploration of the indications rated as "uncertain" will help generate the information required to further define the appropriate use of cardiac catheterization procedures. Addition-

ally, the criteria will need to be updated with the publication of ongoing trials in imaging and revascularization occurs.

In conclusion, this document represents the current understanding of the clinical utility of diagnostic cardiac catheterization. It is intended to provide a practical guide to clinicians and patients when these procedures,

Appendix A: Additional Diagnostic Catheterization Definitions

TIMI Risk Score—For Patients With Suspected ACS (23): Variables (1 point each)

- Age ≥ 65 years
- ≥ 3 risk factors (hypertension, diabetes mellitus, family history, lipids, smoking)
- Known CAD (stenosis $\geq 50\%$)
- Aspirin use in past 7 days
- Severe angina (≥ 2 episodes within 24 hours)
- ST-segment deviation ≥ 0.5 mm
- Elevated cardiac markers

Risk of death or ischemic event through 14 days

- Low: 0 to 2 ($<8.3\%$ event rate)
- Intermediate: 3 to 4 ($<19.3\%$ event rate)
- High: 5 to 7 (41% event rate)

GRACE ACS Risk Model (24): At admission (in-hospital/to 6 months)

- Age
- Heart rate
- Systolic blood pressure mm Hg
- Creatinine
- Congestive heart failure Killip class
- Cardiac arrest at admission
- ST-segment deviation
- Elevated cardiac enzymes/markers

At discharge (to 6 months)

- Age
- Heart rate
- Systolic blood pressure mm Hg
- Creatinine
- Congestive heart failure
- In-hospital PCI
- In-hospital CABG
- Past history of myocardial infarction
- ST-segment depression
- Elevated cardiac enzymes/markers

Appendix B: Additional Methods

Relationships With Industry and Other Entities

The American College of Cardiology Foundation and the Society for Cardiovascular Angiography and Interventions

and its partnering organizations rigorously avoid any actual, perceived, or potential conflicts of interest that might arise as a result of an outside relationship or personal interest of a member of the technical panel. Specifically, all panelists were asked to provide disclosure statements of all relationships that might be perceived as real or potential conflicts of interest. These statements were reviewed by the Appropriate Use Criteria Task Force, discussed with all members of the technical panel at the face-to-face meeting, and updated and reviewed as necessary. A table of disclosures by all participants, listed in Appendix C, in the Appropriate Use Criteria for Diagnostic Catheterization can be found in Appendix D. In addition, to ensure complete transparency, complete disclosure information—including relationships not pertinent to this document—is available online as a document supplement.

Literature Review

The technical panel members were asked to refer to the relevant guidelines for a summary of the relevant literature, guideline recommendation tables, and reference lists provided for each indication table when completing their ratings (Online Appendix).

Appendix C: ACCF/SCAI/AATS/AHA/ASE/ASNC/HFSA/HRS/SCCM/SCCT/SCMR/STS 2012 Appropriate Use Criteria For Diagnostic Catheterization Participants

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Marco A. Zenati, MD, FETCS—Professor of Surgery, Harvard Medical School, Chief of Cardiac Surgery, VA Boston Health Care System, Associate Surgeon, Brigham & Women's Hospital, Boston, MA

Appropriate Use Criteria Task Force

Michael J. Wolk, MD, MACC—Chair, Task Force, Past President, American College of Cardiology Foundation and Clinical Professor of Medicine, Weill-Cornell Medical School, New York, NY

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Erin A. Barrett, MPS, Senior Specialist, Science and Clinical Policy

APPENDIX D: ACCF/SCAI/AATS/AHA/ASE/ASNC/HFSA/HRS/SCCM/SCCT/SCMR/STS 2012 APPROPRIATE USE CRITERIA FOR DIAGNOSTIC CATHETERIZATION WRITING GROUP, TECHNICAL PANEL, INDICATION REVIEWERS, AND TASK FORCE—RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (IN ALPHABETICAL ORDER)

Participant	Consultant	Speaker's Bureau	Ownership/Partnership/Principal	Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Diagnostic Catheterization Appropriate Use Criteria Writing Group						
Manesh R. Patel	None	None	None	None	None	None
Steven R. Bailey	None	None	None	• Palmaz Scientific	None	None
Robert O. Bonow	• Edwards Lifesciences	None	None	None	None	None
Charles E. Chambers	None	None	None	None	None	None
Paul S. Chan	None	None	None	None	None	None
Gregory J. Dehmer	None	None	None	None	None	None
Ajay J. Kirtane	None	None	None	None	None	None
L. Samuel Wann	None	None	None	None	None	None
R. Parker Ward	None	None	None	None	None	None
Diagnostic Catheterization Appropriate Use Criteria Technical Panel						
Pamela S. Douglas	None	None	None	None	None	None
Manesh R. Patel	None	None	None	None	None	None
Steven R. Bailey	None	None	None	• Palmaz Scientific	None	None
Philip Altwegg	None	None	None	None	None	None
Denise D. Barnard	None	None	None	None	None	None
James C. Blankenship	None	None	None	• Boston Scientific • Conor Medsystems	None	None
Donald E. Casey, Jr.	None	None	None	None	None	None
Larry S. Dean	• Edwards • Philips Medical	None	None	• Edwards Lifesciences	None	None
Reza Fazel	None	None	None	None	None	None
Ian C. Glick	None	• Terumo Medical	None	None	None	None
Clifford J. Kavinsky	None	None	None	None	None	None
Susan G. Lakoski	None	None	None	None	None	None
D. Elizabeth Le	None	None	None	None	None	None
John R. Lesser	None	None	None	None	None	None
Glenn N. Levine	None	None	None	None	None	None
Rokana Mehran	• Johnson & Johnson	None	None	None	None	None
Andrea M. Russo	None	• Boston Scientific	None	None	None	None
Matthew J. Sorrentino	None	None	None	None	None	None

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Appropriate Use Criteria for Diagnostic Catheterization

JACC Vol. 59, No. 22, 2012
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Participant	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Mathew R. Williams	• Abbott • Edwards Lifesciences • Medtronic	None	None	None	None	None
John B. Wong	None	None	None	None	None	None
Diagnostic Catheterization Appropriate Use Criteria Indication Reviewers						
Stephan Achenbach	• Siemens	None	None	• Siemens*	None	None
Suhail Q. Alqaaband	None	None	None	None	None	None
Jeffrey L. Anderson	None	None	None	• Toshiba	None	None
Joshua N. Baker	None	None	None	None	None	None
Victor Y. Cheng	None	None	None	None	None	None
Mauricio G. Cohen	• Medtronic	• Terumo Medical	None	None	None	None
Michael J. Davidson	None	None	None	None	None	None
Joseph J. DeRose, Jr.	None	None	None	None	None	None
Rory Hachamovitch	None	None	None	None	None	None
Clifford J. Kavinsky	None	None	None	None	None	None
Kevin P. Landaff	None	None	None	None	None	None
Richard A. Longs	None	None	None	None	None	None
D. Elizabeth Le	None	None	None	None	None	None
John R. Lesser	None	None	None	None	None	None
Sheldon E. Litwin	None	None	None	None	None	None
John J. Mahmarian	• GE Healthcare	None	None	None	None	None
Rick A. Nishimura	None	None	None	None	None	None
Amit R. Patel	None	None	None	None	None	None
Harry R. Phillips	• Abbott Vascular*	None	None	None	None	None
Eric E. Roselli	None	None	None	None	None	None
Amit J. Shanker	None	None	None	None	None	None
Sidney C. Smith, Jr.	None	None	None	None	None	None
Jonathan S. Steinberg	None	None	None	None	None	None
Vinod H. Thourani	• Edwards Lifesciences • Medtronic • Sorin • St. Jude Medical	None	None	None	None	None
Thomas Tu	None	None	• Abbott Vascular • Cordis	None	None	None
Jonathan W. Welosoff	None	None	None	None	None	None
Joseph N. Wight, Jr.	None	None	None	None	None	None
Marco Zenati	None	None	None	None	None	None
Appropriate Use Criteria Task Force						
Michael J. Wolk	None	None	None	None	None	None
Steven R. Bailey	None	None	None	• Palmaz Scientific	None	None
Pamela S. Douglas	None	None	None	None	None	None
Robert C. Hendel	None	None	None	None	None	None
Christopher M. Kiamer	• St. Jude Medical	None	None	• Siemens*	None	None
James K. Min	None	• GE Healthcare	None	None	None	None
Manesh R. Patel	None	None	None	None	None	None
Leslee Shaw	None	None	None	None	None	None
Raymond F. Stainback	None	None	None	None	None	None
Joseph M. Allen	None	None	None	None	None	None

This table represents the relevant relationships with industry and other entities that were disclosed by our authors at the time of publication. It does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of 1% or the voting stock or share of the business entity, or ownership of 1% of the fair market value of the business entity, or funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. A relationship is considered to be modest if it is less than significant under the preceding definition. Relationships in this table are modest unless otherwise noted. Names are listed in alphabetical order within each category of review. Participation does not imply endorsement of this document.

* Significant relationship.

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Key Words: ACCF Appropriate Use Criteria • angiography • catheterization • coronary artery disease • valvular disease.

Top 25 Reasons for Inpatient Hospitalizations

by year, county of residence, age, race and gender.

(Includes Acute Care Hospitals, excludes newborns)

Year: 2014 County: Berkeley Age Range: Total Race: Total Gender: Total

Rank	Primary Diagnosis	Discharges	Percent of Total
1.	038 - SEPTICEMIA*	655	4.5 %
2.	715 - OSTEOARTHRITIS ET AL*	470	3.2 %
3.	428 - HEART FAILURE*	465	3.2 %
4.	648 - OTH CURRENT COND IN PREG*	377	2.6 %
5.	427 - CARDIAC DYSRHYTHMIAS*	358	2.5 %
6.	250 - DIABETES MELLITUS*	333	2.3 %
7.	491 - CHRONIC BRONCHITIS*	288	2 %
8.	722 - INTERVERTEBRAL DISC DIS*	284	2 %
9.	996 - REPLACE & GRAFT COMPLIC*	275	1.9 %
10.	584 - ACUTE RENAL FAILURE*	271	1.9 %
11.	654 - ABN PELVIC ORGAN IN PREG*	268	1.9 %
12.	645 - PROLONGED PREGNANCY*	268	1.9 %
13.	486 - PNEUMONIA, ORGANISM NOS	259	1.8 %
14.	410 - ACUTE MYOCARDIAL INFARCT*	207	1.4 %
15.	434 - CEREBRAL ARTERY OCCLUS*	205	1.4 %
16.	599 - OTH URINARY TRACT DISOR*	194	1.3 %
17.	682 - OTHER CELLULITIS/ABSCESS*	186	1.3 %
18.	296 - AFFECTIVE PSYCHOSES*	186	1.3 %
19.	642 - HYPERTENSION COMPL PREG*	170	1.2 %
20.	276 - FLUID/ELECTROLYTE DIS*	168	1.2 %
21.	780 - GENERAL SYMPTOMS*	162	1.1 %
22.	518 - OTHER LUNG DISEASES*	159	1.1 %
23.	493 - ASTHMA*	153	1.1 %
24.	664 - PERINEAL TRAUM W DELIVER*	148	1 %
25.	414 - OTH CHR ISCHEMIC HRT DIS*	145	1 %

Data is not reported for rows where the number of discharges is less than 5.

Attachment 6

**Accountant's Letter
Financials**



May 4, 2016

Mr. Louis Euhank
DHEC CON Division Director
Bureau of Health Facilities and Services Development
South Carolina Department of Health and Environmental Control
2600 Bull Street
Columbia, South Carolina 29201

Dear Mr. Louis Euhank:

Enclosed you will find the pro-formas developed for the transfer of the Cardiac Cath Lab at Bon Secours - St. Francis Hospital to Roper St. Francis - Berkeley Hospital. The pro-forma analysis for the Hospital alone is the original submission provided by Richardson/Knapp and Associates and will continue to stand. I prepared the proforma for the Cath Lab project and will attest to the reasonableness of the assumptions, calculations, and information contained therein.

The pro-forma budgets were prepared to assist management in evaluating the financial viability of pursuing the proposed project and for details requested by the Department of Health and Environmental Control. They should not be used for any other purpose.

This project will be funded by bond proceeds issued for the development of the Roper St. Francis - Berkeley Hospital. Should you have any questions, please contact me at (843) 402-1793.

Sincerely,

A handwritten signature in black ink, appearing to read "Julie A. Graudin".

Julie A. Graudin, CPA
Roper St. Francis Healthcare

Roper St. Francis - Berkeley
FORECASTED STATEMENTS OF OPERATIONS
 Project Alone

	PROJECTED 2019	PROJECTED 2020	PROJECTED 2021
Volumes			
Right Heart Cath	6	8	10
Left Heart Cath	240	332	439
Combined Right and Heart Cath	34	46	61
PATIENT REVENUE:			
Right Heart Cath	\$39,432	\$50,736	\$67,034
Left Heart Cath	\$2,753,280	\$3,808,245	\$5,031,619
Combined Right and Heart Cath	477,530	650,564	859,554
TOTAL PATIENT REVENUE	\$3,270,242	\$4,509,545	\$5,958,208
DEDUCTIONS FROM REVENUE:			
Contractual allowances	\$1,928,789	\$2,659,730	\$3,514,151
Charity Care	224,666	309,806	409,329
Provisions for Bad Debt	53,959	74,407	98,310
TOTAL DEDUCTIONS FROM REVENUE	\$2,207,413	\$3,043,943	\$4,021,790
NET PATIENT SERVICE REVENUE	\$1,062,829	\$1,465,602	\$1,936,417
TOTAL REVENUE	\$1,062,829	\$1,465,602	\$1,936,417
EXPENSES:			
Labor Expense	\$230,483	\$237,398	\$244,520
Supplies	564,500	778,547	1,028,650
Other expenses	26,973	37,219	49,176
Depreciation and amortization	120,000	120,000	120,000
TOTAL EXPENSES	\$941,956	\$1,173,164	\$1,442,345
Revenue over Expenses	\$120,873	\$292,439	\$494,073

J01-148

CON 0148

R900

Cath Lab Volume Projections

		2014		2013		PERCENTAGES		
		IP	OP	IP	OP	2YR AVG	2014	2013
RHC	3721	28	13	33	17	2%	2%	2%
LHC	3722	897	962	998	984	86%	86%	87%
Combined	3723	106	157	100	158	12%	12%	11%
		1031	1132	1131	1159	100%	100%	100%

		2019	2020	2021
Right		6	8	10
Left		240	332	439
Combined		34	46	61

Supplies		2019	2020	2021
Right	1777	10,662	13,718	18,125
left	2063	495,120	684,833	904,832
Combined	1727	58,718	79,995	105,692

		564,500	778,547	1,028,650
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Other

Right	70.15	421	542	716
left	101	24,240	33,528	44,299
Combined	68	2,312	3,150	4,162

		26,973	37,219	49,176
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J01-149

CON0149

R901

Financial Assumptions – Cardiac Catherization Lab project

Roper St. Francis – Berkeley Hospital

- Projected volumes were developed based on proposed incremental Catherization volume at the Roper St. Francis – Berkeley Hospital

Projected Diagnostic Caths for Roper Berkeley		
2019	2020	2021
280	386	510

- Volumes were further detailed into Right Heart Cath, Left Heart Cath and Combined Right and Left Heart Cardiac Cath based on the current distribution experience at Roper Hospital.
- Contractual adjustments, Bad Debt and Charity were based on the current experience at Roper Hospital
- Labor experience was developed based on the manpower required for the incremental cases.

Title	Year 1	Year 2	Year 3
	Proposed # FTEs	Proposed # FTEs	Proposed # FTEs
Lab Tech	2.0	2.0	2.0
CV Nurse	1.0	1.0	1.0

- All other operating expenses were based on current experience within the Cath Labs at Roper Hospital.
- Depreciation was calculated on the straight line method based on purchase price of \$1.2 million and a useful life of 10 years.

Roper St. Francis - Berkeley
FORECASTED STATEMENTS OF OPERATIONS
Without Project

	PROJECTED 2019	PROJECTED 2020	PROJECTED 2021
PATIENT REVENUE:			
Inpatient revenue	\$26,778,724	\$40,115,987	\$61,317,923
Outpatient revenue	25,657,605	47,059,694	58,750,783
TOTAL PATIENT REVENUE	\$52,436,329	\$96,175,681	\$120,068,706
DEDUCTIONS FROM REVENUE			
Contractual allowances	\$33,648,119	\$62,020,955	\$77,810,309
Charity Care	1,153,599	2,115,865	2,641,512
Provisions for Bad Debt	2,276,864	4,176,092	5,213,563
TOTAL DEDUCTIONS FROM REVENUE	\$37,078,582	\$68,312,912	\$85,665,384
NET PATIENT SERVICE REVENUE	\$15,357,747	\$27,862,769	\$34,403,322
OTHER REVENUE	\$63,880	\$112,785	\$135,541
TOTAL REVENUE	\$15,421,627	\$27,975,554	\$34,538,863
EXPENSES:			
Labor Expense	\$9,203,782	\$11,231,700	\$13,073,617
Supplies	2,359,509	4,280,260	5,284,446
Purchased services	1,820,959	1,943,408	2,029,671
Other expenses	1,941,717	1,999,969	2,059,968
Depreciation and amortization	7,058,000	7,058,000	7,058,000
Interest Expense	4,400,000	4,360,000	4,320,000
Corporate Administration	403,432	415,535	428,001
TOTAL EXPENSES	\$27,187,399	\$31,288,872	\$34,253,703
INCOME FROM OPERATIONS	(\$11,765,772)	(\$3,313,318)	\$285,160
NONOPERATING INCOME, NET	\$0	\$0	\$0
REVENUE OVER EXPENSES	(\$11,765,772)	(\$3,313,318)	\$285,160

J01-152

CON.0152

R904

Financial Assumptions -- Roper St. Francis Hospital -- Berkeley (Incremental)

This submission is the original 2008 financial proforma for Hospital only.

General Assumptions

- The proposed Hospital is assumed to have 50 beds
 - 36 Medical/Surgical
 - 6 ICU beds
 - 8 OB beds
- The service offering will be non-tertiary/non-specialty, similar to the service mix at St. Francis and Roper ST. Francis Mt. Pleasant Hospital
- Construction on the facility is assumed to begin in late 2017 with an expected opening date in calendar year 2019.
- The first three years of operation are assumed to be 2019, 2020 and 2021.

	<u>2019</u>	<u>2020</u>	<u>2021</u>
Projected days at venue	6,388	10,950	12,775
Cannibalized Days	3,194	5,475	6,387
Incremental days	3,194	5,475	6,388

Financial Assumptions

- Inpatient Gross Revenue was projected based upon St. Francis gross inpatient revenue per patient day
- Outpatient Gross Revenue was projected using Roper Hospital and St. Francis Hospital's relationship between gross inpatient revenue and gross outpatient revenue such that the overall outpatient gross revenue was slightly less than the projected inpatient gross revenue.
- Contractual allowances are based upon St. Francis Hospital and Roper Hospital current reimbursement profile trended forward to the expected years.
- Bad Debt is forecasted based upon St. Francis Hospitals' ratio of approximately 4.3% of gross patient service revenue
- Charity was forecasted based upon St. Francis hospitals ratio of 2.2% of gross patient service revenue.

- Other operating Revenue was forecast using Roper and St. Francis Hospitals experience on a PPD basis, trended forward by a 3 percent annual inflation factor.
- Labor expense per adjusted discharge was calculated based upon the incremental FTEs necessary to service the projected incremental adjusted patient days, including both salaries and wages and fringe benefits. Salaries and wages were inflated at 3% annually. Fringe benefits were forecasted at 24% of gross salaries and wages.
- Supplies include such items as drugs, food, chargeable supplies, non chargeable supplies and implants. The Bulk of this category is variable, which was projected based on the ratio of St. Francis Hospital 2008 cost to net revenue.
- Purchased services include such items as professional fees, medical director fees, maintenance contracts, reference la, security and contracted services. The bulk of this is fixed expense
- Other Expense includes such items as utilities and travel and education expense and is virtually all fixed expense. This was calculated based upon St. Francis and Roper Hospital experience.
- Corporate Administration expense was projected based on the expected incremental increase in corporate support FTEs arising from the presence of the Berkeley County Hospital, relative to the absence of the proposed hospital.
- Depreciation expense was projected based on the proposed project cost, using straight line depreciation and the following useful life assumptions:
 - Construction – blended 30 year life
 - Site work – 20 years
 - Equipment – 7 years.
- The following table summarizes the sources and uses of funds related to the proposed project:

Sources

Debt	\$ 88,000,000
Equity	\$ 24,978,119
Total Sources	\$112,978,119

Uses

Construction	\$ 57,876,525
Site Work	6,129,583
Pre-Opening	1,691,909
Equipment	20,340,131
Furniture	1,956,027
Contingency	7,459,218
Architect/other	6,962,226
Land	2,062,500
Bond Costs/Cap interest	<u>8,500,000</u>
Total Uses	\$112,978,119

J01-155

CON-0155

R907

Roper St. Francis - Berkeley
FORECASTED STATEMENTS OF OPERATIONS
 With Project

	PROJECTED 2019	PROJECTED 2020	PROJECTED 2021
PATIENT REVENUE:			
Inpatient revenue	\$26,778,724	\$49,115,987	\$61,317,923
Outpatient revenue	28,927,847	51,569,239	64,708,991
TOTAL PATIENT REVENUE	\$55,706,571	\$100,685,226	\$126,026,914
DEDUCTIONS FROM REVENUE			
Contractual allowances	\$35,576,908	\$64,680,685	\$81,324,460
Charity Care	1,378,265	2,425,671	3,050,841
Provisions for Bad Debt	2,330,823	4,250,499	5,311,873
TOTAL DEDUCTIONS FROM REVENUE	\$39,285,995	\$71,356,855	\$89,687,174
NET PATIENT SERVICE REVENUE	\$16,420,576	\$29,328,371	\$36,339,739
OTHER REVENUE	\$63,880	\$112,785	\$135,541
TOTAL REVENUE	\$16,484,456	\$29,441,156	\$36,475,280
EXPENSES:			
Labor Expense	\$9,434,265	\$11,469,098	\$13,318,137
Supplies	2,924,009	5,058,807	6,313,096
Purchased services	1,820,959	1,943,408	2,029,671
Other expenses	1,968,690	2,037,188	2,109,144
Depreciation and amortization	7,178,000	7,178,000	7,178,000
Interest Expense	4,400,000	4,360,000	4,320,000
Corporate Administration	403,432	415,535	428,001
TOTAL EXPENSES	\$28,129,355	\$32,462,036	\$35,696,048
INCOME FROM OPERATIONS	(\$11,644,899)	(\$3,020,879)	\$779,233
NONOPERATING INCOME, NET	\$0	\$0	\$0
REVENUE OVER EXPENSES	(\$11,644,899)	(\$3,020,879)	\$779,233

J01-157

CON-0157

R909

Attachment 7
Support Letters

SOUTHEAST CARDIOLOGY
SARBABI MASINET, MD, F.A.C.C.
WESTGATE OFFICE PARK
1812 WALLACE SCHOOL ROAD, SUITE 300
CHARLESTON, SOUTH CAROLINA 29407
TELEPHONE: 843-766-2011
FAX: 843-766-2004

April 26, 2016

Michael Grayson, M.D.
Director, Heart and Vascular Services
Roper Hospital
316 Calhoun Street
Charleston, SC 29401

Dear Dr. Grayson:

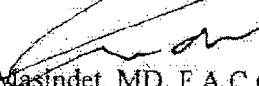
Given the Roper St. Francis Heart & Vascular Center is the leading provider of adult Cardiovascular services in Charleston, please consider this my letter of support for the Certificate of Need application Roper St. Francis Hospital – Berkeley will submit to DHEC for approval to initiate diagnostic cardiac catheterization service at the new hospital.

With the expansion of Roper St. Francis facilities in Berkeley County, the need to provide local diagnostic services for cardiovascular care is essential. This will allow Berkeley County citizens to receive cardiovascular care in their home area and thereby Provide a more time and cost-efficient experience.

I currently refer my patients who reside in Berkeley County and other patients from that vicinity to Roper St. Francis providers and facilities for cardiovascular care, including Diagnostic catheterizations. I anticipate referring patients from these areas to Roper St. Francis Hospital – Berkeley for various services including diagnostic catheterizations. Given it will be a more convenient option for my patients.

I certainly hope that DHEC will give serious consideration to the proposed project, and Should you need further assistance, just let me know.

Sincerely,



Sarbari Masindet, MD, F.A.C.C.



Coastal Cardiology, P.A.

William B. Ellison, MD, FACC
 Jeffery S. Rieder, MD, FACC
 Lars H. Runquist, MD, FSCAI
 Matthew B. O'Steen, MD, FACC
 Troy A. Bunting, MD, FACC
 Minh K. Tran, DO
 Kelly S. Guerrero, PA-C
 Brett R. Dalmay, PA-C
 Christy D. Hawkins, PA-C

May 4, 2016

Michael Grayson, M.D.
 Director, Heart and Vascular Services
 Roper Hospital
 316 Calhoun Street
 Charleston, SC 29401

Dear Dr. Grayson:

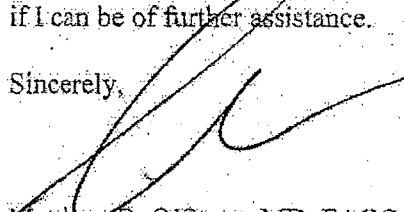
The Roper St. Francis Health System has been serving the Lowcountry community for more than 150 years. Since they are the leading provider of adult cardiovascular services in Charleston, please consider this my letter of support for the Certificate of Need application Roper St. Francis Hospital - Berkeley will submit to DHEC for approval to initiate diagnostic cardiac catheterization service at the new hospital.

It is a critical need to provide local diagnostic services for cardiovascular care in the local Berkeley County area. This will allow Berkeley county citizens to receive cardiovascular care in their home area and thereby provide a more time and cost-efficient experience.

I send my patients who reside in Berkeley County and other patients from that vicinity to Roper St. Francis providers and facilities for cardiovascular care, including diagnostic catheterizations. I expect to continue this referral pattern for these areas to Roper St. Francis Hospital - Berkeley for various services including diagnostic catheterizations, given it will be a more convenient option for my patients.

It is my hope that DHEC will give approve this cath lab, and do not hesitate to contact me if I can be of further assistance.

Sincerely,


 Matthew B. O'Steen, MD, FACC
 Cardiologist

1033 St. Andrews Blvd • Charleston, SC 29407 • (843) 723-6111
 Satellite Offices | Mt. Pleasant • Moncks Corner

CON-0160



William B. Ellison, MD, FACC
 Jeffrey S. Rieder, MD, FACC
 Lars H. Runquist, MD, FSCAI
 Matthew B. O'Steen, MD, FACC
 Troy A. Bunting, MD, FACC
 Minh K. Tran, DO
 Kelly S. Guerrero, PA-C
 Brett R. Dalmau, PA-C
 Christy D. Hawkins, PA-C

May 4, 2016

Michael Grayson, M.D.
 Director, Heart and Vascular Services
 Roper Hospital
 316 Calhoun Street
 Charleston, SC 29401

Dear Dr. Grayson:

I am pleased to hear that Roper is now applying for a CON for a cath lab for the proposed Roper St. Francis Hospital — Berkely. I would like to voice my support for the Certificate of Need application Roper St. Francis Hospital - Berkeley will submit to DHBC for approval to initiate diagnostic cardiac catheterization service at the new hospital.

The Roper St. Francis Heart & Vascular Center is the leading provider of adult cardiovascular services in Charleston. With the expansion into Berkeley County, the need to provide local diagnostic services for cardiovascular care will be vital to the medical services for that area.

My patients who reside in Berkeley County and other patients from that vicinity get referred by me to Roper St. Francis providers and facilities for cardiovascular care, including diagnostic catheterizations. Referring patients from these areas to Roper St. Francis Hospital - Berkeley for various services including diagnostic catheterizations will be a big benefit to my patient in that area.

I think that this cath lab is a worthy project and hope that it receives the approval of the State.

Sincerely,

Jeffrey S. Rieder, MD, FACC
 Cardiologist



Coastal Cardiology, P.A.

William B. Ellison, MD, FACC
 Jeffery S. Rieder, MD, FACC
 Lars H. Runquist, MD, FSCAI
 Matthew B. O'Steen, MD, FACC
 Troy A. Bunting, MD, FACC
 Minh X. Tran, DO
 Kelly S. Guerrero, PA-C
 Brett R. Dalmau, PA-C
 Christy D. Hawkins, PA-C

May 4, 2016

Michael Grayson, M.D.
 Director, Heart and Vascular Services
 Roper Hospital
 316 Calhoun Street
 Charleston, SC 29401

Dear Dr. Grayson:

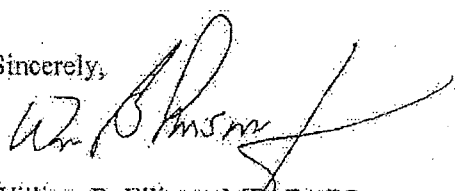
Please consider this my letter of support for the Certificate of Need application Roper St. Francis Hospital - Berkeley will submit to DHEC for approval to initiate diagnostic cardiac catheterization service at the new hospital. Roper St. Francis is the Lowcountry's preferred healthcare provider chosen by more families than anyone else. It has an expert medical staff of over 900 doctors representing every medical specialty has providers located in seven counties including Berkeley County.

The expansion of Roper St. Francis facilities in Berkeley County makes the need to provide local diagnostic services for cardiovascular care essential. This will allow Berkeley county citizens to receive cardiovascular care in their local area. 34 percent of the Berkeley County residents who received diagnostic cardiac catheterizations in 2014 had them performed at a Roper St. Francis Facility.

I continue to refer my patients who reside in Berkeley County and other patients from that vicinity to Roper St. Francis providers and facilities for cardiovascular care, including diagnostic catheterizations. I anticipate that Roper St. Francis Hospital - Berkeley will be an obvious choice for various services including diagnostic catheterizations, given it will be a more convenient option for my patients.

It is my hope that DHEC will give approval to this proposed project.

Sincerely,


 William B. Ellison, MD, FACC
 Cardiologist

WILLIAM J. GROSSMAN, M.D., F.A.C.C.

DIPLOMATE, AMERICAN COLLEGE OF CARDIOLOGY

BOARD CERTIFIED

CARDIOVASCULAR DISEASES
INTERVENTIONAL CARDIOLOGY**CHARLESTON CARDIOLOGY**191 RUTLEDGE AVENUE
CHARLESTON, SC 29403
(843) 723-1614
FAX (843) 727-2980

May 5, 2016

Michael Grayson, M.D.
Director, Heart and Vascular Services
Roper Hospital
316 Calhoun Street
Charleston, SC 29401

Dear Dr. Grayson:

Given the Roper St. Francis Heart & Vascular Center is the leading provider of adult cardiovascular services in Charleston, please consider this my letter of support for the Certificate of Need application Roper St. Francis Hospital - Berkeley will submit to DHEC for approval to initiate diagnostic cardiac catheterization service at the new hospital.

With the expansion of Roper St. Francis facilities in Berkeley County, the need to provide local diagnostic services for cardiovascular care is essential. This will allow Berkeley county citizens to receive cardiovascular care in their home area and thereby provide a more time and cost-efficient experience.

I currently refer my patients who reside in Berkeley County and other patients from that vicinity to Roper St. Francis providers and facilities for cardiovascular care, including diagnostic catheterizations. I anticipate referring patients from these areas to Roper St. Francis Hospital - Berkeley for various services including diagnostic catheterizations, given it will be a more convenient option for my patients.

I certainly hope that DHEC will give serious consideration to the proposed project, and should you need further assistance, just let me know.

Sincerely,

William J. Grossman, MD
191 Rutledge Ave.
Charleston, SC 29403



Coastal Cardiology, P.A.

William B. Ellison, MD, FACC
 Jeffrey S. Reeder, MD, FACC
 Lars H. Runquist, MD, FSCAI
 Matthew B. O'Steen, MD, FACC
 Troy A. Sunning, MD, FACC
 Minh K. Tran, DO
 Katy S. Guenard, PA-C
 Brett R. Damann, PA-C
 Christy D. Hawkins, PA-C

1033 St. Andrews Blvd • Charleston, SC 29407 • (843) 723-6111

Satellite Offices | Mt. Pleasant • Moncks Corner

May 6, 2016

Michael Grayson, M.D.
 Director, Heart and Vascular Services
 Roper Hospital
 316 Calhoun Street
 Charleston, SC 29401

Dear Dr. Grayson:

As a physician who has an office in Berkeley County, I am pleased to learn that Roper is considering a cath lab in Berkeley County. This is my letter of support for the Certificate of Need application that Roper St. Francis Hospital - Berkeley will submit to DHEC for approval to initiate diagnostic cardiac catheterization service at the new hospital. The Roper St. Francis Heart & Vascular Center is the leading provider of adult cardiovascular services in Charleston, and it is fitting that they provide this service to the Berkeley County community.

With the expansion of Roper St. Francis facilities in Berkeley County, the need to provide local diagnostic services for cardiovascular care is essential. This will allow Berkeley county citizens to receive cardiovascular care in their home area and thereby provide a more time and cost-efficient experience.

I currently refer my patients that I see in Berkeley County and other patients from that vicinity to Roper St. Francis providers and facilities for cardiovascular care, including diagnostic catheterizations. I anticipate continuing to refer patients from these areas to Roper St. Francis Hospital - Berkeley for various services including diagnostic catheterizations, given it will be a more convenient option for my patients.

It is my hope that DHEC will give approval to the proposed project, and do not hesitate to contact me if I can be of further assistance.

Sincerely,

Lars H. Runquist, MD, FSCAI
 Cardiologist

*Comprehensive
Cardiology Consultation
and Management*



Lowcountry
Cardiology
Associates, PA

*The Oaks at Centre Pointe
4969 Centre Pointe Drive, Suite 100
North Charleston, SC 29418
Telephone: 843-853-0250
Facsimile: 843-853-0219*

May 5, 2016

Kenneth H. Hanger, Jr., MD, FACC
Robert A. Pringle, Jr., MD, FACC
Donald E. Saunders, III, MD, FACC
Scott L. Woodfield, MD, FACC
Monique K. Sandhu, MD

Christopher A. Davis, PA-C

Satellite Office

Roper Berkeley Center
730 Stony Landing Road
Moncks Corner, SC 29461

Michael Grayson, M.D.
Director, Heart and Vascular Services
Roper Hospital
316 Calhoun Street
Charleston, SC 29401

Dear Dr. Grayson:

Given the large population of patients cared for at Roper St. Francis-Berkeley Hospital, please consider this my letter of support for the Certificate of Need application the Hospital will submit to DHEC for approval to initiate a diagnostic cardiac catheterization laboratory.

This expansion of services will allow for Berkeley County residents to receive much needed cardiovascular care close to home increasing efficiency and patient outcomes.

Patients I see currently at Roper-Berkeley facilities are referred to other Roper St. Francis facilities for diagnostic catheterizations. I anticipate these referrals to be redirected locally to the Berkeley County catheterization laboratory.

I believe the proposed project will meet the need for diagnostic cardiovascular services in a location convenient to Berkeley County and surrounding communities.

Sincerely,

Scott Woodfield, MD
Lowcountry Cardiology Associates, PA
4969 Centre Pointe Drive, Suite 100
North Charleston, SC 29418

*Comprehensive
Cardiology Consultation
and Management*



May 5, 2016

*The Oaks at Centre Pointe
4969 Centre Pointe Drive, Suite 100
North Charleston, SC 29418
Telephone 843-853-0250
Facsimile 843-853-0210*

Kenneth H. Hanger, Jr., MD, FACC

Robert A. Pringle, Jr., MD, FACC

Donald E. Saunders, III, MD, FACC

Scott L. Woodfield, MD, FACC

Monique K. Sandhu, MD

Christopher A. Davis, PA-C

Satellite Office

Roper-Berkeley Center
730 Stony Landing Road
Moncks Corner, SC 29451

Michael Grayson, M.D.
Director, Heart and Vascular Services
Roper Hospital
316 Calhoun Street
Charleston, SC 29401

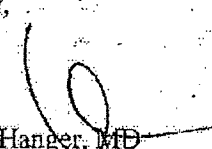
Dear Dr. Grayson:

Please consider this my letter of support for the Certificate of Need application that Roper St Francis Hospital - Berkeley will submit to DHEC for approval to initiate a diagnostic cardiac catheterization laboratory. The Roper St. Francis Health System has been serving the Lowcountry for over 150 years and has become the preferred healthcare system. It is for that reason that I support this expansion to provide these cardiovascular services in Berkeley County.

Patients I see currently at Roper-Berkeley facilities are referred to other Roper St. Francis locations for diagnostic catheterizations requiring patients to drive a long distance for care. I anticipate redirecting these patients to Berkeley Hospital for cardiovascular procedures. This will be of great service and will likely increase patients having procedures done at Roper St Francis.

I strongly support Roper St. Francis Health System and encourage your approval of the project.

Sincerely,


Kenneth Hanger, MD
Lowcountry Cardiology Associates, PA
4969 Centre Pointe Drive, Suite 100
North Charleston, SC 29418

 **ROPER
ST. FRANCIS**
Goose Creek Family Practice
149 St. James Avenue
Goose Creek, SC 29445
PH 843-553-0526

April 27, 2016

Michael Grayson, M.D.
Director, Heart and Vascular Services
Roper St. Francis
316 Calhoun Street
Charleston, SC 29401

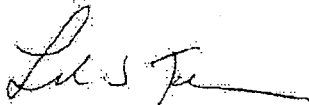
Dear Dr. Grayson:

It is my understanding that Roper St. Francis Hospital - Berkeley which is scheduled to open in 2019, is preparing to submit a Certificate of Need application to the Department of Health and Environmental Control that seeks to initiate diagnostic cardiac catheterization service. Given my familiarity with the high-quality cardiovascular services the healthcare system currently provides, please consider this my letter of support.

Providing this service at the new hospital will greatly increase patient access by allowing patients to be closer to home when receiving this (and other) medical care. Given that approximately 20 percent of the patients that had a diagnostic cardiac catheterization within the Roper St. Francis Healthcare System originated from Berkeley County in 2014, this project is a logical extension of Roper St. Francis' service complement intended to reach a large population base that is traveling to downtown Charleston for catheterization.

I currently refer many of my patients that reside in Berkeley and Dorchester Counties and are in need of cardiovascular care to Roper St. Francis specialists and facilities, and anticipate referring patients to Roper St. Francis Hospital - Berkeley for various services including diagnostic catheterizations. I trust that the Department of Health and Environmental Control will agree the proposed project is needed, and approve it.

Sincerely,



Leah S. Trantham, MD



April 26, 2016

S. Nicole DeBerry, M.D.
Primary Care Partners - Wescott
9500 Dorchester Road, Suite 362
Summerville, SC 29483

Dear Dr. Grayson:

Given the Roper St. Francis Heart & Vascular Center is the leading provider of adult cardiovascular services in Charleston, please consider this my letter of support for the Certificate of Need application Roper St. Francis Hospital - Berkeley will submit to DHEC for approval to initiate diagnostic cardiac catheterization service at the new hospital.

I currently refer my patients who reside in Berkeley County and other patients from that vicinity to Roper St. Francis providers and facilities for cardiovascular care, including diagnostic catheterizations. I anticipate referring patients from these areas to Roper St. Francis Hospital - Berkeley for various services including diagnostic catheterizations, given it will be a more convenient option for my patients. This location will allow patients to be closer to their families and homes when receiving medical care, and will result in a more time and cost-efficient experience.

I certainly hope that DHEC will give serious consideration to the proposed project, and should you need further assistance, just let me know.

Sincerely,

A handwritten signature in black ink, appearing to read "S. Nicole DeBerry". The signature is fluid and cursive, with a large, stylized "S" at the beginning and a long, sweeping flourish at the end.

S. Nicole DeBerry, M.D.



April 26, 2016

Teeresa Sisodia, M.D.
Primary Care Partners - Wescott
9500 Dorchester Road, Suite 362
Summerville, SC 29483

Dear Dr. Grayson:

Given the Roper St. Francis Heart & Vascular Center is the leading provider of adult cardiovascular services in Charleston, please consider this my letter of support for the Certificate of Need application Roper St. Francis Hospital - Berkeley will submit to DHEC for approval to initiate diagnostic cardiac catheterization service at the new hospital.

I currently refer my patients who reside in Berkeley County and other patients from that vicinity to Roper St. Francis providers and facilities for cardiovascular care, including diagnostic catheterizations. I anticipate referring patients from these areas to Roper St. Francis Hospital - Berkeley for various services including diagnostic catheterizations, given it will be a more convenient option for my patients. This location will allow patients to be closer to their families and homes when receiving medical care, and will result in a more time and cost-efficient experience.

I certainly hope that DHEC will give serious consideration to the proposed project, and should you need further assistance, just let me know.

Sincerely,

A handwritten signature in dark ink, appearing to read "T Sisodia MD".

Teeresa Sisodia, M.D



April 26, 2016

Melissa Linton, M.D.
RSF Physician Partners Primary Care
Suite 6B
1724 State Road
Summerville, SC 29486

Dear Dr. Grayson:

Given the Roper St. Francis Heart & Vascular Center is the leading provider of adult cardiovascular services in Charleston, please consider this my letter of support for the Certificate of Need application Roper St. Francis Hospital - Berkeley will submit to DHEC for approval to initiate diagnostic cardiac catheterization service at the new hospital.

I currently refer my patients who reside in Berkeley County and other patients from that vicinity to Roper St. Francis providers and facilities for cardiovascular care, including diagnostic catheterizations. I anticipate referring patients from these areas to Roper St. Francis Hospital - Berkeley for various services including diagnostic catheterizations, given it will be a more convenient option for my patients. This location will allow patients to be closer to their families and homes when receiving medical care, and will result in a more time and cost-efficient experience.

I certainly hope that DHEC will give serious consideration to the proposed project, and should you need further assistance, just let me know.

Sincerely,

A handwritten signature in dark ink, appearing to be "ML", written over a horizontal line.

Melissa Linton, M.D.



April 26, 2016

Amy C. Forren, D.O.
RSF Physician Partners Primary Care
Suite 6B
1724 State Road
Summerville, SC 29486

Dear Dr. Grayson:

Given the Roper St. Francis Heart & Vascular Center is the leading provider of adult cardiovascular services in Charleston, please consider this my letter of support for the Certificate of Need application Roper St. Francis Hospital - Berkeley will submit to DHEC for approval to initiate diagnostic cardiac catheterization service at the new hospital.

I currently refer my patients who reside in Berkeley County and other patients from that vicinity to Roper St. Francis providers and facilities for cardiovascular care, including diagnostic catheterizations. I anticipate referring patients from these areas to Roper St. Francis Hospital - Berkeley for various services including diagnostic catheterizations, given it will be a more convenient option for my patients. This location will allow patients to be closer to their families and homes when receiving medical care, and will result in a more time and cost-efficient experience.

I certainly hope that DHEC will give serious consideration to the proposed project, and should you need further assistance, just let me know.

Sincerely,

A handwritten signature in cursive script, appearing to read "Amy Forren".
Amy Forren, D.O.

**MONCK'S CORNER PRIMARY CARE****EDGAR BARNARD, MD**

730 Stony Landing Rd, Suite 100

Moncks Corner, SC 29461

Phone: (843)-761-6556 Fax: (843)-606-8006

April 26, 2016

Michael Grayson, M.D.
Director, Heart and Vascular Services
Roper Hospital
316 Calhoun Street
Charleston, SC 29401

Dear Dr. Grayson:

Given the Roper St. Francis Heart & Vascular Center is the leading provider of adult cardiovascular services in Charleston, please consider this my letter of support for the Certificate of Need application Roper St. Francis Hospital - Berkeley will submit to DHEC for approval to initiate diagnostic cardiac catheterization service at the new hospital.

I currently refer my patients who reside in Berkeley County and other patients from that vicinity to Roper St. Francis providers and facilities for cardiovascular care, including diagnostic catheterizations. I anticipate referring patients from these areas to Roper St. Francis Hospital - Berkeley for various services including diagnostic catheterizations, given it will be a more convenient option for my patients. This location will allow patients to be closer to their families and homes when receiving medical care, and will result in a more time and cost-efficient experience.

I certainly hope that DHEC will give serious consideration to the proposed project, and should you need further assistance, just let me know.

Sincerely,

A handwritten signature in dark ink, appearing to read 'Edgar Barnard'.

Edgar Barnard, MD



April 27, 2016

Michael Grayson, M.D.
Director, Heart and Vascular Services
Roper St. Francis
316 Calhoun Street
Charleston, SC 29401

Dear Dr. Grayson:

It is my understanding that Roper St. Francis Hospital - Berkeley which is scheduled to open in 2019, is preparing to submit a Certificate of Need application to the Department of Health and Environmental Control that seeks to initiate diagnostic cardiac catheterization service. Given my familiarity with the high-quality cardiovascular services the healthcare system currently provides, please consider this my letter of support.

Providing this service at the new hospital will greatly increase patient access by allowing patients to be closer to home when receiving this (and other) medical care. Given that approximately 20 percent of the patients that had a diagnostic cardiac catheterization within the Roper St. Francis Healthcare System originated from Berkeley County in 2014, this project is a logical extension of Roper St. Francis' service complement intended to reach a large population base that is traveling to downtown Charleston for catheterization.

I currently refer many of my patients that reside in Berkeley and Dorchester Counties and are in need of cardiovascular care to Roper St. Francis specialists and facilities, and anticipate referring patients to Roper St. Francis Hospital - Berkeley for various services including diagnostic catheterizations. I trust that the Department of Health and Environmental Control will agree the proposed project is needed, and approve it.

Sincerely,

A handwritten signature in black ink, appearing to read "Lloyd E. Hepburn".

Lloyd E. Hepburn, M.D.

CON.0173



April 27, 2016

Michael Grayson, M.D.
Director, Heart and Vascular Services
Roper St. Francis
316 Calhoun Street
Charleston, SC 29401

Dear Dr. Grayson:

It is my understanding that Roper St. Francis Hospital - Berkeley which is scheduled to open in 2019, is preparing to submit a Certificate of Need application to the Department of Health and Environmental Control that seeks to initiate diagnostic cardiac catheterization service. Given my familiarity with the high-quality cardiovascular services the healthcare system currently provides, please consider this my letter of support.

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I currently refer many of my patients that reside in Berkeley and Dorchester Counties and are in need of cardiovascular care to Roper St. Francis specialists and facilities, and anticipate referring patients to Roper St. Francis Hospital - Berkeley for various services including diagnostic catheterizations. I trust that the Department of Health and Environmental Control will agree the proposed project is needed, and approve it.

Sincerely,

A handwritten signature in black ink, appearing to read "TuAnh Khuu".

TuAnh Khuu, M.D.



April 27, 2016

Michael Grayson, M.D.
Director, Heart and Vascular Services
Roper St. Francis
316 Calhoun Street
Charleston, SC 29401

Dear Dr. Grayson:

It is my understanding that Roper St. Francis Hospital - Berkeley which is scheduled to open in 2019, is preparing to submit a Certificate of Need application to the Department of Health and Environmental Control that seeks to initiate diagnostic cardiac catheterization service. Given my familiarity with the high-quality cardiovascular services the healthcare system currently provides, please consider this my letter of support.

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I currently refer many of my patients that reside in Berkeley and Dorchester Counties and are in need of cardiovascular care to Roper St. Francis specialists and facilities, and anticipate referring patients to Roper St. Francis Hospital - Berkeley for various services including diagnostic catheterizations. I trust that the Department of Health and Environmental Control will agree the proposed project is needed, and approve it.

Sincerely,

A handwritten signature in dark ink, appearing to read "JCW".

Johnny C. Weeks, M.D.

Attachment 8

Legal Description

00003637 Vol: 7149 Pg: 299

00004342 Vol: 7163 Pg: 116

EXHIBIT A
PROPERTY DESCRIPTION
North Tract Parcel One
95.88 acres

ALL that certain piece, parcel or tract of land, situate, lying and being in Carnes Crossroads, in the City of Goose Creek, Berkeley County, South Carolina, containing approximately 95.88 acres, more or less, and known as "Carnes Crossroads North Tract Parcel One, TMS #209-00-01-080, 95.88 Acres" on that certain survey prepared by F. Elliott Quinn III, R.L.S., of Thomas & Hutton Engineering Co., dated January 28, 2008 entitled "PLAT OF THE ADJUSTMENT OF PROPERTY LINES BETWEEN CARNES CROSSROADS NORTH TRACT (RESIDUAL A), CARNES CROSSROADS NORTH TRACT-PARCEL ONE & CARNES CROSSROADS NORTH TRACT (RESIDUAL B), OWNED BY CARNES CROSSROADS ASSOCIATES, LLC, CARNES CROSSROADS, CITY OF GOOSE CREEK, BERKELEY COUNTY, SC" recorded January 29, 2008 in Plat Cabinet N, at page 320-H in the Office of the Berkeley County Register of Deeds, reference to which is craved for a more complete description (the "Plat").

Together with a non-exclusive, permanent, assignable, commercial, transmissible access easement fifty feet in width for pedestrian and vehicular ingress and egress on, over, and across a strip of land running from Highway 176 across Carnes Crossroads North Tract (Residual A 105.29 acres) to the Hospital Site as defined on Exhibit C at a location to be determined by Grantor. Grantor shall have the right to relocate the easement, at Grantor's expense. Grantee and Grantor agree to join in the dedication of any road constructed within the easement area. The easement contains only one access point into the Hospital Site.

BEING a portion of the property conveyed to Grantor by Deed from Harmon Crossing, LLC, Harmon Run One, LLC, Harmon Run Two, LLC, Harmon Run Three, LLC, Harmon Run Four, LLC, and Carnes Water Tower, LLC to Carnes Crossroads Associates LLC dated April 16, 2007 and recorded April 18, 2007 in Book 6497, Page 246; and Deed from DIA/Carnes, LLC to Carnes Crossroads Associates LLC dated April 16, 2007 and recorded April 18, 2007 in Book 6497, Page 261, Berkeley County Register of Deeds Office.

TMS No. 209-00-01-080

DOC: 2015034027

RE 2632: 519

EXHIBIT A
PROPERTY DESCRIPTION
Area from Residual A to Parcel One
27.13 acres

ALL that certain piece, parcel or tract of land, situate, lying and being in Carnes Crossroads, in the City of Goose Creek, Berkeley County, South Carolina, containing approximately 27.13 acres, more or less, and identified as "Area from Residual A to Parcel One 27.13 Acres" on that certain survey prepared by Phillip P. Gerard, R.L.S. 26596, of Thomas & Hutton Engineering Co., dated May 14, 2014 entitled "A PLAT OF THE PROPERTY LINE ADJUSTMENT BETWEEN PARCEL ONE & CARNES CROSSROADS NORTH TRACT, RESIDUALS A & B, CITY OF GOOSE CREEK, BERKELEY COUNTY, SC" recorded October 6, 2015 in Plat Cabinet S, at page 271A in the Office of the Berkeley County Register of Deeds, reference to which is craved for a more complete description.

BEING a portion of the property conveyed to Grantor by Deed from Harmon Crossing, LLC, Harmon Run One, LLC, Harmon Run Two, LLC, Harmon Run Three, LLC, Harmon Run Four, LLC, and Carnes Water Tower, LLC to Carnes Crossroads Associates LLC dated April 16, 2007 and recorded April 18, 2007 in Book 6497, Page 246; and Deed from DIA/Carnes, LLC to Carnes Crossroads Associates LLC dated April 16, 2007 and recorded April 18, 2007 in Book 6497, Page 261, Berkeley County Register of Deeds Office.

Portion of TMS No.: 209-00-01-049

To Be Included in TMS No. 209-00-01-080

DOC: 2015034027
RB 2032: 523

STATE OF SOUTH CAROLINA)
) AFFIDAVIT
COUNTY OF BERKELEY)

PERSONALLY appeared before me the undersigned, who being duly sworn, deposes and says:

1. I have read the information on this Affidavit and I understand such information.
2. The Property containing 27.13 acres portion of TMS 209-00-01-049 to be included in TMS 029-00-01-080 identified as Area from Residual A to Parcel One 27.13 acres, located at Carnes Crossroads North Tract, City of Goose Creek, Berkeley County is being transferred by Carnes Crossroads Associates, LLC to Roper St. Francis Hospital-Berkeley, Inc. on October 8, 2015.
3. Check one of the following: The DEED is:
 - (a) ☒ subject to the deed recording fee as a transfer for consideration paid or to be paid in money or money's worth.
 - (b) _____ subject to the deed recording fee as a transfer between a corporation, a partnership, or other entity and a stockholder, partner or owner of the entity, or is a transfer to a trust or as a distribution to a trust beneficiary.
 - (c) _____ EXEMPT from the deed recording fee because Exemption No. ____ (If exempt, please skip items 4-7, and go to item 8 of this affidavit).
4. Check one of the following if either item 3(a) or item 3(b) has been checked:
 - (a) ☒ The fee is computed on the consideration paid or to be paid in money or money's worth in the amount of \$3,744,457.00.
 - (b) _____ The fee is computed on the fair market value of the realty which is \$ _____.
 - (c) _____ The fee is computed on the fair market value of the realty as established for property tax purposes which is \$ _____.
5. Check YES _____ or NO ☒ to the following: A lien or encumbrance existed on the land, tenement, or realty before the transfer and remained on the land, tenement or realty after the transfer. If "Yes", the amount of the outstanding balance of this lien or encumbrance is \$ _____.
6. The Deed recording fee is computed as follows:
 - (a) \$3,744,457.00 the amount listed in item 4 above.
 - (b) \$ -0- the amount listed in item 5 above (no amount place zero).
 - (c) \$3,744,457.00 Subtract Line 6(b) from Line 6(a) and place the result.
7. As required by Code Section 12-24-70, I state that I am a responsible person who was connected with this transaction as: _____
8. I understand that a person required to furnish this affidavit who willfully furnishes a false or fraudulent affidavit is guilty of a misdemeanor and, upon conviction, must be fined not more than one thousand dollars or imprisoned not more than one year, or both.

Print Name: _____
Print Title: _____

SWORN to before me this 7 day
of October, 2015.

(SEAL)
NOTARY PUBLIC FOR SOUTH CAROLINA
My Commission Expires: 10-17-2018

Cynthia Smith Morton

J01-180

NOTES:

1. THE ABOVE-RECORDED 200-401-014-15 IS A COPY
2. ACCORDING TO THE ABOVE-RECORDED, ANSWER 39002
RECEIVED 8/5/00, THE PROPERTY NUMBER ON THIS FILE IS
HUBBARD 200-1.
3. COMMUNICATIONS AND INVESTIGATIONS DIVISION OF THIS BUREAU AND
CARROLL COUNTY POLICE COMMUNIST SYMPATHIZER (MADON)
AND THE INFORMATION HAS BEEN OBTAINED.
4. THIS BUREAU IS AWARE OF THE FACT THAT THE NAME "MADON"
RESEMBLES AND IS LANGUAGED AS BEING THE SAME AS THE NAME
A FIELD SEARCH HAS BEEN PERFORMED BY INVESTIGATIVE UNIT
AT THE TIME OF THIS BUREAU.
5. THE ABOVE-RECORDED INFORMATION IS SUBJECT OF A
RECORDING OF RECORD.

REFERENCES

1. PLAT 81, 1100455A - MUTTON ENGR.
DATED 05/27/03

2. PLAT CASHI-11, PAGE 1036

3. PLAT 81, 1100455A - MUTTON ENGR.
DATED 05/27/03

4. PLAT CASHI-11, PAGE 1177A-107M

5. PLAT 81, 1100455A - MUTTON ENGR.
DATED 05/27/03

6. PLAT CASHI-11, PAGE 1037

7. PLAT 81, 1100455A - MUTTON ENGR.
DATED 05/27/03

8. PLAT CASHI-11, PAGE 1036

9. PLAT 81, 1100455A - MUTTON ENGR.
DATED 05/27/03

10. PLAT CASHI-11, PAGE 1036

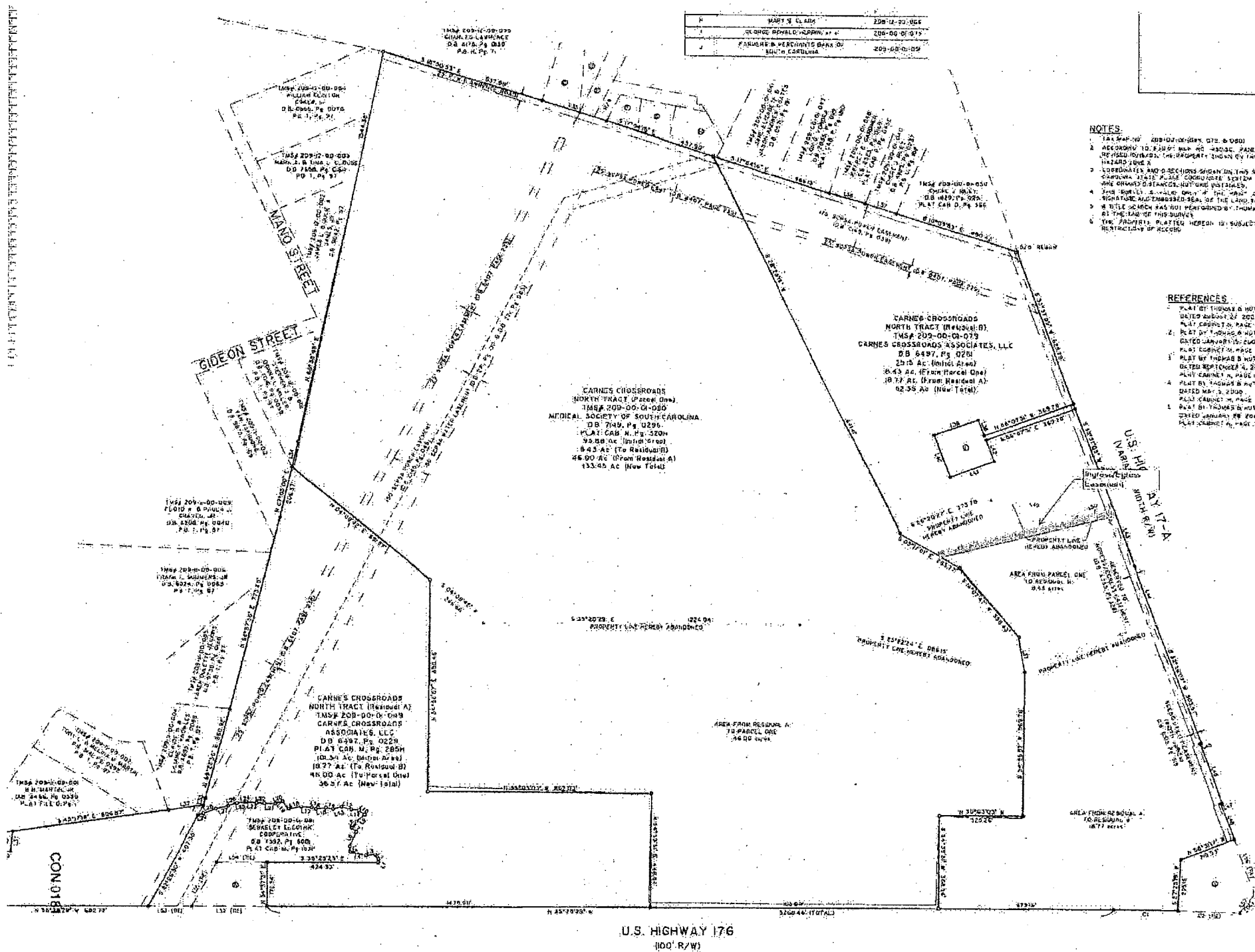
11. PLAT 81, 1100455A - MUTTON ENGR.
DATED 05/27/03

12. PLAT CASHI-11, PAGE 1036



1 And Simon Again

JO1-181



R933

Attachment 9
Resolution of Board Approval

CareAlliance Health Services

BOARD OF DIRECTORS

RESOLUTION WITH RESPECT TO APPROVAL FOR THE
ADDITION OF A CARDIAC CATHETERIZATION LAB AT
ROPER ST. FRANCIS HOSPITAL-BERKELEY, INC.

TAKEN FROM THE MINUTES OF THE APRIL 28, 2016 MEETING

WHEREAS, the Board of Directors (the "Board") of CareAlliance Health Services, doing business as Roper St. Francis Healthcare ("Roper St. Francis") has been advised that to continue the development of Roper St. Francis and Roper St. Francis Hospital - Berkeley, Inc., it is critical to patient care that it place a Cardiac Catheterization Lab at Roper St. Francis Hospital - Berkeley, Inc. to better serve the community with quality patient health services;

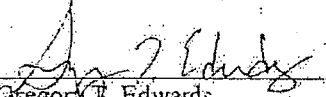
WHEREAS, the Board discussed the purpose and need for the placement of a Cardiac Catheterization Lab at Roper St. Francis Hospital - Berkeley, Inc. and has determined that it is in the community's best interest that Roper St. Francis proceed with necessary regulatory and business actions, including but not limited to the development and submission of a Certificate of Need ("CON") application, for the placement of a Cardiac Catheterization Lab at Roper St. Francis Hospital - Berkeley, Inc.

WHEREAS, as Management continues to contemplate the necessary services to be located at the new hospital, it was made clear during discussions with stake holders within the Cardiovascular service line that cardiac catheterization procedures were a necessary service for the community wherein the hospital will be located and such information was presented to the Board.

WHEREAS, the motion was made and the Board approved that Management should proceed with the process for placement of a Cardiac Catheterization Lab space at a proposed capital cost of the project of roughly Two Million Four Hundred Sixty Thousand Four Hundred and 00/100 Dollars (\$2,460,400.00).

NOW, THEREFORE, BE IT RESOLVED by the Board of Directors of Roper St. Francis Healthcare, that the Board hereby authorizes Management proceed with the necessary regulatory and business actions, including but not limited to the development and submission of a Certificate of Need ("CON") application for the addition of a Cardiac Catheterization Lab and related expenditures. Further, the Board has authorized such action with the expectation that the cost of such a project would be roughly Two Million Four Hundred Sixty Thousand Four Hundred and 00/100 Dollars (\$2,460,400.00), which Management may utilize funds incorporated in the Roper St. Francis Hospital - Berkeley, Inc. debt issuance.

The above is a true copy of the Roper St. Francis Board resolution passed on April 28, 2016.


Gregory J. Edwards

Secretary, CareAlliance Health Services

R936

CON-0184

R937

CON 0185

J01-185

AP & Opposition Tab



William R. Thomas
Partner
 Telephone: 803.255.8658
 Direct Fax: 803.255.8017
 willthomas@parkerpoe.com

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

June 24, 2016

SCDHEC
 Received

VIA HAND DELIVERY AND EMAIL

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

JUN 24 2016
 Certificate of Need Program

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

TRIDENT MEDICAL CENTER'S AFFECTED PERSON STATUS AND OPPOSITION

Louis
 Dear Mr. Eubank:

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

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

Sincerely,

William R. Thomas

WRT/ccq

PPAB 3281931v1



R940

Catherine E. Hiegel, Director

"Promote and preserve the health of the public and the environment"

June 29, 2016

William R. Thomas, Esquire
Parker Poe
P.O. Box 1509
Columbia, SC 29201

Re: Trident Medical Center, LLC, d/b/a Trident Medical Center ("Trident")

Dear Mr. Thomas:

This letter acknowledges receipt of your letter dated June 24, 2016 regarding Trident's "affected person" status and in opposition to the following Certificate of Need application(s):

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

We will provide you with notifications and the scheduling of any meetings or hearings with regard to the above in accordance with Regulation 61-15.

If you have any questions, please contact us at 803.545.4200 or coninfo@dhec.sc.gov.

Sincerely,

Louis Eubank
Director
Certificate of Need Program

cc: Ralph Barbier, Esquire
Shannon Cantwell
(all w/copy of June 24, 2016 letter)



Catherine E. Heigel, Director

Promote and protecting the health of the public, and the environment

July 13, 2016

Via Mail and Email

William R. Thomas, Esquire
Parker Poe Adams & Bernstein
1221 Main Street, Suite 1100
Columbia, SC 29201

**Re: Your Status as an Affected Person and in Opposition to the Transfer of
Diagnostic Cardiac Catheterization Services from Roper St. Francis Xavier
Hospital to Roper St. Francis Berkeley Hospital
Berkeley County, South Carolina**

No.: 2340

Dear Mr. Thomas:

By letter dated June 24, 2016, you made known to the South Carolina Department of Health and Environmental Control (Department) your status as outlined above. In this same letter, you requested a project review meeting be held prior to the Department rendering a decision in the referenced matter. Based on the grounds outlined in your letter, the Department has determined that a project review meeting need not be held in this matter. Should you wish to present more specific arguments in opposition to this application, please do so in writing no later than July 21, 2016.

Should you have any question regarding the above information, please contact me directly at 803.545.3652.

Very truly yours,

Louis Eubank
Director, Certificate of Need Program
South Carolina Department of Health and Environmental Control

Sullivan Consulting Group, Inc.

2030 Bethany Way · Alpharetta, Georgia 30004 · (770) 753-4222 · Fax: (770) 753-4223

July 21, 2016

VIA E-MAIL

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

RE: CON Application 2340

Dear Mr. Eubank:

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

1. Summary of Trident's Objections to the Project

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

CON-0190

Mr. Louis Eubank

July 21, 2016

Page 2

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

The Project is not a Transfer of an Existing Service.

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

Compliance with the South Carolina Health Plan

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

Cardiac Catheterization Standards

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

Mr. Louis Eubank

July 21, 2016

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

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

Exhibit 1

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

Primary Service Area

Berkeley County - All ZIP Codes

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

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

Secondary Service Area

Remainder of Charleston County

Remainder of Dorchester County

Colleton County

Source: Roper-Berkeley Application, Exhibit 2

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

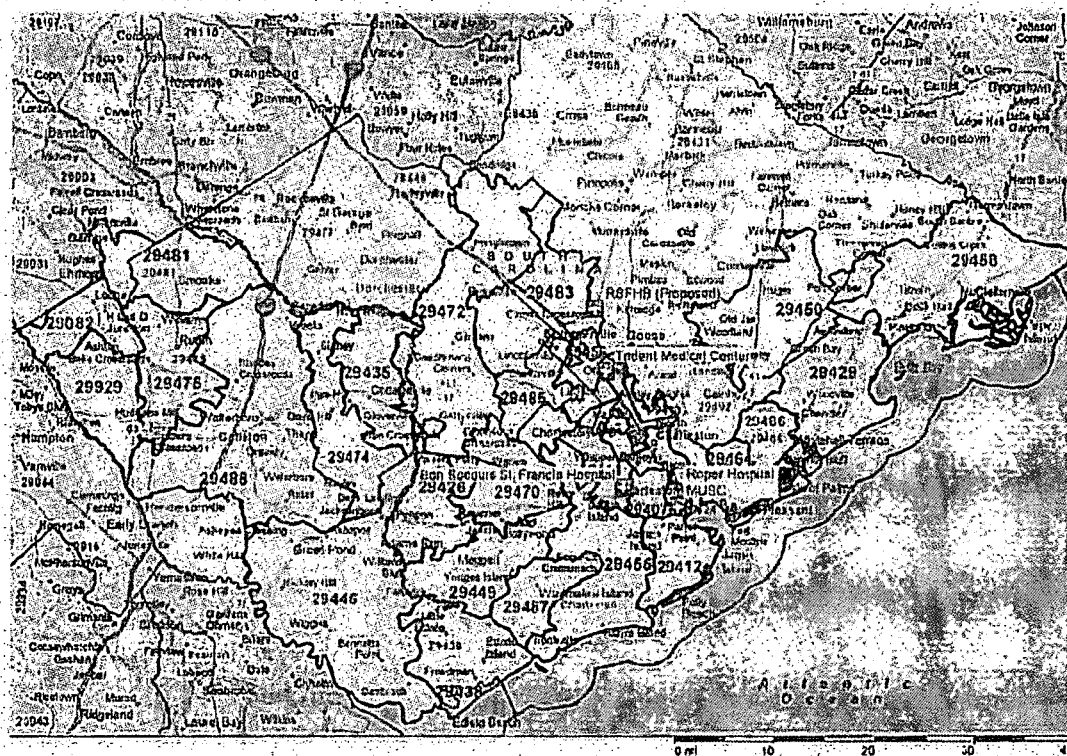
Mr. Louis Eubank

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Exhibit 2

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



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

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

Mr. Louis Eubank

July 21, 2016

Page 5

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

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

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

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

Diagnostic and Mobile Catheterization Services

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

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

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

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

*Includes adult and pediatric procedures

Source: Joint Annual Reports of Hospitals

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

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

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

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

Exhibit 4

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

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

Source: Roper-Berkeley Application, Exhibit 13

Source: Roper-Berkeley Application, Exhibit 13

J01-196

CON 0196

R948

Mr. Louis Eubank

July 21, 2016

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

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

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

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

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

*Includes adult and pediatric patients.

Source: Joint Annual Reports of Hospitals

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

Mr. Louis Eubank

July 21, 2016

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

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

Exceptions to Service Area Standards

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

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

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

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

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

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

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

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

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

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

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

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Community Need

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

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

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

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

Financial Feasibility

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

Cost Containment

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

Mr. Louis Eubank

July 21, 2016

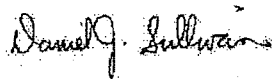
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Moreover, the proposed program will increase costs and time for the patients who otherwise would have received diagnostic cath services at Roper Hospital but will be redirected to Roper-Berkeley. Currently, when a patient presents to Roper Hospital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

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

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

Sincerely,



Daniel J. Sullivan

Correspondence Tab



Catherine E. Heigel, Director

Promoting and protecting the health of the public and the environment.

May 26, 2016

VIA CERTIFIED MAIL

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

Article #: 92148969009997901404889441

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

Dear Ms. Cantwell:

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

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

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

May 26, 2016

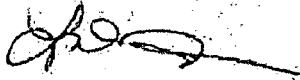
Page 2

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

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

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

Sincerely,



Louis Eubank

Director

Certificate of Need Program

Enclosures: Application Fee Invoice



South Carolina Department of Health
and Environmental Control

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

Invoice No.

PC18401-0

Invoice To:

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

Ship To:

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

Date:
5/26/2016

Terms:
DUE UPON RECEIPT

Department Name
Planning and Programs

Order Filled By:
GERRALN

Description of Services: CERTIFICATE OF NEED APPLICATION FEE

Qty	Unit Description	Loc	Organ.	Fund	Account	Analytical	Unit Price	Amount
1	CERTIFICATE OF NEED APPLICATION FEE (2340)	400	402011	428015	4486701	0000000	\$7,000.00	\$7,000.00
Total:								\$7,000.00

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



July 25, 2016

VIA CERTIFIED MAIL

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

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

Dear Ms. Cantwell:

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

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

Compliance with the State Health Plan

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

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

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

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

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

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

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

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

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

Community Need Documentation

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

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

Distribution (Accessibility)

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

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

Financial Feasibility

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

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

Cost Containment

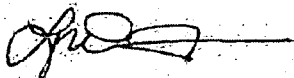
Integrating the contemplated laboratory into the pre-construction phase of the new Roper St. Francis Hospital - Berkeley realizes certain economies of practice which are otherwise lost during later renovation. Quality of cardiac care is increased through the provision of diagnostic services wherein early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

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

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

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

Sincerely,



Louis Eubank
Director
Certificate of Need Program

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

Enclosures: Guide to Board Review

CON 0208

South Carolina Board of Health and Environmental Control

Guide to Board Review

Pursuant to S.C. Code Ann. § 44-1-60

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

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

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

I. Filing of Request for Final Review

1. A written Request for Final Review (RFR) and the required filing fee of one hundred dollars (\$100) must be received by Clerk of the Board within fifteen (15) calendar days after notice of the staff decision has been mailed to the applicant, permittee, licensee, or affected persons. If the 15th day occurs on a weekend or State holiday, the RFR must be received by the Clerk on the next working day. RFRs will not be accepted after 5:00 p.m.
2. RFRs shall be in writing and should include, at a minimum, the following information:
 - The grounds for amending, modifying, or rescinding the staff decision;
 - a statement of any significant issues or factors the Board should consider in deciding how to handle the matter;
 - the relief requested;
 - a copy of the decision for which review is requested; and
 - mailing address, email address, if applicable, and phone number(s) at which the requestor can be contacted.
3. RFRs should be filed in person or by mail at the following address:
 South Carolina Board of Health and Environmental Control
 Attention: Clerk of the Board
 2600 Bull Street
 Columbia, South Carolina 29201
 Alternatively, RFR's may be filed with the Clerk by facsimile (803-898-3393) or by electronic mail (boardclerk@dhec.sc.gov).
4. The filing fee may be paid by cash, check or credit card and must be received by the 15th day.
5. If there is any perceived discrepancy in compliance with this RFR filing procedure, the Clerk should consult with the Chairman or, if the Chairman is unavailable, the Vice-Chairman. The Chairman or the Vice-Chairman will determine whether the RFR is timely and properly filed and direct the Clerk to (1) process the RFR for consideration by the Board or (2) return the RFR and filing fee to the requestor with a cover letter explaining why the RFR was not timely or properly filed. Processing an RFR for consideration by the Board shall not be interpreted as a waiver of any claim or defense by the agency in subsequent proceedings concerning the RFR.
6. If the RFR will be processed for Board consideration, the Clerk will send an Acknowledgement of RFR to the Requestor and the applicant, permittee, or licensee, if other than the Requestor. All personal and financial identifying information will be redacted from the RFR and accompanying documentation before the RFR is released to the Board, Department staff or the public.
7. If an RFR pertains to an emergency order, the Clerk will, upon receipt, immediately provide a copy of the RFR to all Board members. The Chairman, or in his or her absence, the Vice-Chairman shall based on the circumstances, decide whether to refer the RFR to the RFR Committee for expedited review or to decline in writing to schedule a Final Review Conference. If the Chairman or Vice-Chairman determines review by the RFR Committee is appropriate, the Clerk will forward a copy of the RFR to Department staff and Office of General Counsel. A Department response and RFR Committee review will be provided on an expedited schedule defined by the Chairman or Vice-Chairman.
8. The Clerk will email the RFR to staff and Office of General Counsel and request a Department Response within eight (8) working days. Upon receipt of the Department Response, the Clerk will forward the RFR and Department Response to all Board members for review, and all Board members will confirm receipt of the RFR to the Clerk by email. If a Board member does not confirm receipt of the RFR within a twenty-four (24) hour period, the Clerk will contact the Board member and confirm receipt. If a Board member believes the RFR should be considered by the RFR Committee, he or she will

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

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

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

II. Final Review Conference Scheduling

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

III. Final Review Conference and Decision

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

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

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